

# Excellence in anticoagulant care

*Defining the elements of an  
excellent anticoagulation service*



London Clinical Networks



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### Contents

Key recommendations.....	6
Context.....	7
<i>Components of an excellent anticoagulation service for patients with atrial fibrillation</i>	
1. Designated clinical lead.....	8
2. Service responsibilities in the anticoagulation pathway.....	8
3. Patient user group.....	8
4. Anticoagulation medication.....	9
5. Patient-centred service.....	9
6. Patient information and education.....	10
7. Initiation of anticoagulation treatment.....	11
8. High quality, safe care for patients on vitamin K antagonist treatment.....	12
9. Self-monitoring and self-management of vitamin K antagonist treatment.....	13
10. Non vitamin K antagonist treatment.....	13
11. Patient review.....	14
12. Special circumstances.....	15
13. Training and support for providers.....	15
14. Safety, clinical effectiveness and clinical governance arrangements.....	15
15. Service audit and review.....	16
16. Review of capacity.....	17
References.....	18

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## Foreword

As part of the wider work in improving the identification and management of atrial fibrillation (AF) across London, high quality anticoagulation services are seen as a priority to ensure that patients with AF at high risk of stroke are optimally protected to prevent ischaemic stroke, avoid adverse events related to anticoagulant treatment, and to ensure that patients are supported with choice, education, access and adherence to treatment. A consensus view on what constitutes an excellent anticoagulation service for patients with AF will support providers and commissioners in ensuring the provision of best quality practice for their local populations.

**To that end, the Quality Anticoagulation and AF Prevention working group in London has developed this definition and description of what an excellent anticoagulation service should look like.**

Anticoagulation therapy is indicated for a wide range of conditions including AF, prosthetic heart valves, venous thromboembolism treatment and prevention, thrombotic disorders, and other cardiac conditions. The focus of this document is aimed at anticoagulation for AF. (AF is the largest cohort of patients within the majority of anticoagulation services; as such it has been used as an exemplar.)

Many of the defined elements of an excellent anticoagulation service for patients with AF are transferrable to anticoagulation care in general. However, other medical conditions will need to be considered as commissioners decide what services best fit the needs of their local populations.

This document is a result of in-depth reviews of clinical evidence and best practice guidelines, as well as examples of good practice from across the country. A list of references and useful resources are detailed at the end. This document is consistent with the National Institute for Health and Care Excellence (NICE) clinical guidelines, quality standards, commissioning guides and technology appraisals. Recommendations from the British Society of Haematology (BSH), the National Patient Safety Agency (NPSA), NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) have also been taken into consideration. This is not a systematic review, but provides a consensus summary of the important constituents of an excellent anticoagulation service.

### Key recommendations

- » Excellent anticoagulation services for a local population should be **patient-centred and directly involve users and carers**.
- » **All anticoagulation options should be available and discussed** where appropriate, in line with NICE guidance. These include:
  - » Vitamin K oral antagonists, such as warfarin, including the ability to self-monitor or self-manage
  - » Direct oral anticoagulants (DOACs): apixaban, dabigatran, edoxaban and rivaroxaban.
- » All **treatment decisions should be made in partnership with patients** following a comprehensive education and decision support consultation, with an ongoing package of patient monitoring, review, education and support.
- » Excellent anticoagulation services should ensure that the whole population of patients requiring anticoagulation has access via a **clear and simple electronic referral pathway**.
- » Clear written protocols should be in place to **support the reassessment of patients who have poor warfarin anticoagulant control**. The minimum acceptable time in therapeutic range (TTR) is 65 per cent, and in patients where this is not achieved, alternative treatment options should be offered, if clinically appropriate.
- » **Protocols for the initiation of DOAC treatment** should be in place, consistent with NICE recommendations, and with clear follow up arrangements.
- » **Support for medication adherence** is crucial, and excellent anticoagulation services should have mechanisms in place to address this. Community pharmacy New Medicine Service (NMS) and Medicines Use Reviews (MUR) should be central to optimising medication use.
- » Excellent anticoagulation services should have **locally agreed formal links with relevant local specialist departments**, including hospital-based cardiology and haematology services. Integrating multidisciplinary expert care across hospital-based and primary care services will enhance the delivery of high quality anticoagulation care, especially for more complex patients, such that care can be provided closer to the patient's home.
- » Excellent anticoagulation services should be able to **provide regular and transparent performance data** to commissioners and patients. Regular review of the quality and safety of services will be key to continually improving outcome.

