One year on

Why are patients still having unnecessary AF-related strokes?

In 2014 The National Institute for Health and Care Excellence (NICE) issued a clinical guideline on the management of atrial fibrillation (AF), which included recommendations on the use of optimal anticoagulation for prevention of AF-related stroke. This report looks at data one year on to consider what has changed.

This report and the work of ABPI SAFI is collectively funded by its five members, all research-driven pharmaceutical companies that have developed and gained regulatory approval for a NOAC. Our members are Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Daiichi Sankyo and Pfizer.
One year on – why are patients still having unnecessary AF-related strokes?

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7,000 strokes and 2,000 premature deaths could be avoided each year with effective management of AF – which can significantly reduce the risk of AF-related stroke, as recognised in numerous Government policies including the Cardiovascular Disease Outcomes Strategy and specific indicators in the Quality and Outcomes Framework.

In 2014, when NICE updated its AF clinical guideline (CG180) it recommended that Non-Vitamin K Antagonist Oral Anti Coagulants (NOACs) should be considered as equal first line options alongside warfarin for non-valvular AF; and in a significant change to established practice stated that aspirin should not be used as monotherapy to prevent AF-related stroke. In 2014 the Royal Colleges published a Consensus Statement reiterating this advice and emphasising the importance of ensuring patients are supported to make an informed choice of anticoagulant.

Despite this, data one year after the publication of NICE CG180 show that more than one in five patients admitted to hospital because of stroke were known to have AF prior to admission, less than half were taking anticoagulants, and over a quarter were still taking aspirin. Almost two thirds of CCGs are below the level of 20% NOAC use (as a proportion of all oral anticoagulant use) that NICE estimated would be achieved in the first year. CCG uptake of NOACs varies hugely, ranging from approximately 4% to nearly 70% of all oral anticoagulant use, which means that patients are subject to a postcode lottery.

Consistent adoption of NICE guidance and widespread dissemination of best practice in service redesign in all CCGs is essential to save lives and prevent what are potentially avoidable AF-related strokes, benefitting patients, the NHS and the economy.

The information in this report is based on data as at the end of December 2015.

Foreword

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Despite this, data one year after the publication of NICE CG180 show that more than one in five patients admitted to hospital because of stroke were known to have AF prior to admission, less than half were taking anticoagulants, and over a quarter were still taking aspirin. Almost two thirds of CCGs are below the level of 20% NOAC use (as a proportion of all oral anticoagulant use) that NICE estimated would be achieved in the first year. CCG uptake of NOACs varies hugely, ranging from approximately 4% to nearly 70% of all oral anticoagulant use, which means that patients are subject to a postcode lottery.

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The information in this report is based on data as at the end of December 2015.
The ABPI Stroke in Atrial Fibrillation (SAFI) group is calling for consistent adoption of NICE guidance on management of atrial fibrillation (AF) and widespread dissemination of best practice in anticoagulation to help save lives and prevent avoidable AF-related strokes.

There were over 16,000 strokes in people with AF in the UK in the 12 months to June 2015.10

In 2014 NICE published a clinical guideline (CG180) on management of AF and predicted that effective management including optimal anticoagulation of patients with AF could save 7,000 strokes and 2,000 premature deaths each year.5

NICE CG180 recommends Non Vitamin K Antagonist Oral Anti Coagulants (NOACs) as equal first-line options alongside warfarin, and that antiplatelet agents (aspirin) should not be used as monotherapy to prevent non-valvular AF-related stroke.8

Data a year after the publication of NICE CG180 show fewer than half of patients with AF who suffered a stroke were taking anticoagulants prior to hospital admission and around a quarter were still taking antiplatelet agents.10 This means that many patients are receiving suboptimal treatment to prevent AF-related stroke.

Uptake of NOACs has been lower and slower than NICE anticipated, and use varies widely across CCGs, ranging from approximately 4% to nearly 70% of all oral anticoagulant use,11 which means that patients are subject to a postcode lottery.

The data show that we need to do more to reduce variation, to ensure consistent adoption of NICE guidance and optimal anticoagulation of patients with atrial fibrillation (AF) to prevent AF-related stroke.

AF is the most common cardiac arrhythmia, estimated to affect up to 1.4 million people in England.4

Patients with AF have a significantly increased risk of having a stroke. AF-related strokes are more likely to be fatal or cause severe disability than non-AF-related strokes.1,2
We need to do more to reduce the risk of unnecessary AF-related strokes

One year on, NICE guidance on preventing AF-related stroke is not fully implemented, there is postcode variation in management,11 less than half of patients admitted to hospital with a stroke were anticoagulated prior to admission10 and patients remain at risk of dying from AF-related stroke.

NICE estimated that for people with AF implementing CG180 would result in 10,000 fewer strokes per year and the risk of stroke would be reduced by 31%13.

**Patients with AF are 5–6 times more likely to suffer a stroke than patients who do not have AF**

**AF-related strokes are more severe and more likely to be fatal than non-AF-related strokes**

**Nearly 1.4 million people in England have AF, it is the most common cardiac arrhythmia**

There were over 16,000 strokes in patients with AF in the 12 months to June 201510.

