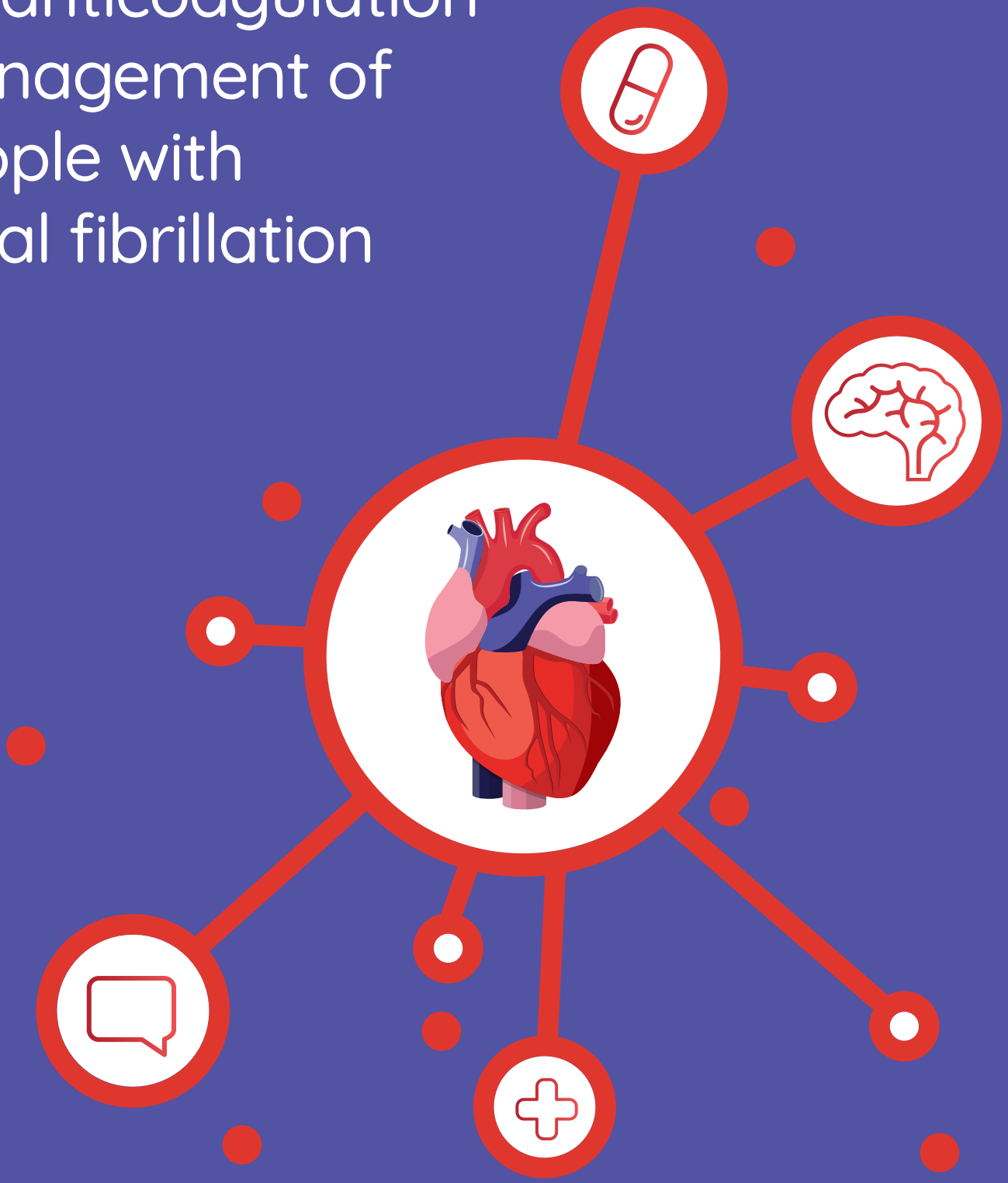
Framework service specification for anticoagulation management of people with atrial fibrillation



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Anticoagulation UK

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Contents

Introduction

This document is a framework service specification for the delivery of anticoagulation services for people with atrial fibrillation (AF).

It has been developed by Anticoagulation UK (ACUK) with input from a multidisciplinary expert panel. The expert panel members were chosen and convened by Anticoagulation UK. This project has been fully funded by Bayer plc. The content is independent of and not influenced by Bayer plc who checked the final document for technical accuracy only. WA Communications provided support for Anticoagulation UK to deliver this project. WA's services are fully funded by Bayer.