**A review of best practice anticoagulant care reveals common elements that improve outcomes and patient experience.**

## Context

Atrial fibrillation is the most common sustained cardiac rhythm disorder and is a significant risk factor for stroke. People with AF have a five-fold increased risk of stroke when compared to people with a normal heart rhythm<sup>1</sup>. One of the aims of AF treatment is to prevent ischaemic stroke through the anticoagulation of those at-risk. Warfarin, a vitamin K antagonist, has been established as an anticoagulant treatment option for more than 60 years. When used appropriately, warfarin is effective in stroke prevention, reducing the risk of AF-related stroke by 64 per cent<sup>2</sup>. Clinical guidelines recommend vitamin K antagonists as a treatment option for patients with AF<sup>3,4</sup>. Aspirin should not be offered solely for stroke prevention in patients with AF<sup>3</sup>.

Warfarin has a narrow therapeutic window and multiple food and drug interactions, necessitating close monitoring of the drug's effect on a patient through the international normalised ratio (INR) blood test. The effect of warfarin is strongly linked to the level of INR. In general, the recommended target INR for patients with AF is between 2 and 3. The risk of ischaemic stroke increases substantially when the INR is below 2, and the risk of intracranial bleeding increases above an INR of 3<sup>5</sup>. One of the aims of warfarin monitoring and other vitamin K antagonist anticoagulants is to ensure that the INR remains in the therapeutic range for as long as possible. Anticoagulation services can be provided in a number of settings across the healthcare system, including hospital-based outpatient clinics, GP practices, community pharmacy-led services, and other community settings, including the patient's own home.

Newer non-vitamin K antagonists, commonly referred to as DOACs (direct oral anticoagulants), are at least as effective as warfarin in stroke prevention in patients with non-valvular AF (NVAf)<sup>6,7,8,9</sup>. Dabigatran etexilate, rivaroxaban, apixaban and edoxaban have all been approved in the UK for stroke prevention in patients with NVAf who have one additional risk factor for stroke<sup>10,11,12,13</sup>. When introduced, these newer agents did not require routine monitoring of the anticoagulant effect. Alternative monitoring requirements are indicated, as outlined by the relevant summary of product characteristics and recommended by the European Heart Rhythm Association practical guides<sup>14</sup>, but these will not entail the routine use of facilities currently available in anticoagulation services. The introduction of DOACs will require significant pathway redesign and realignment of existing anticoagulant services as the need for traditional vitamin K antagonist monitoring diminishes. Existing services will not become completely redundant, as some patients will be required to remain on vitamin K antagonists for some indications, such as patients with mechanical heart valves.

There is no standard definition of what constitutes an anticoagulation service, and models of care have evolved to meet the needs of local populations. There have been concerns around the variation in the activities, and in the quality and safety of anticoagulation therapy across the country<sup>13</sup>. Whereas there is an abundance of clinical guidelines, commissioning advice, and expert consensus statements<sup>16-22</sup>, we feel that a summary of what constitutes an excellent anticoagulant service would be helpful for providers and commissioners when redesigning services according to advances in medical technology and changing patient needs. It is clear that one service model will not meet the needs of all service users or patient populations, and that commissioners may choose to consider several different service models for their local health populations. Defining the components of an excellent anticoagulation service will help support the consistent development of modern day high quality services in different settings. Commissioners should ensure that all aspects of an excellent anticoagulation service are provided, through a combination of different service models if necessary, for the whole patient population.

## Components of an excellent anticoagulation service for patients with AF

### 1. Designated clinical lead

The identification of a designated clinical lead is viewed as an essential component of an excellent service. This lead must have undergone appropriate training, have the relevant work competencies, and be a qualified healthcare professional.

Existing community-based services should develop partnerships with specialist hospital services such that as many people as possible, regardless of clinical complexity, are able to be managed closer to home (in line with individual preference). This will require the development of innovative models of working across traditional hospital and community boundaries. Examples of integrated care include community-based multidisciplinary clinics and virtual clinics where more complex patients are discussed.

### 2. Service responsibilities in the anticoagulation pathway

An excellent anticoagulation service should include all of the following:

- » Patient education and counselling during initiation and maintenance of treatment
- » Initiation and/or monitoring of vitamin K antagonist treatment
- » Initiation and/or monitoring of DOAC treatment
- » Prescribing of anticoagulation medication
- » Management of bridging treatment / perioperative anticoagulation
- » Cessation of anticoagulation treatment
- » Regular patient and medication review relevant to AF and anticoagulation.
- » Service performance monitoring

Examples of more complex medical conditions that may require specialist medical input include patients with any of the following characteristics:

- » History of haemorrhagic stroke
- » History of clinically significant bleeding
- » Significant renal or liver disease
- » Underlying haematological disorders
- » Pregnant
- » Planned for cardioversion
- » Under the age of 18 years old
- » Active cancer who may be on chemotherapy
- » Mechanical heart valves
- » Cognitive impairment
- » Intravenous drug users
- » Prescribed vitamin K antagonists other than warfarin
- » Recurrent strokes due to AF despite anticoagulation
- » Require other antithrombotic treatment in addition to anticoagulant therapy for the management of other medical conditions.