Mortality at 30 days is estimated at 25%12 so applying this estimate, these strokes would result in an estimated 4,000 deaths at 30 days.10,12

**Effective management of AF** and optimal anticoagulation can significantly reduce the risk of AF-related stroke:

- NICE CG180 recommends NOACs as a cost-effective option for anticoagulation equally with warfarin8
- Aspirin monotherapy is not recommended8

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3

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Nearly 1.4 million people in England have AF, it is the most common cardiac arrhythmia.
One year on, AF management remains suboptimal: NICE guidance is not fully implemented, there is postcode variation in management, more than half of patients with AF who are admitted to hospital with a stroke are still not anticoagulated, and over a quarter are taking only antiplatelet drugs which NICE does not recommend.10,17

SSNAP audit data for April – June 2015 (a year post-NICE CG180) show patients in AF are still not receiving optimal anticoagulation:10

- Over one fifth of patients were in AF on admission10
- Only 45.6% of these patients were taking anticoagulants10
- 27.9% were taking only antiplatelet drugs which NICE does not recommend for prevention of AF-related stroke10

NOAC uptake has been low and slow, and remains variable:†

- NICE estimated NOAC uptake of approximately 20% in the first year after publication of NICE technology appraisals (2012 and 2013)14,15,16 but by June 2015 almost three quarters of CCGs (73%) had NOAC uptake below 20% of all oral anticoagulants11
- More recently NICE estimated NOAC use would increase to 35% based on a scenario whereby aspirin use reduced in line with NICE recommendations to discontinue its use as monotherapy for stroke prevention,13 but by June 2015:
  - Only 3% CCGs had NOAC prescribing at or above 35% of all oral anticoagulants11
  - NOAC uptake showed wide variation across CCGs ranging from 4.2% to 69.3% of all oral anticoagulants11

One year on, AF management remains suboptimal: NICE guidance is not fully implemented, there is postcode variation in management, more than half of patients with AF who are admitted to hospital with a stroke are still not anticoagulated, and over a quarter are taking only antiplatelet drugs which NICE does not recommend.10,17

†The denominator for NICE estimations included warfarin, aspirin and ‘no treatment’. The Medicines Optimisation Dashboard figures for NOAC uptake include warfarin in the denominator but not aspirin or ‘no treatment’. The figures for NOAC uptake would become lower still if aspirin and ‘no treatment’ were included in the denominator.
Atrial Fibrillation – the facts

Atrial fibrillation (AF) affects around 1 in 50 (or 2.4%) people in England.\(^4\)

It is estimated that nearly 1.4 million people in England have AF.\(^4\) Of these, 890,000 have been diagnosed with AF and up to 474,000 more may be undiagnosed.\(^4\)

The prevalence of AF increases with age, so CCGs with older populations will have higher prevalence. Public Health England estimates that prevalence of AF ranges from 1.0 to 3.8% across CCGs in England.\(^4\) Comparing these estimates with Quality and Outcomes Framework (QOF) data shows wide variation between CCGs in the proportion of cases which have been diagnosed and, data suggest that overall in England up to 35% of cases remain undiagnosed and untreated.\(^4\)

Approx 1.4 million with AF

AF is increasing:

- Incidence in the UK is expected to double over the next 50 years.\(^1^8\)
- Both the population and proportion of older people are increasing: from 2012 to 2032 the populations of 65–84 year olds and the over-85s are expected to increase by 39% and 106% respectively.\(^1^9\)
- Risk of AF increases with age: about 1 in 200 people aged 50–59 have AF, increasing to almost 1 in 10 people over 80.\(^2^0\)

If you have AF your annual risk of stroke is 5–6 times greater than if you have normal heart rhythm.\(^3\)

| 890,000 Diagnosed |
| 474,000 Undiagnosed |

Up to 15% of strokes are due to AF.\(^2^1\)

People with AF who suffer a stroke have greater mortality, more disability, more severe strokes, a longer hospital stay and a lower rate of discharge to their own homes compared to those without AF.\(^1^2\)

AF-related strokes are more likely to recur\(^2\) – fear of another stroke is likely to cause anxiety and affect quality of life.
Case studies - integrating primary and secondary care and sharing specialist expertise

Case study: Primary Care Atrial Fibrillation (PCAF) Service Merseyside

The Primary Care Atrial Fibrillation (PCAF) service was first launched in Merseyside in June 2012 by Inspira Health Solutions in collaboration with clinicians at Liverpool Heart and Chest Hospital. It utilises a four phase protocol to identify high risk AF patients (CHA2DS2-VASc≥1), who are sub-optimally anticoagulated, and delivers consultant-led anticoagulation assessment within the local GP practice. The service is now available across England and Wales.

The PCAF service was developed in response to the fact that AF–related stroke risk can be significantly reduced through appropriate treatment but, as NICE has estimated, around half of patients that should be treated with oral anticoagulation are not. Indeed, NICE Clinical Guideline 180 on the management of AF focuses on the need for improved rates of anticoagulation in AF patients at elevated risk of stroke.

Foreseeing this healthcare priority, the PCAF service was developed to provide a hospital consultant-led service offering specialist expertise in the management of patients with AF at high stroke risk within GP practices. This service was specifically designed to overcome the fact that hospital clinicians, with specialist training in the management of AF or stroke, may have greater experience in assessment of patients with AF and of the full range of therapeutic options available than may be the case with some GPs.