Anticoagulation UK would like to thank the expert panel members for their input into the development of this specification, including: **Frances Akor** (Consultant Pharmacist, Anticoagulation), **Chris Arden** (GP and Cardiovascular Clinical Lead), **Yassir Javaid** (GP and Primary Care Cardiovascular Lead), **Susan Wintle** (Anticoagulation Pharmacist).

Why have a framework specification?

Improving the coverage and quality of anticoagulation services is a key priority of the health system. The NHS Long Term Plan states that cardiovascular disease (CVD) is "the single biggest area where the NHS can save lives" and introduced the ambition to help prevent 150,000 heart attacks, strokes and dementia cases over the next ten years.[1] As part of this, the health system has ambitious new targets for better detection and management of atrial fibrillation (AF) and other high-risk conditions. By 2029, the NHS aims to ensure that 90% of people with AF who are known to be at high risk of stroke are optimally anticoagulated in order to reduce their risk of stroke.[2]

COVID-19 and anticoagulation services

The COVID-19 pandemic has also highlighted the importance of ensuring that anticoagulation services are focused on ensuring the safety of patients prescribed anticoagulation therapy, many of whom are at high risk of negative outcomes from infection. Services need to protect anticoagulation patients from exposure to COVID-19, while ensuring that they continue to receive appropriate, timely and high-quality anticoagulation therapy.[3] Clinical guidance from NHS England has advised services to consider transitioning patients from warfarin to a direct oral anticoagulant (DOAC) where appropriate, and to improve self-testing and reduce frequency of physical contact with services for those patients on warfarin who are unable to transition to a DOAC.[3] The clinical guidance can be viewed online via this link.

As anticoagulation services adapt to the changing landscape as a result of COVID-19, it is more important than ever that standards are aligned across the country and all services are performing to clearly defined specifications, so that patients on anticoagulation receive the best possible care regardless of where they are located.

This framework specification is intended to support this ambition. It has been developed by ACUK in close collaboration with experts in anticoagulation from across primary, community and secondary care. The standards within this framework reflect best practice for services to adhere to, both during and beyond the COVID-19 pandemic. It will, of course, have been necessary during the peak of the pandemic to adapt certain aspects of service delivery, for example by decreasing the frequency of monitoring, however it is important that all anticoagulation services aim wherever possible to meet these standards as the health system resumes the provision of routine services.

By 2029, the NHS aims to ensure that 90% of people with AF who are known to be at high risk of stroke are optimally anticoagulated in order to reduce their risk of stroke.[2]

[1] NHS, The NHS Long Term Plan, January 2019. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf [Accessed July 2020].

[2] Public Health England, Health matters: preventing cardiovascular disease, 14 February 2019. Available from https://www.gov.uk/government/publications/health-matters-preventing-cardiovascular-disease/health-matters-preventing-cardiovascular-disease [Accessed September 2020].

[3] NHS England and NHS Improvement, Clinical guide for the management of anticoagulant services during the coronavirus pandemic, 31 March 2020. Available from https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0077-Specialty-guide_Anticoagulant-services-and-coronavirus-v1-31-March.pdf [Accessed September 2020].

How to use this framework specification

This framework specification has been designed for use by commissioners of anticoagulation services for people with AF. It is intended to be adaptable for services delivered in primary, community or secondary care settings. For ease of use, it has been developed within the template for anticoagulation services utilised by the majority of commissioners across the country.

The framework provides NHS commissioners and providers with key components to include in an anticoagulation service specification which is consistent with NICE guidelines and quality standards, and can be tailored according to local need through different service models.

While this specification has been developed for the anticoagulation of patients with AF, who form the majority of most anticoagulation service patient cohorts across the country, anticoagulation therapy is also indicated in other conditions including prophylaxis and treatment of venous thromboembolism, prophylaxis after insertion of prosthetic heart valves, and other cardiac and thrombotic disorders. Many of the key components and principles of this service specification can be applied to general anticoagulation services that address a broader patient population.

What makes a gold standard service specification?