### 3. Patient user group

An excellent anticoagulation service should be able to manage all patients with AF, regardless of the complexity of their medical conditions.

Historically, more “complex” patients (*see list, next column*) and patients with unstable warfarin control, may have been managed in hospital-based anticoagulation services, with less “complex” patients being managed in the community.

### Components of an excellent anticoagulation service for patients with AF

#### 4. Anticoagulation medication

All patients for whom anticoagulation is indicated for stroke prevention in AF should have access to the full range of treatment options where clinically indicated. Not all medication types will be relevant or appropriate for all patients (eg DOAC treatment is not appropriate for patients with severe renal disease).

However, if indicated, all options should be discussed:

- » Warfarin (with the ability to self-monitor and/or self-manage if appropriate)
- » Other vitamin K antagonists (eg phenindione and acenocoumarol) when warfarin and DOACs cannot be used
- » DOACs, including apixaban, dabigatran, edoxaban and rivaroxaban
- » In certain circumstances, some heparins can be used, often as a temporary measure (eg peri-operative management in high-risk patients on warfarin).

An excellent anticoagulation service will be able to decide the best treatment option with the patient, following full discussion of the advantages and disadvantages of each option. An excellent anticoagulation service must not restrict the availability of certain treatment options. If a service is unable to provide all options, then this should be discussed with the patient, and clear and agreed referral protocols to another provider must be present.

#### 5. Patient-centred service

An excellent anticoagulation service should be built around the needs of its patient population, and commissioners should actively involve patients and carers in the design and improvement of services.

Components of a patient-centred excellent anticoagulation service include:

- » A service as convenient and close to the person's home as possible, and in close proximity to public transport links and with accessible parking facilities.
- » A service that is accessible to all patients registered with GP services within the CCG.
- » Rapid access to the service in a time frame depending on clinical need. Commissioners should monitor the referral-to-treatment time. Same day or next working day appointments must be offered if required. Innovative methods of patient and clinician communication and consultation should be available including the use of teleconference and video-conference calls.
- » Adequate capacity to ensure that a patient's hospital discharge is not delayed due to a delay in accessing an anticoagulant service by offering same day or next working day appointments if required.
- » A convenient "one-stop" clinic where patient education, discussion and support, and blood tests, dose changes and follow up arrangements are all made during the patient consultation.
- » Accessible services to meet the needs of patient lifestyles (eg convenient appointment times for working-age adults).
- » Explicit patient pathways and management plans, and written contact details for patients who need emergency access to a healthcare professional both during normal working hours, and outside of standard hours.

### Components of an excellent anticoagulation service for patients with AF

In addition to this, an excellent service should specifically have procedures and protocols in place to meet the needs of:

- » People who want to, and are able to self-monitor or self-manage warfarin anticoagulation.
- » People who are house bound. A domiciliary service should be available for patients who are housebound and therefore cannot easily attend anticoagulation services. Carers and family members should be made aware of the option of point of care INR monitoring.
- » People who are unable to adjust the dose of their vitamin K antagonist.
- » People who are unable to self-administer medication. This may require close liaison with social services.
- » People taking multiple medications and who might need medicines compliance aids.
- » People whose first language is not English, or have limited English.

Patients should also have the opportunity to choose which designated provider site they wish to attend.

Patient and carer feedback should be actively obtained at every opportunity, and services should act on feedback, and have systems in place to incorporate this into service improvement. Feedback mechanisms should be tailored to patient and carer preferences and should include paper forms, telephone, text, portable device and web-based mechanisms, and patient and carer forums. Results of feedback should be made available to commissioners to enable them to drive improvements in quality of services. Feedback should include:

- » Accessibility of the venue
- » Access to domiciliary visits where required
- » Availability of convenient appointment times, particularly for working-age adults
- » Waiting times
- » Support and information (written and verbal) provided by staff

- » Degree of involvement in management decisions and the choice of anticoagulant
- » Whether they would recommend the service to others.

#### 6. Patient information and education

NICE recommends that patients with AF should be offered a personalised package of care that includes stroke awareness and measures to prevent stroke, as well as up-to-date and comprehensive education and information on the range of anticoagulation options. NICE has also produced guidance on the components of good patient experience, which should be taken into account when offering patient information and support.

Patient information and education in an accessible and understandable format should be provided by a trained professional. This should be both in verbal and written form, and through innovative mechanisms such as web-based information and other visual and audio tools. Information and education should be provided at the initiation of anticoagulant treatment, and at every subsequent patient attendance and review whenever required. Patient and carers should be actively involved in the creation of materials.

