Warfarin Oral Anticoagulation Management

Service Specification

Service Specification No.	FINAL – June 2023
Service	Oral Anticoagulation Management
Commissioner Lead	NHS Lincolnshire Integrated Care Board (ICB)
Period	1st April 2023 – 31st March 2024
Date of Review	June 2023

1. Population Needs

1.1 Context

National figures indicate that approximately 1.3% of the population requires oral anticoagulation management. This is higher in Lincolnshire at 1.8% due to Lincolnshire having a much older population than the national average. As at January 2023, the Lincolnshire population is 813,240. The estimated number of patients therefore who will need access to this service is approximately 14,638. Guidance from the National Institute for Clinical Excellence (NICE) and demands from the Quality and Outcomes Framework (QOF) means that the number of patients requiring this care is likely to continue to increase. PACEF (Prescribing and Clinical Effectiveness Forum) have considered a range of key opinion leaders in terms of developments in AF. These include the All Party Select Committee on AF (GRASP-AF), East Midlands Cardiac and Stroke Network and European Society of Cardiology. Recent National data from the GRASP-AF initiative reports that 8.5% of AF patients at high risk of stroke are receiving no treatment, 35% are on aspirin and 56.9% are receiving an oral anticoagulant.

There are a number of people who require anticoagulation but have not been identified. It is estimated that as many as 700,000 people in the UK may have undiagnosed atrial fibrillation (AF). It is estimated that in Lincolnshire there are 3,500 people with undiagnosed AF (0.5%) of the UK population. Undiagnosed AF rates are much higher in the older population.

The management of patients requiring oral anticoagulation therapy includes those with conditions such as atrial fibrillation and the prevention and treatment of deep vein thrombosis and pulmonary embolism and those patients who have undergone cardiac surgery. Many of these patients will have oral anticoagulation therapy initiated in secondary care whilst others require therapy initiation within the primary care setting. If a patient is stabilised on Warfarin anticoagulation therapy, the average number of International Normalized Ratio (INR) tests necessary in order to remain stable is 8 to 10 per year. Increasingly patients may be initiated on either warfarin or one of the new oral anticoagulants (DOAC/NOACs), (Dabigatran, Rivaroxaban, Edoxaban and Apixaban). The management of patients prescribed NOACs is excluded from this specification.

There are 4 localities within the CCG in Lincolnshire all working together to improve the delivery of healthcare and to improve the health of our population.

1.2 Local Context and Summary Statistics

Lincolnshire's Integrated Care System and Integrated Care Board

The NHS Lincolnshire Integrated Care System (ICS) was created on 1 July 2022 following an amendment of the Health and Social Care Act 2006.

The ICS is a partnership that brings together providers and commissioners of NHS services across Lincolnshire with local authorities and other local partners (such as the voluntary sector), to collectively plan health and care services to meet the needs of their population.

The 4 aims of the ICS are:

- improve outcomes in population health and healthcare
- tackle inequalities in outcomes, experience, and access
- enhance productivity and value for money
- help the NHS support broader social and economic development

NHS Lincolnshire Integrated Care Board (ICB) is the statutory body within Lincolnshire ICS responsible for the provision of health services, in accordance with the Health and Care Act 2022.

Lincolnshire ICB will use its resources and powers to collaboratively tackle complex challenges, including:

- improving the health of children and young people
- supporting people to stay well and independent
- acting sooner to help those with preventable conditions
- supporting those with long-term conditions or mental health issues
- caring for those with multiple needs as the population ages
- getting the best from collective resources so people get care as quickly as possible

Lincolnshire ICB statistics

- Lincolnshire ICB has 81 practices
- The total registered population is 813,240 (as of January 2023)
- The registered population live in 7 different lower tier Local Authorities
- As of 2021, the male average life expectancy in Lincolnshire (78.3 years) is slightly lower than the national average (78.7 years). The average Lincolnshire life expectancy for females is 82.8 years, which is the same as the national average
- The 2021 overall premature mortality rate in Lincolnshire (deaths <75 years per 100,000) is 366.3, which is slightly higher than the national figure of 363.4
- The average level of deprivation in England as of 2019 was 21.7. Lincolnshire ICB as a whole is slightly less deprived than this, at 20.2. However, there are pockets of deprivation across the county that are within the national 20% most deprived areas (mainly around coastal and inner urban areas)

Further information on the locality can be found at the following:
Lincolnshire Health Intelligence Hub (lhih.org.uk)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

2.2 Local defined outcomes

The service will be delivered within the primary care setting and must be as easily accessible as possible for all patients. Uniformity of standards and procedures are necessary to provide a

high-quality service for patients who are mobile and are able to attend a monitoring appointment and for patients who are temporarily in the area and patients that are housebound[1] and require domiciliary care. Novel (or Direct) Oral Anticoagulants (NOACs or DOACs) provide an alternative for patients whom regular INR monitoring is hard to access (subject to local guidance). The decision to initiate a patient on a NOAC within this context must be based on sound clinical reasoning and should not simply reflect the convenience of the patient or practice. **NOACs/DOACs are not covered under this service specification.**

The service must:

- Ensure that where appropriate, patients are initiated onto oral anticoagulation therapy in primary care
- Provide increased capacity in the community to meet the rising demand for oral anticoagulation monitoring
- Ensure a quality approach to testing, sampling and dosing across providers
- Ensure that maintenance of patients is properly controlled and the need for continuation of therapy is reviewed regularly and therapy is discontinued where appropriate.