As of September 2014 the PCAF service had been delivered in 56 GP practices with a patient population of 386,624. A total of 1,063 previously untreated high risk patients with AF had attended for review and been offered anticoagulation. Of these, 55 per cent were prescribed a NOAC, 41 per cent were prescribed warfarin whilst four per cent declined anticoagulation. This shows that with appropriate counselling and patient education it is possible to initiate oral anticoagulation in the overwhelming majority of patients with AF, including in those who had previously refused anticoagulation. It is estimated that these increased treatment rates have prevented over 30 AF-related strokes per year.*

Overall, the PCAF service has two distinct advantages. Firstly, patients currently managed solely within primary care are reviewed and, where appropriate, their anticoagulation treatment is optimised. Secondly, the educational legacy left within the GP practice following completion of the PCAF pathway enables optimal treatment to be carried forward for future patients.

Dr Dhiraj Gupta, Cardiology Lead for the PCAF service says: ‘As many AF patients are elderly and infirm, they are unable to access specialist cardiology care that has historically been based in hospitals. Through partnership working, we were able to set up an innovative consultant-led service within GP practices. Our data show that this collaborative working has resulted in many strokes being prevented, and likely lives being saved.’

Case study: West of England AHSN – Don’t Wait to Anticoagulate

West of England Academic Health Science Network (WEAHSN) identified the need to:

- Optimise anticoagulation use in untreated patients with AF who were identified as high risk from AF-related stroke.
- Optimise the anticoagulation of patients with AF deemed to be unstable on warfarin.
- Increase clinical confidence and knowledge.

In response, Don’t Wait to Anticoagulate was developed. The aims were to increase the use of anticoagulant medicine and improve management of AF.

Supporting quality and service improvement, Don’t Wait to Anticoagulate was designed to drive innovative service models; upskill general practice in order to create service capacity and resource; and draw on under-utilised NHS expertise and resource, such as practice pharmacists. A suite of information materials and toolkits were developed to support patients and clinicians and four innovative care models developed. (See www.weahsn.net/what-we-do/using-evidence-based-healthcare/atrial-fibrillation-toolkits/)

To date several initiatives and the learnings from them are helping achieve the goals:

1. The development of clinical champions have been essential in the roll-out of the project and should continue as a key enabler.
2. Ensuring high levels of patient and public engagement through local Public and Patient Involvement groups and via the support of voluntary sector organisations such as the Atrial Fibrillation Association and Arrhythmia Alliance has been of significant benefit.
3. The model of working collaboratively across the NHS, business and universities has been strengthened and should be continued.
4. There is a need to continue to upskill primary care and community pharmacy staff in knowledge about atrial fibrillation, its detection and management and the use of anticoagulants. Training and knowledge mobilisation need to be a core element for success.
5. The case for change needs to be made by using data and patient stories and be embedded in a clear communications strategy to promote the project and the benefits for patients of working in this way.
6. Linking data between primary and secondary care is important to show the impact on the wider healthcare system, for example via the further development of the use of Out-Patient Readmissions Avoidance (OPRA) data for quality improvement.

To date, results from 11 innovative practices have been pooled and are extremely positive. The number of patients with a CHADS2-VASc >1 on anticoagulation has increased by 144, among an AF-registered patient population of 2,733, whilst the optimisation of anticoagulation for high risk patients has prevented an estimated 6.3 strokes. The supportive toolkits have been well received by users and patients have been increasingly empowered to move to effective anticoagulation therapies.

One year on – AF-related strokes are still a significant burden

Stroke (from all causes) is a major burden both to patients and the NHS

AF-related strokes are more severe and more likely to be fatal than non-AF-related strokes\(^1,2\)

NICE estimated that with appropriate management the risk of stroke for people with AF would reduce by 31% and there would be approximately 10,000 fewer strokes per year in people with AF\(^13\)

Stroke is a major burden for patients and the NHS

For those who survive, stroke causes a greater range of disabilities than any other condition\(^2,22,23\).

Patients newly admitted with stroke may need extensive hospital assessment, including a brain scan\(^24\), admission to a specialist stroke unit, and multidisciplinary specialist assessments from a range of healthcare professionals including physicians, physiotherapists, occupational therapists, clinical psychologists and speech and language therapists\(^25\).
Over time, patients are likely to require treatment for complications and rehabilitation therapy, and have ongoing health and social care needs.

Of patients admitted for stroke (all causes) in the 12 months to June 2015:

- Around 40% of patients were discharged needing help with activities of daily living.10
  - Nearly one fifth had help solely from unpaid carers and approximately two thirds from only paid carers, with the remainder receiving help from both.10
  - 18% needed three or more visits a day from social services.10
- 85% patients required physiotherapy.10
- 48% required speech and language therapy.10

**Stroke from all causes has an enormous financial impact on the NHS**

| Estimated cost of a stroke in the first year is £12,22813,26 | NICE estimates that ongoing treatment costs post-stroke may be as high as £16,000 per year for a major stroke27 | The average cost per patient day for stroke patients in day-care facilities is £20828 | For an ambulance to ‘see, treat and convey’ a patient the average cost is £23328 |

These costs do not take into account the impact on the patient or their family, or the societal impact of those unable to return to work or live independently.

**Stroke has a considerable impact on society**

“Most patients who suffer a non-fatal stroke suffer a massive change to their lives and their families’ lives and experience a devastating change in their quality of life”29

About 1.2 million people in the UK live with the effects of stroke,22 and over a third of stroke survivors are discharged from hospital dependent on other people.22,30

Using 2005 costs, the total societal costs of stroke (all causes) to the UK economy were estimated at nearly £9 billion per year:31

- Almost £4.4 billion direct health and social care costs
- £2.4 billion informal care
- £1.3 billion lost productivity
- Over £841 million benefits payments

This would equate to a total of almost £11.3 billion per year at current values.32

**AF-related strokes are a great burden on patients, the NHS and society**

AF-related strokes are more severe and more likely to be fatal than non-AF-related strokes1,2

There were over 16,000 AF-related strokes in the 12 months to June 201510

Effective management and optimal anticoagulation can significantly reduce the risk of AF-related stroke5,13
There were over 16,000 strokes in patients with AF between July 2014 and June 2015 (in England, Wales and Northern Ireland).\textsuperscript{10}

Patients are more likely to die from AF-related stroke than other types of stroke.