Patient and carer education and information should include:

- » An overview of atrial fibrillation
- » Importance of stroke prevention
- » Personalised stroke and bleeding risk assessment (in understandable terms)
- » Options available for stroke prevention and choice of different medications
- » Duration of treatment
- » Importance of long-term monitoring and attendance at follow up appointments
- » Importance of medication adherence



### Components of an excellent anticoagulation service for patients with AF

- » Availability of self-monitoring and self-management in patients on long-term warfarin treatment
- » Relevant lifestyle, dietary and alcohol advice (eg leisure and sporting activities)
- » Reasons for / need to carry a patient anticoagulant alert card
- » Role of the yellow anticoagulant book (or alternative local system)
- » Importance of informing other healthcare practitioners that they are on anticoagulant treatment
- » Side effects of anticoagulant drugs and what to look out for especially with regards to bleeding
- » Signs of stroke and TIA
- » What to do when medications are missed
- » How to take specific medication (eg rivaroxaban should be taken with food)
- » Drug interactions with other medications including aspirin, non-steroidal anti-inflammatory drugs and antibiotics
- » For warfarin in particular:
  - » Different tablet strengths and how to make up the correct dose
  - » Effect of diet and alcohol on warfarin
- » What to do in acute illness
- » What to do before surgical procedures including dental intervention
- » Contraception and pregnancy advice, if relevant
- » Importance of ensuring an adequate supply of anticoagulant drug and actions to take before supplies run out
- » What precautions to take when planning for holidays
- » Contact details for more information and who to contact in the case of an emergency.

Pharmacists have important roles to play in education through the new medicines services and medicines use reviews. Systems should be established to ensure that the patient pathway is mapped and efforts should be made to ensure that pharmacists are included in the patient pathway.

#### 7. Initiation of anticoagulant treatment

Clear evidence based protocols which are consistent with NICE and offer patients the choice of all recommended and licensed treatment options, should be available. In particular, as per NICE guidelines and technology appraisals, access to warfarin self-management and DOACs should not be restricted.

Prior to the initiation of anticoagulation, stroke and bleeding risk need to be assessed using the CHA<sub>2</sub>DS<sub>2</sub>-VASc stroke risk score and the HAS-BLED score respectively:

- » People who have a CHA<sub>2</sub>DS<sub>2</sub>-VASc stroke risk score  $\geq 2$  should be offered anticoagulation taking bleeding risk into account.
- » Anticoagulation should also be considered for men with a CHA<sub>2</sub>DS<sub>2</sub>-VASc stroke risk score of 1 taking bleeding risk into account.
- » Anti-platelet monotherapy is not a treatment option for stroke prevention in atrial fibrillation.
- » The risk of bleeding in people who are starting or are already on anticoagulation treatment should be assessed using the HAS-BLED score.
- » Modification of bleeding risk factors should be undertaken and should include assessment of uncontrolled hypertension, fluctuations in the INR if patients are on warfarin ("labile" INRs), review of concurrent medications such as anti-platelet agents and non-steroidal anti-inflammatory drugs, and harmful alcohol consumption (>8 units per week).

It is recommended that decision support tools are used to help patients and carers decide in conjunction with the responsible healthcare professional, which treatment strategy is the most suitable and preferred.

## Components of an excellent anticoagulation service for patients with AF

### 8. High quality, safe care for patients on vitamin K antagonist treatment

Warfarin and other vitamin K antagonists have a narrow therapeutic window, and are affected by dietary intake of food and alcohol, as well as other medication. They require regular blood test monitoring of the INR.

Computer clinical decision support software (CDSS) such as DAWN, INRStar and ProTime can augment warfarin prescribing and have been shown to improve markers of anticoagulant control (such as TTR) and clinical outcomes versus practitioner-only dosing.

The frequency of monitoring is determined by the stability of the INR, and should normally be determined by the CDSS algorithm. The maximum length of time between tests should not be longer than 12 weeks.

Each patient should be given an NPSA Oral Anticoagulation Therapy (OAT) patient information booklet and monitoring yellow book (or local alternative). Patients should be advised to carry an anticoagulant card for use in emergency situations.

The quality of anticoagulation can be assessed by calculating the person's TTR. There are a number of ways of calculating individual patient TTR and NICE recommends that either the Rosendaal<sup>25</sup> method for computer-assisted dosing or proportion of tests in range for manual dosing, should be used. Anticoagulation control should also be assessed by reviewing individual INR blood tests. The target INR is 2.5, and values < 2 and > 3 predispose patients to an increased chance of ischaemic and haemorrhagic stroke respectively. Individual review of outlying INRs will help to inform the adequacy of overall anticoagulation control.