Guidance can be obtained at: https://cks.nice.org.uk/anticoagulation-oral

3. Scope

3.1 Aims and objectives of service

To provide a safe and effective initiation, stabilisation, monitoring and dosing 'One Stop Shop' Oral Anticoagulation Management service in a community setting for patients with the majority being defined as non-complex.

It is anticipated that the service will be provided on a geographical footprint ensuring 100% population coverage, with each Primary Care Network deciding which Provider would be the most appropriate to deliver the service for their population. Providers could either be Primary Care Networks themselves, or other community/primary care Providers.

Patients who become unstable should continue to be managed by the service where medically appropriate, and those patients who are otherwise medically fit for discharge from hospital, should be accommodated if clinically appropriate even when their INR is not yet stable. To ensure a seamless service for patients aged 16 and over, registered to a GP practice in Lincolnshire who have been initiated on oral anticoagulation therapy in primary care and where appropriate; patients initiated in secondary care, in line with National Guidance.

Please note that if and when patients present to the service who are under 16 years of age or an obstetric patient, they should be discussed and reviewed on a case-by-case basis, this review should include the provider, supervising Consultant (paediatrician or obstetrician) with a view to reaching a decision as to whether it is appropriate for that patient to be treated.

The service will minimise the potential adverse effects of oral anticoagulation therapy by providing patients with regular monitoring to stabilise the International Normalised Ratio (INR) levels while continuing to maximise the effective benefits of such treatment.

The service will have equitable access, ensuring that patients are treated with dignity and respect, are fully informed about their care and are able to make decisions about their care in partnership with healthcare professionals.

[1] **Definition of Housebound** – *"A patient is deemed to be housebound when they are unable to leave their home environment through a physical or psychological illness. A patient is not considered housebound if he or she is able to leave their home with minimal assistance. For example unassisted/assisted visit to the Doctor, dentist, hairdresser, supermarket, social events. Some patients may not be housebound permanently but rather are housebound temporarily as a consequence of an episode of illness."*

The key objectives are as follows:

- To provide standardised and clinically effective oral anticoagulation management to patients receiving Warfarin therapy whilst minimising the risks associated with anticoagulation, following nationally recognised and clinical safe standards
- To initiate Warfarin anticoagulation therapy for suitable patients
- To produce optimum management of INR control
- To educate patients in understanding their treatment, in terms of their condition requiring oral anticoagulation therapy, target range for INR, the effects of over and under anticoagulation, diet, lifestyle and drug interactions
- To appropriately manage patients who are over anti-coagulated, INR 4.5 – 7.9 (with no bleeding or minor bleeding e.g. epistaxis), directly refer patients to A&E with major bleeding or where INR>8.0, check guidance
- To maintain a register of all patients receiving Warfarin therapy and have a treatment plan for each patient that is reviewed on a regular basis
- To review the need for continuation of therapy at each visit
- To identify and manage appropriately, patients with specific needs i.e. poor compliance, unstable INR control or frequent non attendees
- To optimise care to patients receiving anticoagulant therapy in terms of accessibility, continuity and waiting times
- To ensure complete and accurate documentation of the clinic process
- To respond appropriately and in a timely way following notification of changes in co-prescribed medication.
- To undertake an annual review and update of the protocol
- Consider the impact of patient choice (patient satisfaction questionnaire annually e.g. accessibility, waiting time, confidence in staff ability and continuity of care).

3.2 Service description/care pathway

This specification refers to vitamin K antagonists, which for the purpose of this specification will be referred to as Warfarin. This specification requires Warfarin oral anticoagulation therapy to be delivered in primary care. The provider will test and make any alterations to the patient's warfarin dosage in one visit. Providers will also initiate patients onto Warfarin oral anticoagulation therapy where appropriate including the continuation of initiation started in secondary care.

Service providers are expected to follow a protocol for an anticoagulation clinic, an example protocol which sets out minimum requirements is included in (Appendix A). Providers can also refer to the comprehensive DOAC monitoring template on Ardens as a basis for this protocol.