- 30-day mortality from AF-related stroke is around 25%\textsuperscript{12} so approximately 4,000 of these patients are likely to have died within a month.
- The impact is not only immediate but persists longer term, with death rates about 40% at one year, 52% at two years and 73% by five years.\textsuperscript{12}

With an estimated mortality in the first year of 40%,\textsuperscript{12} the estimated costs for around 60% of these patients who survive the first year (9,676 patients) are up to £118 million.\textsuperscript{13,26}

The outcomes data from the group of patients with known AF who were not anticoagulated prior to their stroke is captured in the Sentinel Stroke National Audit Programme (SSNAP) annual report. Between April 2014 and March 2015, 9,369 patients with known AF who were not anticoagulated had a stroke, a quarter of these patients died and over 1 in 10 were left with severe disability. Fewer than 10% were symptom free.\textsuperscript{33,34}

**We need to do more to stop unnecessary AF-related strokes**

**We need to ensure that all appropriate patients with AF at high risk of stroke are offered effective anticoagulation**
Case studies - integrating primary and secondary care and sharing specialist expertise

Case study: The AF Interest Group (Sheffield)

The Atrial Fibrillation (AF) Interest Group comprises healthcare professionals from across primary and secondary care and the CCG who has an interest in the diagnosis, treatment and management of AF, and AF-related stroke prevention. One key aim of the Group is to encourage primary care practitioners to build on excellent work already undertaken by practices to improve rates of anticoagulation in patients with AF at high risk of stroke.

In order to promote improved anticoagulation in primary care, the Group developed new local guidance in early 2015. This takes a stepwise approach to the assessment of stroke and bleeding risk, and it provides prescribing considerations for the full range of NICE-approved treatments. This guideline was agreed at the Sheffield Area Prescribing Committee, making it the official guidance relating to anticoagulation prescribing for AF in Sheffield. The guidance has been disseminated widely across primary and secondary care in the city.

The Group also took this a step further, and developed a comprehensive education programme to raise awareness and facilitate a greater understanding of stroke prevention in AF. As well as hosting the guidance online across both secondary and primary care intranets in the area, the following activities took place:

- For primary care: A stroke physician and cardiologist attended GP locality education meetings to provide further information and education on the guidance. These meetings highlighted the impact that appropriate treatments to prevent ischaemic strokes could have on patients with AF and aimed to improve primary care confidence in this area.
- For secondary care: A haematologist and cardiologist undertook an education session as part of a Grand Round Meeting.

In addition, larger study days were arranged, which focused specifically on the guidance.

The AF Interest Group was aware that there was some risk aversion to prescribing anticoagulation in certain circumstances, and in particular there was evident concern and misunderstanding around bleeding risk. Indeed, stroke physicians, haematologists, and cardiologists reported receiving quite a lot of anticoagulation queries from primary care. This was considered to be in light of the fact that treatment initiation had previously been largely undertaken by secondary care based warfarin clinics, and because GPs were not familiar with the newer treatment options. This indicated a real need and an appetite for further education and continued provision of support into primary care to improve prescribing rates.

The guidance was approved and published in April 2015, so it is early yet to see significant measurable outputs. However, the context for this is that Sheffield has a history of undertaking annual GRASP-AF audits in primary care, and this has been instrumental in enabling improvements in AF anticoagulation to be tracked over time. A significant increase in high stroke risk anticoagulation has already been achieved to date, and a measurable reduction in the incidence of AF-related strokes has been observed. It is anticipated that the new guidance will contribute significantly to further improvement.

In addition to providing clinical education, Sheffield CCG is continuing to work proactively to ensure an effective uptake of the new local guidance. The Medicines Management Team and the Primary Care Development Nurse Team will be assisting practices to identify, review and anticoagulate in line with the new Sheffield guidance and NICE guidelines, their high stroke risk patients who are not presently receiving effective anticoagulation. This will include targeted work with practices having the lowest rates of anticoagulation.
One year on – implementation of NICE recommendations is extremely variable across England

National guidance gives clear recommendations to cut the risk of AF-related stroke

NOACs are recommended as a cost-effective option for anticoagulation equally with warfarin

Aspirin monotherapy is not recommended

In 2014 NICE CG180 recommended:

- NOACs are offered as an equal option alongside warfarin
- The choice of anticoagulant is based on the patient’s clinical features and personal preferences
- Aspirin monotherapy is NOT an effective option for stroke prevention

NICE estimated that implementing CG180 could result in:

- A 31% reduction in the risk of stroke for people with AF
- Approximately 10,000 fewer AF-related strokes per year
- People with AF better able to manage their condition

NICE recommendations were reinforced by the 2014 NIC (NICE Implementation Collaborative) and the Royal College of Physicians Consensus statement, which said:

- NOACs must be made available for prescribing and automatically included in local formularies.
- One of the barriers to appropriate use of anticoagulants in stroke prevention in AF is the ‘myth about the superior safety of aspirin compared with vitamin K antagonists’.
- The move away from aspirin is based on its poor efficacy in reducing the risk of stroke compared with the oral anticoagulants.
- Patients should be actively involved with their clinician in decision making and agree the anticoagulant which is best for them.