In line with NICE guidance, the following recommendations for patients on vitamin K antagonists should be observed:

- » The TTR should be calculated and recorded at each visit. TTRs should be calculated over a maintenance period of 6 months, excluding the first six weeks following initiation.
  - » Individual TTR results should be provided to patients, and collected by the service for feedback to commissioners.
  - » The target TTR should be as high as possible, but as a minimum, should be > 65%.
  - » INR results > 5 or < 1.5 should be specifically highlighted and recorded for audit purposes
  - » If the TTR < 65%, or 2 INR tests are < 1.5, or 2 INR tests > 5 or 1 INR test > 8, then the quality of anticoagulation control should be reassessed, and possible contributing factors addressed. These factors include:
    - » Patient adherence to prescribed treatment
    - » Intercurrent illness
    - » Interacting drug therapy
    - » Lifestyle factors including dietary and alcohol intake
    - » Cognitive impairment
- If improved control cannot be achieved, then alternative strategies for stroke prevention including the use of DOACs should be offered. Non-adherence to vitamin K antagonist treatment on its own, is not an indication for DOAC initiation. Instead, the reasons for non-adherence should be addressed at each visit.
- » An excellent anticoagulation service should audit out of range INR results and individual patient TTRs. This information should be available to commissioners and patients.
  - » An excellent anticoagulation service should demonstrate that there are mechanisms in place to reassess and address the quality of anticoagulation in all patients with suboptimal control as described above.

## Components of an excellent anticoagulation service for patients with AF

### 9. Self-monitoring and self-management of vitamin K antagonist treatment

Patient self-testing and self-management in selected motivated patients can improve anticoagulation control and decrease the number of thrombotic events, as well as reduce the frequency of hospital or clinic visits. NICE has approved the use of two point-of-care test (POCT) devices<sup>17</sup>. The CoaguChek XS system and INRatio2 PT/INR monitor are recommended for self-monitoring if the person prefers this form of testing, and the person or carer is both physically and cognitively able to self-monitor effectively.

An excellent anticoagulation service should ensure that:

- » All suitable patients on warfarin treatment are given information, education and the opportunity to opt for self-monitoring and/or self-management if they prefer this.
- » Patients and carers are trained in the effective use of the POCT devices. They need to demonstrate competency in the use of the device. Patients who aim to self-manage should demonstrate their competency in dose adjustment. A simple warfarin-dosing algorithm should be used. Clinicians involved in their care should regularly review their ability to self-monitor, at least every six months.
- » The POCT equipment should be regularly checked using reliable quality-control procedures, and by testing the equipment against a healthcare professional's coagulometer which is checked in line with an external quality assurance scheme such as the UK National External Quality Assessment Service (NEQAS), the NHS Supply Chain or a local laboratory hospital scheme (UKAS/CPA accredited laboratory.) This should take place at least every six months. The MHRA is the regulatory body for POCT devices and should be notified of any adverse incidents.

- » An INR > 8.0 (if confirmed on a repeat sample) requires that a venous sample is analysed in a hospital laboratory, and that patients seek medical advice.

### 10. Non vitamin K antagonist treatment

DOACs are a treatment option for patients with NVAF and one additional risk factor for stroke. In line with NICE guidance and technology appraisals, DOACs should be available to all patients where clinically indicated. There should be very clear pathways for patients to access DOACs. If local protocols for anticoagulation initiation are in use, then these protocols should be consistent with the NICE recommendation that both vitamin K antagonists and DOACs are equal treatment options for stroke prevention. In addition, DOACs may be suitable alternatives to vitamin K antagonists where good INR and TTR control cannot be achieved (*as detailed in section 8*).

The initiation of anticoagulation with DOACs should follow the same stroke risk and bleeding assessment (*as described in section 7*). Healthcare professionals initiating a DOAC must be trained and fully aware of the summary of product characteristics of the various approved drugs. In addition, clinical resources such as the [European Heart Rhythm Association practical guide for DOAC use in non-valvular AF](#) provide useful guidance for clinicians in the safe prescribing, monitoring, and review of these newer treatments. In particular, guidance is detailed with regards to the frequency of renal and liver function monitoring with the various agents.

All patients who are due to be initiated or maintained on DOAC treatment should be counselled in accordance with the topics outlined in section 6. In addition, patients should be given written information and asked to carry an anticoagulant alert card. Specific information for patients in addition to that

### Components of an excellent anticoagulation service for patients with AF

outlined in section 6 includes:

- » What to do if a dose of a DOAC is missed
- » Whether the DOAC should be taken with or without food (rivaroxaban should be taken with food as this increases its bioavailability; the absorption of apixaban, dabigatran and edoxaban are largely unaffected by food).