The service provider is expected to provide the following service:

- Initiation
- Regular monitoring and follow-up
- Planned discontinuation
- Adjustment for in-practice procedures (surgeons must specify their own requirements for procedures in hospital)
- Treatment of temporary resident patients
- Liaison with cardiology regarding treatment before and after cardioversion

It is possible that anticoagulation patient self-testing will become part of the service specification, pending assurances concerning patient safety and also evaluation of the FLO pilot currently being undertaken as part of a national telehealth pilot. If approved, this will be subject to a clearly laid out policy separate to the service specification.

Formal referral into the service will be made:

- By a hospital consultant, if patient is medically fit for discharge or GP (if the patients registered GP is not providing the service) or other service provider, for ongoing

monitoring and maintenance of Warfarin Anticoagulation therapy.
- By a GP (if the patients registered GP is not providing the service) for the initiation of Warfarin therapy.

In either case an appropriate referral form must be used (sample form can be found at Appendix B). The referrer retains duty of care for their patient until the provider has acknowledged acceptance of the patient.

A list of service providers is to be made available to empower ambulant patients with a choice of provider of their anticoagulation management.
Patients, who choose to change providers during their period of treatment, may only do so following formal referral from their current provider.

Housebound patients will have the choice of registering for their management with either the provider closest to their home or their registered GP (if a provider of this service).

All referrals into the service will be acknowledged to the patient's GP (if the patient's registered GP is not providing the service) within two working days by letter, secure email (e.g. NHS.net).

When a patient is referred to the Service Provider for anticoagulation therapy, this referral will identify the anticipated end date of monitoring.

Where necessary the provider will be expected to initiate and continue the management of oral anticoagulation treatment.

The Service Provider will have appropriate arrangements in place to ensure the prescribing of Warfarin therapy and immediate access to vitamin K antidote treatment.

The Service Provider will provide information on a range of relevant issues to enable patients to fully understand their treatment. Patients will receive appropriate verbal and written information at the start of their therapy and on the first anticoagulation appointment and when necessary throughout the course of their treatment. It is important that the healthcare practitioner who first provides this information records in the patient's healthcare record that this information has been supplied.

Each patient should be provided with a yellow Department of Health oral anticoagulation 'Yellow Patient Record Book' by the Service Provider and all relevant details in the book completed and kept up to date. This may also have been referred to as a British Society of Haematology (BCSH) Standards Task Force / National Patient Safety Agency (NPSA) booklet.

On-line reference to example: https://www.medicines.org.uk/emc/rmm/1081/Document

It is intended to support the patient's onward management. The Provider should emphasise and explain to each patient the importance of carrying this booklet and presenting this booklet when attending clinical appointments, including Accident and Emergency attendance and dental reviews.

Defined areas of responsibility will be mutually agreed locally between the service provider and the Commissioner to ensure the best possible coverage of the Warfarin anticoagulation service throughout the area.

All patients will be seen in person either in a clinic or at home by a member of the oral anticoagulation team (service provider) who has undergone appropriate training. (See section 4.3.5 Accreditation and Training).

Service Providers will be expected to run oral anticoagulation clinics at a frequency to achieve appropriate clinical care. Supporting clinicians must be available for non-routine appointments and advice between 8am and 6.30pm Monday to Friday (excl. Bank Holidays).

Patients' anticoagulation therapy will be in keeping with the latest NICE guidelines on oral anticoagulation. Reference: https://cks.nice.org.uk/anticoagulation-oral

To aid dosing of oral treatment, the Service Provider must use accredited Computerised Decision Support Software through an IT solution compliant with Health and Social Care Information Centre standards and which is registered with the MHRA as a medical device. Reference: https://webarchive.nationalarchives.gov.uk/20130502102046/http://www.hscic.gov.uk/systems This should have suitable algorithms for calculating warfarin dosage. One example is INR Star.

All patients, whether housebound or clinic attendees, will have a regular review, at a frequency determined by assessed clinical need. However, patients will have their INR checked at least every 12 weeks. Less stable and new patients will require more frequent tests.

Once treatment has been established the length of time between test dates will vary according to clinical need. The review will include an assessment of whether the patient should discontinue oral anticoagulation treatment.

Service providers must take reasonable steps to ensure that the prescriber is kept informed of the patient's ongoing condition and must be kept informed of any changes which could influence the treatment dose. Recording of updates in the yellow book is an essential element of this service delivery.

As a minimum, once the referrer has assessed the patient's suitability for Warfarin therapy and the patient has received appropriate information and demonstrated the ability to fully understand their treatment the following information must be sent by secure facsimile (up to April 2020), or secure email to the patients registered GP and Service Provider:

- Name of Practitioner
- Patients NHS number
- A statement confirming that the patient demonstrated an appropriate understanding of their treatment dose
- Location of Anticoagulation Clinic
- Indication for treatment
- Duration
- INR Target
- INR Reading in Clinic
- Recommended Oral Anticoagulant type and Dose
- Next Appointment

This list is not exhaustive and further information should be provided to the patient's registered GP when deemed clinically appropriate.