NICE further supports commissioning of best practice with a NICE Quality standard (QS 93) and anticoagulation commissioning guidance (CMG 49).
Case study: Norwich CCG

Throughout 2015, Sheila Glenn, Director of Quality, Strategy and Innovation at Norwich CCG, has been working hard alongside Norwich GPs to drive improvement in the identification, treatment and management of AF and AF-related stroke prevention.

Interrogation of the local AF and stroke data for Norwich CCG, alongside anecdotal evidence received from local stroke physicians, highlighted that there were a number of patients with AF who may not be receiving optimal anticoagulation. These also included some patients with a diagnosis of AF not receiving any anticoagulation at all.

Further, this analysis suggested that the prevalence of AF for the population of Norwich was higher than was being reported in actual cases. This meant that there were a number of individuals that had not been diagnosed with AF and therefore may unknowingly be at risk of a potentially avoidable stroke.

With the devastating impact of AF-related strokes on patients clearly visible in local hospitals, AF became a priority area for the CCG to look at.

Having witnessed the impact of AF-related strokes on patients and identified the specific problems that needed to be addressed, advice was sought from a number of clinicians as to what activity should be delivered to change current clinical behaviour and improve patient outcomes. The following therefore commenced in April 2015:

- Firstly, an existing and ongoing local education programme, ‘Medi-Bites’, was utilised to ensure maximum outreach to local GPs to raise awareness of this activity. At the dedicated Medi-Bites session on AF, Dr Yassir Javaid (GP and Cardiovascular Lead and Clinical Champion at the East Midlands Strategic Clinical Network) and Dr Kneale Metcalf (Consultant Stroke Physician, Norfolk and Norwich University Hospitals NHS Foundation Trust) spoke passionately about the need for a greater focus on AF locally and the different treatment options available. For many of the attendees, this may have been the first time that the case for better identification, treatment and management of AF and AF-related stroke prevention had been put to them by their peers.

- Secondly, a successful request was made for some of the money received by the CCG from the Quality Premium scheme to be used to create a local incentive scheme on AF and AF-related stroke prevention. Following the Medi-Bites session, this local incentive scheme required GP practices to undertake the following activities:
  - Identify a named GP for AF and AF-related stroke prevention in each practice.
  - Download the free-to-use GRASP-AF tool.
  - Utilise GRASP-AF to interrogate practice data. As part of this, GP practices were encouraged to identify ‘new’ patients who had not previously received a diagnosis of AF, and to ensure that those patients with an existing diagnosis were receiving optimal anticoagulation for their individual stroke risk. (Support was offered to do this, for example, via access to assistance from PRIMIS).

  Crucially, this incentive scheme went further than previous attempts to get GPs using GRASP AF, as it stipulated how it should be used rather than simply requesting that it be downloaded. In addition, Dr Javaid has also since developed a freely available template, which can be uploaded onto SystmOne, to help support GPs to ensure patients received optimal anticoagulation. This forms an optional part of the local incentive scheme.

- Thirdly, Norwich CCG held a follow-up meeting in October 2015 for the 23 GP practices who have undertaken the above programme of activity. It provided the opportunity for GPs to come together with their peers to share learning and experience, as well as to outline how they have changed their clinical behaviour as a result of using GRASP AF.

Anecdotally, Sheila has heard that many GPs have changed their clinical practice in an informed way since the local incentive scheme has been implemented. The peer to peer GP education session included representation from all practices. In undertaking the work all practices had identified a number of patients with undiagnosed AF. These patients were started on treatment. Other patients who were already diagnosed with AF had their treatment reviewed and the prescribing of NOACs for eligible patients has increased. Whilst it is too early for detailed analysis of the outputs, the difference that this programme of activity has had will be seen in future iterations of national audits, such as the Sentinel Stroke National Audit Programme and NHS England’s Medicines Optimisation Dashboard.
One year on – little change in anticoagulation rates since NICE CG180

Good AF management to prevent stroke is essential, but one year on, little has changed, NICE guidance is not fully implemented, many patients are still not anticoagulated, over a quarter are taking only antiplatelet drugs which are poorly effective, and there is postcode variation in management.

Prior treatment of patients with known AF on admission for stroke 2014-15 SSNAP data show little change since NICE CG180

From July 2014 to June 2015, following the publication of NICE CG180, 16,126 patients in AF were hospitalised with a stroke. With an estimated 25% mortality at 30 days, around 4,000 of them will have died within 30 days.

One year after the publication of NICE CG180, between April and June 2015, considering patients admitted to hospital with a stroke who had known AF:

- Fewer than half (45.6%) were taking anticoagulants.
- Over a quarter (27.9%) were taking only antiplatelet drugs, such as aspirin, despite NICE CG180 which states that aspirin monotherapy should not be offered for stroke prevention.