A gold standard service specification will deliver high-quality anticoagulation services that:

- **Are patient-centric**
  - Ensure that patients/carers are involved in all treatment decisions and supported to be active in their own care, including through self-testing for patients on warfarin
  - Provide regular, tailored patient education and support from initiation through to ongoing management, both face-to-face or via remote consultation and through written information
  - Offer at least an annual patient review
- **Offer choice and flexibility**
  - Offer patients an appropriate choice of anticoagulation according to their needs and preferences, in line with NICE guidance and encompassing both vitamin K antagonists, such as warfarin, and DOACs[4]
  - Provide an accessible, timely and convenient service
- **Support medication adherence**
  - Provide all patients with advice and support on medication adherence
  - Regularly follow-up with patients to identify those who may be poorly controlled, taking timely action and offering appropriate alternative treatment options
- **Provide clear referral pathways**
  - Use a clearly defined referral pathway to and from the service that offers access to all appropriate patients and ensures that onward referral pathways are well-defined
- **Use written protocols for patient management**
  - Have written protocols that align with national guidance and quality standards, including protocols for the management of patients poorly controlled on warfarin or other vitamin K antagonists as denoted by:
    - Two International Normalised Ratio (INR) values higher than five or one INR value higher than eight within the past six months
    - Two INR values less than 1.5 within the past six months
    - Time in Therapeutic Range (TTR) less than 65%[4]
  - Ensure that written protocols are also able to identify patients who may be poorly controlled on a DOAC, as denoted by poor compliance, change in weight or renal function, or other indicators
- **Deliver regular service performance monitoring against defined metrics**
  - Provide regular and transparent reporting on service performance against benchmarks

The following service specification encompasses these key features.

[4] NICE, Atrial fibrillation: management clinical guideline [CG180], June 2014. Available from: https://www.nice.org.uk/guidance/cg180/chapter/1-Recommendations#assessment-of-stroke-and-bleeding-risks-2 [Accessed September 2020].

Service Specification No.	
Service	
Commissioner Lead	*Include a designated commissioning lead for the service*
Provider Lead	*Include a designated service provider lead*
Period	
Date of Review	

1. Population needs

1.1 National/local context and evidence base

Use this section to summarise the relevant national policy that the specification will support and the local context and needs that the service should meet.

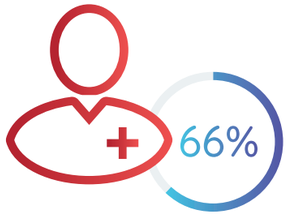
National context:

The NHS Long term plan sets out the ambition to help prevent up to **150,000** cases of **heart attack, strokes and dementia** cases by 2029.[5]

The identification and optimal anticoagulation of patients with atrial fibrillation (AF) has been prioritised at national level as key to meeting this ambition.

Between April 2018 and March 2019,

39.1% of patients with known AF who had a stroke had not been prescribed anticoagulation prior to their stroke.[7] In addition, some patients on warfarin are on a sub-optimal dose, leaving them at significant risk of having a stroke.[6]



Effective anticoagulation therapy for managing people with AF who are at risk of stroke can reduce the risk of stroke by up to 66%.[6]

However, many people with AF are not receiving any anticoagulants or are receiving ineffective treatment such as aspirin alone.[6]

To deliver this ambition to prevent many more cases of stroke and heart attacks, NHS England and Public Health England have set the following treatment and detection targets:

of the expected number of people with AF to be detected by 2029

of people with AF who are known to be at high risk of a stroke to be adequately anticoagulated by 2029.[6]

Local context:

Include:

- *The estimated prevalence of AF in the local population; and*
- *The estimated percentage of detected AF in the local population.*

  *[The above data can be obtained from the Public Health England Profiles at **https://fingertips.phe.org.uk/**]*
- *The number of local stroke patients with known AF who were not anticoagulated prior to having a stroke; and*
- *The percentage of applicable patients in atrial fibrillation on discharge who are discharged on anticoagulants or with a plan to start anticoagulation.*

  *[The above data can be obtained from the Sentinel Stroke National Audit Programme (SSNAP) at **https://www.strokeaudit.org/**]*
- *The value of identifying and treating patients with AF in the local population using the Atrial Fibrillation High Impact Intervention Tool available at **http://afhiit.imperialcollegehealthpartners.com/afimpact***
- *Relevant evidence from the CVD Prevention Partnership Resource Pack available at **https://www.england.nhs.uk/london/london-clinical-networks/our-networks/cardiac/cardiovascular-disease-prevention-partnership-resource-pack/***

[5] NHS, The NHS Long Term Plan, January 2019. Available from: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf [Accessed July 2020].