There is no need for routine coagulation monitoring with DOACs. Anticoagulation services should ensure that patients understand why they are taking a DOAC, and the importance of medication adherence. Pharmacists can reinforce the importance of adherence each time they dispense medication and through medicines use reviews.

Follow up monitoring for DOAC treatment is different to that required for warfarin anticoagulation. We recommend following EHRA guidance above. Ensuring that the patient receives follow up monitoring is the responsibility of the prescriber. All patients initiated on anticoagulant treatment

#### 11. Patient review

should be followed up. The frequency of follow up depends on a number of factors including the type of anticoagulant prescribed, stability of anticoagulant treatment, compliance with treatment, patient co-morbidities such as renal impairment or patients at higher risk of bleeding, and intercurrent illnesses. Patients whose anticoagulant treatment is temporarily discontinued (for example due to significant bleeding) will also need to be followed up in order to reassess stroke and bleeding risk. These patients should not automatically be discharged from a service without a formal review.

The NICE AF quality standard 3 ([Venous thromboembolism in adults](#)) recommends that all patients should have the opportunity to discuss their

anticoagulation options with a healthcare professional at least once a year. This should be the minimum time, and for some patients, especially for those with difficult to manage INR and TTR, or at higher risk of bleeding, clinical review will need to be more frequent.

A regular review should include the following:

- » Review of the indication for anticoagulation and reassessment of thromboembolic risk
- » Assessment and correction of bleeding risk factors (eg by using HAS-BLED)
- » Patient education, information, and decision support
- » Assessment of medication adherence
- » Complications related to AF (eg TIA or stroke)
- » Complications related to anticoagulation treatment
- » For all patients, review of the alternative anticoagulant strategies including the self-monitoring for long-term vitamin K antagonist users if indicated
- » For patients on warfarin:
  - » Assessment and documentation of TTR
  - » Assessment of INRs that fall outside of the therapeutic range (especially INRs < 1.5 and > 5)
- » For patients on DOACs:
  - » Renal +/- liver function as indicated
- » Medicines optimisation (including ensuring that anti-platelets are not concomitantly prescribed unless there is a definite reason as recommended by a named specialist).

Complex cases may require the multidisciplinary discussion between different specialists. Care should be taken to ensure that all healthcare professionals are fully informed of changes in clinical status.

If a patient is deemed to have a very high risk of bleeding complications or is otherwise ineligible for anticoagulant use, but has a high thromboembolic risk, then referral to a cardiologist should be considered for left atrial appendage occlusion if indicated. Clear local protocols and pathways will need to be written in conjunction with local cardiology

### Components of an excellent anticoagulation service for patients with AF

services.

All patient reviews should be supported with written advice and documentation. A follow up review should be arranged. The service is responsible for informing all those healthcare professionals involved in the care of the patient.

This document cannot cover every individual

#### 12. Special circumstances

circumstance. However, we recommend agreed protocols and referral mechanisms are in place for the following situations:

- » Management pathway for the re-assessment of patients with poor vitamin K antagonist control
- » Management pathway for low and high INRs especially for those at high risk of thromboembolic events
- » Management pathway for anticoagulant associated bleeding (include supplies of vitamin K where required to reverse the effect of vitamin k antagonists)
- » Protocols for bridging therapy (include supplies of low molecular weight heparin)
- » Referral pathways and contacts to allied services including haematology, cardiology and stroke departments
- » Clinical protocols for the initiation of anticoagulation treatment
- » Clinical protocols for the switching of anticoagulant therapy
- » Agreed pathways for the discussion and multidisciplinary assessment of complex patients where additional expertise is required. This offers the opportunity of utilising innovative forms of practice such as integrated community care clinics, virtual clinics or teleconferences.
- » Agreed contact details in case of emergencies both during normal working hours, and out of hours.

#### 13. Training and support for providers

The NPSA highlights staff training and competencies as crucial in ensuring effective and safe provision of anticoagulation treatment. Providers should ensure that healthcare professionals who initiate, monitor and review anticoagulation therapy have the necessary access to training, skills and competencies to meet the requirements of their role. Providers should be adequately trained to provide effective education and support to patients and carers. Providers should also ensure that there is a mechanism for on-going continued professional development for all professionals involved in an anticoagulation service.

There is no national consensus on the minimum competencies required for healthcare professionals working in this area of care. Commissioners should specify standards of training and competency for different healthcare professionals at a local level, and specify the necessary documented evidence of training and competency required.

#### 14. Safety, clinical effectiveness, and clinical governance arrangements

Warfarin is one of the most common causes of drug-related adverse events and is responsible for 5.6 per cent of fatal and severe drug-related incidents, many of which require hospital admission<sup>20</sup>. The NPSA Patient Safety Alert 18 in 2007 acknowledged warfarin as a common avoidable cause of emergency attendances and admissions and asked the NHS to reinforce training competencies of staff involved in the management of anticoagulation.