“…These data are similar to the last National Sentinel Stroke Audit and reveal that there are still major issues in primary and secondary care about ensuring that patients have effective stroke prevention. Over one fifth of patients are in atrial fibrillation (AF) on admission. Only 45.6% of patients in AF on admission are taking anticoagulants, with 27.9% taking only antiplatelet drugs which are considered ineffective for patients in AF. Over a quarter of patients have had a prior stroke or TIA.”
A postcode lottery remains: amongst 206 CCGs in England in 2013/14 the percentage of people with known AF who were prescribed anticoagulation before their stroke ranged from 12.5% to 72.7% – a 5.8-fold variation.36

Quality is incentivised but local variation persists: QOF incentivises good quality management of AF, but 2014/15 QOF exception reporting rates varied widely for AF indicators (from 5.23% to 20.44% for individual CCGs), possibly reflecting local variation in how AF-related stroke prevention is managed.37

One year after the publication of NICE CG180, between April and June 2015, considering patients admitted to hospital with a stroke who had known AF:10

Approximately 46% anticoagulated

Approximately 28% only on antiplatelets
Case study: Bradford City and Bradford Districts CCGs

When two Bradford CCGs found that people with AF were not anticoagulated sufficiently to protect them against stroke they embarked on a real-world quality improvement project lasting 18 months which improved quality and outcomes of prescribing in Bradford by over 30%.

The project aimed to ensure that at least 70% of the 6,500 patients identified as having AF (according to the QOF register) and considered at risk of a stroke were receiving anticoagulation and that those patients receiving warfarin had adequate control.

The Bradford CCGs believed they would be most successful if the GP practices within the CCGs worked collaboratively with them and therefore asked those practices interested to volunteer to participate. No additional incentive was necessary to encourage participation because any improvement in quality and outcomes would complement the existing QOF framework. In total 64 (out of the total 80) GP practices volunteered to participate.

The CCGs established a multi-disciplinary project team of clinical and public health leadership accompanied by active support from a wide range of disciplines. The project team developed two indicators and established a method of extracting data out of primary care clinical information systems in a way that enabled all participating practices to compare achievement across the CCGs.

A target was set for each practice based on the number of patients considered for anticoagulation. Evidence-based strategies were implemented to encourage and motivate each practice to achieve its target. This helped to standardise the approach to anticoagulation decisions in general practice and bring evidence to the point of clinical decision making.

The strategies were as follows:
- Provision of bespoke support and advice to practices
- Q&A events
- Practice visits
- IT tools and templates
- Simplified pathways and algorithms
- Bi-monthly newsletters
- Information on drug contraindications
- Advice on the dosing of non-vitamin K antagonists
- Regular data updates to track progress

Over 18 months the number of patients on the practice databases being prescribed warfarin increased from 2,274 to 2,978 – an absolute increase of 714 patients (31%) and importantly the increase was highest in those patients with the highest risk of stroke. This is in direct comparison with a 4% change in non-participating practices.

This scale of improvement would prevent 29 strokes and 17 deaths.

Overall cost of the project to achieve this outcome was approximately £100,000 for 18 months – mainly made up of project implementation staff salaries.

Commenting on the project, Dr Matt Fay, GP, Westcliffe Medical Practice, Shipley, Bradford (one of the leaders of the project) said: “We have developed a simple and effective model for Quality Improvement in primary care that primary care really engages with. There has been consistently positive feedback from practices and those that didn’t initially participate are now requesting to do so. The work has enabled practices to make a substantial shift in an important and highly clinically relevant process indicator in a short period. This is an indicator that has been historically difficult to shift.”

Dr Greg Fell, Consultant in Public Health, Bradford Metropolitan Council (another leader of the project) commented on how easy the project was to implement: “This innovation is not rocket science but the result of hard work and sustained implementation of evidence based clinical behaviour change strategies. This model does however rely on enthusiastic individuals with a common goal.”
Case studies - designing a patient-centred service

Case study: Buckinghamshire Healthcare NHS Trust

To improve provision of patient-focused anticoagulation services, Buckinghamshire Healthcare NHS Trust has set up its GP practice-based anticoagulation clinics. The clinic provides a service for both new and existing patients on anticoagulants. Patients are able to have anticoagulant dosing managed locally.

Patients newly identified as needing anticoagulant therapy are seen in the GP practice clinic and all options for anticoagulation are discussed with the patient. Patients are provided with information and support to enable them to fully participate in informed decision making about their treatment and the most appropriate anticoagulant option is prescribed. Follow up is carried out at the GP practice clinic rather than in a hospital-based clinic.

Existing patients on warfarin have regular appointments at the GP practice-based clinic instead of travelling to the hospital for monitoring and patients who are poorly controlled, or unable to cope with the complex warfarin dosage regime, are switched to NOACs. This is not only more convenient for patients but has enabled improvements in patient care and patient experience.

Some patients living furthest away from the CCG’s hospital anticoagulation clinic were previously reliant on postal anticoagulant dosing recommendations but are now able to attend the practice-based service and receive face-to-face consultations. An additional advantage is that the use of NOACs, rather than warfarin in clinically appropriate housebound patients who are poorly controlled perhaps due to multiple co-morbidities, has freed up district nursing time previously spent by them taking blood samples for INRs.

The outcomes are positive in terms of both reducing the number of patients with poorly controlled INR and hence not deriving any benefit from taking anticoagulants, GP feedback and patient experience.

This service redesign offers increased patient convenience and supports improved patient experience of care, it is also in line with national initiatives to provide care closer to home and recent RPS / RCGP work to promote the uptake of practice-based pharmacists.
One year on – the NHS is increasing its use of NOACs as an option in anticoagulation but most CCGs fall short of NICE estimates

NOAC uptake continues to be slow and shows significant variation across England

NOACs should be offered as an option to clinically appropriate patients with non-valvular AF at high risk of stroke

NOAC uptake ranges from 4.2% to 69.3% across CCGs (April–June 2015)

NOAC use in England – the proportion of prescription items for apixaban, dabigatran etexilate and rivaroxaban as a percentage of the total number of prescription items for oral anticoagulants (the three NOACs plus warfarin).11

NOAC uptake has been low and slow, and remains variable.