[6] Public Health England, Health matters: preventing cardiovascular disease, 14 February 2019. Available from https://www.gov.uk/government/publications/health-matters-preventing-cardiovascular-disease/health-matters-preventing-cardiovascular-disease [Accessed September 2020].

[7] Sentinel Stroke National Audit Programme (SSNAP), Outcome data at discharge from inpatient care for patients with prior AF who are not on anticoagulation, Version 1: Updated June 2019. Available from: https://www.strokeaudit.org/results/Clinical-audit/National-Results.aspx [Accessed September 2020].

2. Outcomes

2.1 NHS outcomes framework domains & indicators

Domain 1	Preventing people from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long-term conditions	✓
Domain 3	Helping people to recover from episodes of ill-health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓

2.2 Local defined outcomes

Specify the local outcomes that the anticoagulation service will contribute to. These could be drawn from local system strategic plans. Examples of locally-defined outcomes that anticoagulation services could support include:

By *[specify timeframe]*, to ensure that 90% of patients with AF known to be at risk of a stroke in the local population are adequately anticoagulated; through:

1. Ensuring 90% of people with AF are considered for anticoagulant therapy within one week of referral.
2. Ensuring 80% of patients with a CHA2DS2VASc score ≥ 2 are offered anticoagulation treatment, taking bleeding risk into account.
3. Ensuring 100% of patients being initiated on anticoagulation are offered a choice of treatment tailored to their needs and preferences, to facilitate adherence and long-term control.
4. Ensuring 100% of patients taking warfarin have their anticoagulation quality reassessed at least once every three months.
5. Ensuring 100% of patients on a DOAC have their dosing checked at least once every six months.

3. Scope

3.1 Aims and objectives of service

This section should clearly specify the overarching aims and objectives of the anticoagulation service.

Aims and objectives:

Outcomes and quality:

- **Improve clinical outcomes for patients with AF by ensuring all known AF patients receive optimal anticoagulation to minimise stroke and bleeding risks, following national guidance and quality standards.**
- **Provide a high-quality service that is underpinned by the NHS Outcomes Framework.**
- **Improve accountability and incentivise continuous quality improvement through regular monitoring and evaluation of the service.**

Choice and access:

- **Enhance patients' experience of anticoagulant services.**
- **Improve patient choice by providing a greater range of services that are more easily accessible.**
- **Have an integrated streamlined service across the anticoagulation pathway.**
- **Support more patients to be involved in their own healthcare.**

Cost effectiveness and return on investment:

- **Provide a cost-effective anticoagulation service.**
- **Reduce the demand on system-wide capacity and resources.**

3.2 Population covered and any acceptance and exclusion criteria

Use this section to clearly define the population covered by the service. Ensure that the specification clearly stipulates:

- *The geographic coverage of the service.*
- *Whether the service should include both patients on warfarin (or other Vitamin-K antagonists) and DOACs, or only on one type of anticoagulation.*
- *Whether the service should cover non-complex and stable patients only, or include patients with complex needs. Ensure that clear definitions of all patient types are provided.*
- *Whether the service should cater for house-bound patients and those with specific additional needs.*

Services should cover all anticoagulation patient needs, including patients on warfarin, low molecular weight heparin and DOACs, in order to offer holistic services that provide seamless care which is adaptable to patient needs.

Where relevant, services should include patients from neighbouring areas known not to be providing an anticoagulation service.

3.3 Service description/care pathway

Describe in full the services to be commissioned. Consider breaking the service description into the following sections:

1. Scope of services to be covered

Specify whether the service is to cover any/all of the following:

AF detection, anticoagulation initiation, patient counselling, stabilisation, monitoring, dosing, and/or prescribing of anticoagulants.

*Where any of the above is **not** covered, ensure that the specification outlines where these services can be accessed and all relevant referral pathways.*

2. Service place in care pathway

a) Specify who can make referrals into the service.

Referrals should be accepted from a broad variety of sources including directly via the patient's GP, DOAC clinic, non-medical prescribers in the community, from secondary care or via A&E or Out of Hospital services.

b) Outline the referral process from the anticoagulation service to specialist support and clearly specify the circumstances in which patients should be referred to emergency care or named specialist secondary services.

Include a flowchart to summarise the care pathway within which the service sits and all inclusion/exclusion criteria.

3. Availability and accessibility of services

a) Specify the availability required of the service and whether the service needs to provide a minimum level of ad-hoc access to patients outside of regularly scheduled clinic times.