All anticoagulation services should follow the NPSA recommendations, and ensure that there are robust clinical governance, risk assessment and quality assurance mechanisms in place.

## Excellence in anticoagulant care

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### Components of an excellent anticoagulation service for patients with AF

All of these should be agreed with commissioners. In particular, attention should be paid to:

- » A register of all patients under the care of the anticoagulant service including name, date of birth, NHS number, indication for treatment, duration of treatment, discontinuation dates if temporary anticoagulation, target INR (if on vitamin K antagonist treatment) and type of treatment.
- » The use of clinical decision support software in warfarin dosing
- » Monitoring and reporting of adverse events related to anticoagulant treatment. This will involve the linking of hospital admission information from acute providers. All cases of bleeding requiring hospital admission or deaths associated with anticoagulation must be reported to the commissioners as a significant event.
- » Prescribing errors
- » Clear patient call and recall systems with protocols of what to do if patients do not attend appointments
- » Quality control mechanisms for POCT devices (both service and patient-owned devices). This includes both internal and external quality assurance mechanisms. Service POCT devices should be registered with the National External Quality Assessment Service (NEQAS), and operated, maintained and quality assured in keeping with the manufacturer's guidelines. Patient-owned devices should be tested against a service device that is registered with NEQAS.
- » Clear guidance related to the recording of patient details, results of blood tests, patient records and documentation in patient-facing hand held records.
- » Clear guidance related to communication with other relevant healthcare professionals such as general practitioners, hospital specialists and pharmacists when required (eg in a situation where there has been a clinical or medication change).
- » A mechanism for reporting quality metrics and a method of continuously improving service performance.
- » Transparent and regular process of review led by commissioners.
- » Regular audits against pre-defined metrics and reports to patients and commissioners with action plans disseminated to relevant stakeholders.
- » Adequate capacity within the service to ensure timely access for patients and the regular frequency of blood test monitoring for patients taking vitamin K antagonists.
- » The provision of service and business continuity plans including the provision for breakdown of equipment or software.
- » Patient satisfaction surveys should be carried out and results evaluated. Survey evidence should be used to inform patient-centred service improvement.

#### 15. Service audit and review

In line with NPSA recommendations, good systems of clinical governance practice including audit should be embedded into the service specifications of an excellent anticoagulant service. The process of audit, reporting of results to stakeholders, regular review, and service improvement should be transparent and agreed with commissioners. There should be processes in place to address poor performance against the service specification or locally agreed standard.

Computer software used in clinical decision-making can provide a variety of metrics such as TTR to highlight the quality of service provision. The use of regional quality dashboards will also provide a useful benchmarking tool and act as a driver for continual service improvement.

An excellent anticoagulation service should provide regular (at least quarterly) information on the following to commissioners:

- » Numbers of patients seen
- » Number of anticoagulation appointments
- » Time to first available appointment from referral
- » Patient non attendance rates

### Components of an excellent anticoagulation service for patients with AF

- » Frequency of drug reactions
- » Serious incident reporting
- » Number of patients whose anticoagulation treatment is stopped
- » Number of vitamin K antagonist users
- » Number of patients self-monitoring and self-managing warfarin anticoagulation
- » Number of DOAC users
- » Serious events including hospital admissions due to anticoagulation treatment
- » Strokes and other thromboembolic events in patients on anticoagulant treatment
- » Death of patients treated with anticoagulant therapy
- » For patients on vitamin K antagonist treatment:
  - » The frequency of blood tests (average interval between INRs)
  - » Percentage of patients within therapeutic range (service level TTRs)
  - » Percentage of INRs tests > 5
  - » Percentage of INR tests > 8
  - » Percentage of INR tests < 1.5

The NHS is currently prioritising projects which aim to increase the identification of new patients with asymptomatic AF (eg through opportunistic screening programmes), and aim to increase the uptake of anticoagulation for patients with already identified AF at risk of stroke. In addition to this, local improvement programmes are looking at identifying patients with AF who are on aspirin treatment with the aim of assessing them for anticoagulant treatment.

These changes in prevalence and anticoagulant uptake will need to be considered when planning future anticoagulant service capacity. The changes in the rates of prescribing of both vitamin K antagonist treatment and DOAC therapy will have a significant impact on the modelling of capacity within existing anticoagulant services. Providers are encouraged to work closely with commissioners to ensure there is an adequate provision of anticoagulant services to meet the needs of the local population.

An annual service review with commissioners is recommended. This should also incorporate patients and other user feedback.