- NICE individual technology appraisals for the NOACs in 2012 and 2013 estimated NOAC uptake of approximately 20% in the first year14,15,16 (the denominator included warfarin, aspirin and ‘no treatment’).
- The recent NICE CG180 costing report estimated 35% uptake for the NOACs as a class (and included warfarin, aspirin and ‘no treatment’ in the denominator).13 This estimate was based on a scenario whereby aspirin usage was significantly reduced in line with NICE CG180 which no longer recommended aspirin monotherapy for prevention of AF-related stroke.
- Comparing the actual NOAC uptake figures from the Medicines Optimisation (MO) dashboard11 (April–June 2015) with the estimates from NICE, it can be seen that:
  - Only 27% of CCGs are above 20% uptake and only 3% of CCGs are above 35% uptake.11
  - Average NOAC uptake was 16.5%, which is below the level predicted by NICE for uptake in the first year.11,14,15,16
  - NOAC uptake showed wide variation across CCGs ranging from 4.2% to 69.3%.11
- The MO dashboard figures for NOAC uptake include warfarin in the denominator but not aspirin or ‘no treatment’. The figures for NOAC uptake would become still lower if aspirin and ‘no treatment’ were included in the denominator.
NOAC uptake is symptomatic of local variations in AF management and the need to provide all patients high quality anticoagulation.
Case studies - designing a patient-centred service

Case study: Southeast Essex

Patients with AF who are poorly controlled on their current vitamin K antagonist (VKA) are a high priority group for the NHS, as poor control (indicated by time-in-therapeutic range [TTR] <65%) indicates diminishing treatment benefit and increased risk of AF-related stroke.† The Anticoagulant Medicine Review Clinic (MRC) was a 6-month, pharmacist-led pilot project to assess and review these patients for suitability for a switch to a NOAC.

Throughout the project, suitable patients were referred to the MRC by GPs or secondary care, and subsequently reviewed by a pharmacist (including calculating CHA2DS2-VASc score). A joint decision was then made to either switch to a NOAC or continue with VKA, according to NICE guidance.‡ Patients were also followed up via telephone after two weeks to monitor compliance and side effects on their chosen treatment. The service was designed to integrate with the existing INR monitoring service, and would be replicable in any other centralised anticoagulation service.

The project was supported in full through joint working with Bayer, Boehringer Ingelheim, Bristol-Myers Squibb and Pfizer.

The service was successful on a number of fronts:

- 74.7%* of patients with poor control had their VKA switched to a NOAC, an increase vs. the estimated 41% switch rate within primary care in the region.
- All aspects of the service achieved 97–100% positive responses in a patient survey.
  - 100% of patients felt they had a better understanding of the benefits and risks of NOACs.
- The clinic also met the required performance standards (including patients reviewed, bloods assessed, clinical risk documented, risk/benefits explained, letter/management plan sent to GP, reported inappropriate treatment and reported adverse reactions), showing the quality and safety of prescribing by the MRC.

Monitoring of patient outcomes is ongoing, including analysing predicted strokes avoided and major bleeds from switching from a VKA to a NOAC. This will be supported using a five-year registry of patients involved in the pilot, and is likely to further highlight the benefits of the MRC for this high-risk patient group.


* Of the patients who continued on their VKA, the majority (76.2%) declined to switch
UK use of NOACs lags behind that of other European countries

UK NOAC use has been compared with use in other European countries. Data on NOAC use based on days on therapy compared to the total anticoagulant market (which includes anticoagulants for all indications, not just AF) show:

- UK NOAC use lags behind other countries
- The NOAC share of the UK anticoagulant market is 9.5% – less than half the EU average of 20.7%
- The UK ranks 19th out of 22 European countries
- Eight European countries have NOAC share at over 30% and four at over 35%.

NOACs usage as a % of total anticoagulant market* MAT**
June 2015 (based on days on therapy***)

* Total anticoagulant market = apixaban + dabigatran + rivaroxaban + warfarin + heparins (fractionated + unfractionated) + fondaparinux
** MAT: Moving Annual Total – the total over the previous 12 months
*** Days on therapy are based on IMS Standard Units data converted using Average Daily Dose assumptions based on IMS Medical Audit Data & BMS/Pfizer Alliance assumptions
Medicines optimisation – using NICE CG180 to make the best use of medicines to improve patient outcomes

- NOACs support medicines optimisation, offering an opportunity to improve patient outcomes and experience whilst simultaneously delivering value for the NHS in the prevention of AF-related stroke.
- NICE CG180 recommendations set out a scenario in which anticoagulants are offered to all appropriate high risk patients with AF, and aspirin use is reduced significantly as it should not be offerd solely for AF-related stroke prevention.
- This highlights the importance of the principles of medicines optimisation in moving patients with AF off aspirin which offers insufficient protection against AF-related stroke and offering alternative effective treatment options.
- The availability of the NOACs provides a significant opportunity to address some of the limitations of current anticoagulation management and respond to individual patient needs.
- Patients should be offered treatment with NOACs or warfarin as equal first-line options in line with CG180. Patients who have only been on aspirin will not previously have required regular blood monitoring, and so all appropriate options for anticoagulation should be discussed to enable patients to make an informed choice between NOACs and warfarin with its associated INR monitoring requirements.
- Patients who are able to express their needs and share in the decisions that are made about their treatment are more likely to engage in their healthcare and improve their outcomes because of this.