Services should be contactable seven days a week and operate as frequently as possible to provide patients with optimal access and reduce waiting times.

b) Specify the desired location(s) of the service (e.g. community based) and whether the service needs to include provision for:

- *Housebound patients or those with additional needs*
- *Remote/digital consultations*
- *Electronic appointment scheduling*

c) Specify the minimum time-frame required from referral to the service to patient attendance.

Services should aspire to deliver a maximum 48-hr turnaround from referral to first available appointment.

4. Service delivery team

a) Specify the required range of roles and competencies required for the delivery of anticoagulation services to patients, including whether patient care should fall under the responsibility of a multidisciplinary team (MDT).

Services should be delivered by a medically led, multi-disciplinary team including [for community-based services:] a general practitioner, community-based clinical pharmacist, and anticoagulation nurse specialist. The Provider should nominate a named clinical lead to ensure that the service is delivered in accordance with the specification.

b) Specify the minimum educational/continuing professional development (CPD) requirements for all staff delivering the service. Clearly stipulate the competencies, training and professional accreditation required for personnel managing the dosing of anticoagulant therapy.

The initiation, dosing and management of patients on anticoagulation should only be undertaken by qualified health care professionals that are currently registered with the General Medical Council, General Pharmaceutical Council or the Nursing & Midwifery Council; and who have successfully completed specialist training and are competent in managing the anticoagulated patient.

5. Patient monitoring requirements

Specify in detail the required frequency of in-person patient reviews and the full range and frequency of clinical monitoring required at each visit.

- **All patients accessing the anticoagulation service should be clinically reviewed in person (or remotely via a video or telephone call) at least every three months during the initiation period and at least every six months upon stabilisation.**
- **Patients being managed on warfarin should have their International Normalised Ratio (INR) and Time in Therapeutic Range (TTR) assessed at least every three months. TTR should also be calculated on a six-monthly rolling basis.**
- **All patients (both on warfarin or a DOAC) should receive, on at least an annual basis:**
  - **A weight check**
  - **Full blood count**
  - **Liver function tests**
  - **Renal function tests**
- **Patients on DOACs and warfarin should have their CHA2DS2-VASc and HAS-BLED scores calculated and recorded.**
- **Patients being managed on warfarin should be offered access to self-testing where appropriate.**
- **Clinical reviews should assess the appropriateness of anticoagulant dosing and where relevant ensure that dose adjustments are implemented.**

- Patients found to be poorly controlled should have the reasons for poor control explored and, where appropriate, offered a choice of alternative anticoagulant and additional counselling and support on adherence if non-adherence is found to be an issue.
- Clinical reviews should record adverse outcomes, including bleeding complications and thrombotic events, and ensure that appropriate onward referral pathways are in place and acted upon promptly.

6. Patient counselling and support

Specify the requirements for patient counselling, support and education, including provisions for patient education around choice of anticoagulant, drug-drug interactions, side-effects, when and how to seek help, adherence, and self-monitoring (for patients on warfarin).

- All patients accessing the anticoagulation service should be offered counselling on anticoagulant choice, dosing, interactions, adherence and self-management at initiation and on at least an annual basis thereafter. Counselling should include as a minimum:
  - The purpose of treatment, its benefits and risks; explained in understandable terms.
  - Discussion of the patient's circumstances and preferences for treatment, enabling patient choice and involvement.
  - The name and dose of their treatment, including how to identify individual tablet colours and corresponding strengths.
  - The expected duration of treatment.
  - (For patients on warfarin:) An explanation of Target INR and TTR and its significance.
  - Any drug, alcohol and food interactions and impact on treatment.
  - Potential complications resulting from treatment and what to do in the event of an adverse event.
  - Explanation of how to use the yellow book (or equivalent) and anticoagulant alert card.
  - Importance of adherence to treatment and what to do in the event of a missed or incorrect dose, including awareness of symptoms of under and over-dosing.
  - Circumstances in which anticoagulation dosing should be discussed and potentially adjusted (such as in advance of dental treatment or elective surgery).
  - Procedures for travel/holidays.
- Patients should be provided with enough time to discuss their options and ask any questions they may have regarding their care. Patients must be invited to contact the service with any further queries and provided with contact details.
- Clear instructions (both verbal and written) must be provided to all patients on anticoagulation regarding what to do in the case of bleeding, thrombosis or any other adverse event.
- All patients should be offered written information. This should be clearly written and available in a variety of formats to increase accessibility, including hard copy and electronic versions.
- All patients on warfarin deemed to be suitable for INR self-testing should be offered the opportunity to self-test and provided with suitable equipment with which to do so. Self-monitoring equipment should undergo external quality control checks on at least an annual basis.