#### 16. Review of capacity

Data suggests that the proportion of adults aged 18 years or older needing anticoagulation therapy is approximately 2.4 per cent of the adult population of England. The prevalence of AF increases with age, and primary care data suggests that 85 per cent of people diagnosed with AF are 65 or over. The England population aged 65 or older is predicted to rise by 23.6 per cent between mid-2011 and 2021. This is likely to have a significant impact on the number of people with AF who will need anticoagulation.

## References

- 1 Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke* 22:983-8.
- 2 Hart RG, Pearce LA, Aquilar MI. Meta-analysis: antithrombotic therapy to prevent stroke in patients who have nonvalvular atrial fibrillation. *Ann Intern Med.* 2007 June 19; 146(12):857-67.
- 3 National Institute for Health and Care Excellence clinical guideline 180 Atrial fibrillation: the management of atrial fibrillation (2015).
- 4 Camm AJ, Lip GY, De Caterina R et al. On behalf of the ESC Committee for Practice Guidelines. 2012 focused update of the ESC Guidelines for the management of atrial fibrillation: an update of the 2010 ESC Guidelines for the management of atrial fibrillation-developed with the special contribution of the European Heart Rhythm Association. *Eur Heart J.* 2012 Nov; 33(21):2719-47.
- 5 Oden A, Fahlen M, Hylek EM. Optimal INR for prevention of stroke and death in atrial fibrillation: a critical appraisal. *Thromb Res* 2006; 117:493-9.
- 6 Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2009;361:1139-51.
- 7 Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus warfarin in nonvalvular atrial fibrillation. *N Engl J Med* 2011;365:883-91.
- 8 Granger CB, Alexander JH, McMurray JJ, et al. Apixaban versus warfarin in patients with atrial fibrillation. *N Engl J Med* 2011;365:981-92.
- 9 Giugliano RP, Ruff CT, Braunwald E, et al. Edoxaban versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med* 2013;369:2093-2104.
- 10 Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation. NICE technology appraisal guidance 249 (2012).
- 11 Rivaroxaban for the prevention of stroke and systemic embolism in people with atrial fibrillation. NICE technology appraisal guidance 256 (2012).
- 12 Apixaban for preventing stroke and systemic embolism in people with nonvalvular atrial fibrillation. NICE technology appraisal guidance 275 (2013).
- 13 Edoxaban for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation. NICE technology appraisal guidance 355 (2015).
- 14 Heidbuchel H, Verhamme P, Alings M et al. Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with non-valvular atrial fibrillation. *Europace* (2015) 17(8).



- 15 NICE Commissioning guide 49 (2013). Support for commissioning: anticoagulation therapy.
- 16 NICE clinical guideline 138. Patient experience in adult NHS services.
- 17 NICE diagnostics guidance 14 (2014). Atrial fibrillation and heart valve disease: self-monitoring coagulation status using point-of-care coagulometers (the CoaguChek XS system and the INRatio2 PT/INR monitor).
- 18 NICE interventional procedure guidance 349 (2010). Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism.
- 19 NICE quality standard 93 (2015). Atrial fibrillation: treatment and management.
- 20 Makris M, Van Veen JJ, Tait CR, et al, on behalf of the British Committee for Standards in Haematology. Guideline on the management of bleeding in patients on antithrombotic agents. *Br J Haematol* 2012;160:35-46.
- 21 Bakhai A, Lip GY, McCormack T et al. Developing best practice in anticoagulation service delivery for patients with atrial fibrillation: Defining consensus to enhance time in therapeutic range.
- 22 Jennings I et al. on behalf of the BCSH committee. Patient self-testing and self-management of oral anticoagulation with vitamin K antagonists: guidance from the British Committee for Standards in Haematology. *Br J Haem*, 2014, 167:600-607
- 23 Setting the Standards in Anticoagulation Service Delivery. Anticoagulation Europe. 2006
- 24 Commissioning effective anticoagulation services for the future. A resource pack for commissioners. Anticoagulation Europe. 2012
- 25 Rosendaal FR, Cannegieter SC, van der Meer FJ, Briet E. A method to determine the optimal intensity of oral anticoagulant therapy. *Thrombosis and Haemostasis*. 1993; 69 (3) 236-239

## About the London Clinical Networks

The London Clinical Networks bring together those who use, provide and commission the service to make improvements in outcomes for complex patient pathways using an integrated, whole system approach.

The Clinical Networks work in partnership with commissioners (including local government), supporting their decision making and strategic planning, by working across the boundaries of commissioner, provider and voluntary organisations as a vehicle for improvement for patients, carers and the public. In this way, the networks will:

- » Reduce unwarranted variation in services
- » Encourage innovation in how services are provided now and in the future
- » Provide clinical advice and leadership to support their decision making and strategic planning.