Warfarin

- Has been available for over 50 years. Optimally managed warfarin remains an effective treatment for AF-related stroke prevention and an appropriate option for many patients. However, it has recognised limitations and the need for regular INR monitoring may affect patients’ work, social and family life.\(^\text{29}\)
- Has a narrow therapeutic range which means patients require regular monitoring to achieve maximum therapeutic effect and minimum risk of harm.\(^\text{39,40}\)
- Studies in patients with non-valvular AF show:
  - A significant increase in stroke risk if INR is in range less than 70% of the time\(^\text{41}\)
  - Even well-monitored patients were outside therapeutic range approximately one third of the time\(^\text{42}\)
  - A 10% increase in time outside range was associated with a 29% increased risk of death and a 10% increased risk of stroke.\(^\text{42}\)

NOACs

- Were developed to overcome some of the limitations of warfarin.
- Have undergone regulatory scrutiny to demonstrate their efficacy and safety in prevention of non-valvular AF-related stroke and have been available in the UK since 2011.
- Are comparable to or superior to warfarin in reducing the risk of stroke in patients with non-valvular AF.\(^\text{43-47}\)
- Are comparable to or superior to warfarin with regard to the incidence of major bleeding and deaths from major bleeds.\(^\text{31-46}\)
- Are associated with a lower risk of intracranial haemorrhage than warfarin.\(^\text{43-47}\)
One year on – why are patients still having unnecessary AF-related strokes?
One year on – optimising anticoagulation services

There are a number of examples of optimising anticoagulation management in line with NICE guidance – there is a need to adopt this universally:

Understand current service provision

- Calculate local prevalence of AF.
- Estimate the number of people using local anticoagulation services, their cost and quality.
- Ensure anticoagulation is in line with the latest guidance.

Note: Freedom of Information (FOI) requests to CCGs during their first two years as commissioners of anticoagulation services found:

- Nearly half (48% n=85) of responding CCGs had not assessed the local prevalence of AF.
- 43% (n=74) had not assessed the number of people using local anticoagulation services.
- Only one third (n=58) had assessed the total cost of their local anticoagulation services.
- 41% (n=71) of CCGs had not assessed the quality of their local anticoagulation services.
- 78% (42 of 54 CCGs) either referred to warfarin as the preferred option, or did not refer to NOACs as a treatment option for people with non-valvular AF.

Ensure local leadership and champions

- A commissioning lead for stroke is essential to ensure high-quality commissioning and services.
- Almost one in four commissioning bodies do not have an allocated lead for stroke services and only 56% have a commissioning group for stroke. Stroke services, from prevention to longer-term care, should be commissioned coherently without duplication or gaps that could result in poor patient outcomes.
- “Primary care prescribing of NOACs needs local leadership. Not all GPs can be expected to be expert in the area of anticoagulation for atrial fibrillation.”
- “As the epidemic of atrial fibrillation continues to increase, local anticoagulant ‘champions’ will be needed to take the lead.”
One year on – why are patients still having unnecessary AF-related strokes?

Develop standards to ensure consistency and quality of services

NICE identified key issues in the commissioning of anticoagulation therapy, including:

- Variation in the quality and safety of anticoagulation therapy.
- Variation in the activities of anticoagulation services, because there is no standard service model or definition of an anticoagulation service.

Integrate primary and secondary care, educate and share expertise

- NICE-approved treatments have to be made available. CCGs have flexibility to use different models to suit local needs.
- Anticoagulation in AF should be reviewed and policies developed for integrating NOACs into the local care pathway taking into account NICE recommendations.
- NICE guidance emphasises the importance of stakeholder engagement, communication and dissemination.
- There should be agreed protocols across primary and secondary care for initiation of NOAC therapy.
- In some cases CCGs might choose to commission a service from the hospital anticoagulant clinics. In primary care, not all GPs will want to take responsibility for the first prescription of a NOAC. A designated health care professional with expertise in the area of anticoagulation in AF could take the lead.
**Incentivise performance**

NICE identified key issues in the commissioning of anticoagulation therapy, including:¹

- Commissioners can consider developing local goals e.g. based on the Commissioning for Quality and Innovation (CQUIN) payment framework to incentivise performance.¹

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**Focus on prevention**

- Better management of diseases can prevent deterioration and hospitalisation.⁵¹
- The NHS is committed to becoming a service that prevents as well as treats illness.⁵¹

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**Put patients at the centre of services**

- Patients must be actively involved with their clinician in decision-making about their anticoagulant treatment options and agree the therapy that is best for them.⁹
- Pharmacists with the appropriate skills and experience, based in GP practices, will be able to contribute to the clinical work related to medicines, relieve service pressure and increase capacity to deliver improved patient care.⁵²
- Healthcare professionals need to be adequately trained in order to provide education and support to patients, including education on the NOACs.¹
- Commissioners may wish to consider local arrangements for supporting people taking medications over long periods or for lifelong treatment. This may include use of new medicines review by community pharmacists.¹
One year on – why are patients still having unnecessary AF-related strokes?

References


38. IMS. NOACs usage as a % of total AC market, MAT June 2015 (based on days on therapy).