3.4 Interdependence with other services/providers

List all other service providers that the service should maintain strong working links with to deliver seamless, safe and high-quality person-centred care.

Providers should have a close working relationship with all Health and Social Care professionals relevant to the pathway including:

- GP Practices
- Acute services
- Community Pharmacies
- Specialist services
- Commissioners
- GP IT system providers
- Nursing and Residential Homes
- Medicines Management
- CCG Quality and Safety Teams

4. Applicable service standards

Specify all guidelines and quality standards the service must adhere to.

4.1 Applicable national standards (e.g. NICE)

The service must adhere to the latest national standards and guidance including:

- NICE Clinical Guideline – Atrial fibrillation: management [CG180]
- NICE Quality standard – Atrial fibrillation [QS93]
- NICE Clinical Knowledge Summary on Anticoagulation – oral

4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

- British Society Haematology Guidelines on oral anticoagulation with warfarin
- 2018 European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist oral anticoagulants in patients with atrial fibrillation
- 2016 European Society of Cardiology Guidelines for the management of atrial fibrillation
- EHRA Practical Guide on the use of non-vitamin K antagonist oral anticoagulants (NOACs) in patients with atrial fibrillation

4.3 Applicable local standards

Specify all local guidelines and quality standards the service must adhere to.

5. Applicable quality requirements

5.1 Applicable quality requirements

Outline all Key Performance Indicators (KPIs) that the service will be expected to meet. Specify the frequency, format of expected reporting, and consequences of any breaches.

Ensure that KPIs cover a comprehensive range of clinical and service performance indicators, including (but not limited to):

- *Number of patients accessing the service*
- *Number of appointments held*
- *Patient non-attendances*
- *Average time from first appointment to referral*
- *Data recording and information sharing*
- *Personalised care and planning*
- *Patient satisfaction*
- *Infection control measures*
- *Clinical parameters to indicate how effectively patients are being managed, including minimum expected standards for TTR at individual patient and population level*

Providers will need to ensure the following key performance indicators for clinical quality are met and will be asked to report on these at the intervals specified below:

Quality Performance Indicator	Threshold	Frequency of measurement	Consequence of Breach
Warfarin patients			
Number of patients on a Vitamin K Antagonist currently registered with service provider	N/A		N/A
Percentage of patients that have had an INR checked in the last 12 weeks			
Clinic's proportion of patient time in therapeutic range +/- 0.5 target INR			
Clinic's proportion of patient time in therapeutic range +/- 0.75 target INR			
Percentage of INRs < 1.5			
Percentage of patients that have had an INR > 5 recorded			
Percentage of patients that have had an INR equal to or greater than 8 recorded			
Percentage of patients on warfarin with CHA2DS2-VASc and HAS-BLED scores calculated and recorded			

Quality Performance Indicator	Threshold	Frequency of measurement	Consequence of Breach
DOAC patients			
Number of patients on a DOAC currently registered with service provider	N/A		N/A
Percentage of patients on a DOAC with CHA2DS2-VASc and HAS-BLED scores calculated and recorded			
Percentage of patients on a DOAC who have had their adherence/compliance with medication assessed at least once in the last six months			
Percentage of patients on a DOAC who have had their dose and choice of DOAC checked at least once in the last six months			
All patients			
Percentage of patients with a CHA2DS2VASc score ≥ 2 offered anticoagulation treatment			
Number of patients on aspirin monotherapy	0		
Percentage of patients who have attended an annual review in the last year			
Percentage of patients with weight check recorded in the last year			
Percentage of patients with full blood count recorded in the last year			
Percentage of patients with liver and renal function test results recorded			
Total number of serious events due to anticoagulation treatment			
Number of strokes and other thromboembolic events in patients on anticoagulant treatment			
Number of hospital admissions due to anticoagulant treatment			
Percentage of new patients referred to the service who were seen within 48 hours of referral			
Percentage of patients satisfied with their experience of the service as indicated by patient survey			
General service metrics	**Current quarter**	**Previous quarter**	**Rolling average**
Number of patients accessing the service			
Number of appointments held			
Patient non-attendances			
Average time from first appointment to referral			