In order to minimise the risk of misunderstanding around dosing. Service providers must comply with the recommendations from National Patient Safety Alerts. In addition, whenever possible, standard terminology should be used to record information both in the Yellow Patient Record Book and on patient clinical records.

In addition, if a patient is to miss a dose of oral anticoagulant the Yellow Patient Record Book must be annotated 'No Warfarin' (or equivalent oral anticoagulation medication specific to that patient).

If a patient fails to attend an appointment the service provider retains responsibility for the patient. The service provider should offer another appointment and where the patient repeatedly fails to attend appointments or when it has not proven possible to make contact with the patient, should contact the patient's GP.

The service provider will have in place a system for referring patients promptly onto acute services

and relevant support agencies when their clinical condition / circumstances warrant it: i.e. if they have signs or symptoms of major bleeding or thromboembolism. These services will include, but are not limited to, the Accident & Emergency Department and Medical Emergency Admissions Unit.

When a patient subsequently completes their recommended course of anticoagulation treatment and is discharged from the service, the service provider will contact the patient's GP / Consultant to ascertain whether it's appropriate to discontinue anticoagulation. If anticoagulation is discontinued inform the patient's GP by letter, facsimile (to April 2020) or secure email within five working days. The communication method chosen should reflect the patient's clinical need and urgency.

The reason for stopping Warfarin will be noted within this letter and reflected in the patient's INR record

The Service Provider must work together with other professionals to promote holistic patient care and safety.

It is expected that Service Providers will deliver infection control levels consistent with professional standards and those set out by the Care Quality Commission.

Patients must; at all times, be respected and treated in a kind and considerate way by staff who should at all times demonstrate a professional and patient friendly attitude.

The Provider will conduct an annual patient satisfaction survey using a questionnaire (see sample survey at Appendix E) this questionnaire should be provided to 25% of patients seen in the last 12-month period.

3.2.1 Data Collection and Record Keeping

The Service Provider will develop and maintain an up-to-date register of all patients for whom they provide an oral anticoagulation monitoring service. Quarterly Activity reports will be compiled with the Minimum Data Set as follows:

Minimum Data Set		
	Provider Code	Y
Patient	Date Of Birth	Y
	Sex	Y
	Post Code	Y
	NHS Number	Y
Clinician	Referring GP / Consultant	Y
	Referring Practice / Hospital Code	Y
	Number of DNAs	Y
	Date Of Referral	Y
	Date Of Treatment	Y
	Name Of treating Clinician	Y
	Date onward appointment booked with secondary care	Y

	Date results sent to GP	Y
Trans-port	Domiciliary Visit	Y

The Service Provider will develop and maintain an up-to-date register of all patients for whom they provide an oral anticoagulation monitoring service.

Service Providers will ensure that an up-to-date systematic call and recall system is in place.

The oral anticoagulation therapy Service Provider will be responsible for maintaining each patient's oral anticoagulation record (electronic and manual) and ensuring it is updated following each clinical contact. The information recorded will include:

- Medical Condition leading to requirement for INR testing
- Date of Initiation
- The patient's INR reading
- The dose of oral anticoagulant medication
- The date of the next appointment
- Information supplied by the patient
- Information from the prescriber where appropriate
- Patient specific unusual event
- Clinical indication
- Target INR
- Expected duration of treatment Stop date (if known)

Patient satisfaction with the service will be reviewed, reported on and improved, on a regular basis using a validated questionnaire see (appendix E)

All staff are required to protect personal data in accordance with the requirements of the Data Protection Act 1998. 'Personal data' means data relating to a living individual who can be identified from data or other information in the possession of Lincolnshire CCG or the provider organisation. Staff must not make unauthorised access to, modification to or copy computer material in breach of the Computer Misuse Act 1990. If there is any doubt about staff obligations under any of this legislation the Commissioner must be contacted for clarification.

Staff may have access to, see or hear information of a confidential nature. Staff are required not to disclose such information, particularly that relating to patients, clients and staff of the Commissioner and the provider organisation. Any breach of confidentiality should be reported to the Commissioner using IR1 reporting process and is likely to result in an investigation under the Lincolnshire CCGs confidentiality policy and/or the provider confidentiality policy. Details of the policy can be obtained by contacting the Commissioner.

3.2.2 Reporting and Audit

The service provider will undertake a 6-monthly audit of the quality of the service provided using the audit tool provided; this is based on the NHS Improvements suggested criteria for assessing control and performance of providers. This minimum audit data set is described in (Appendix C).

The service provider will use the audit results to inform local actions to improve the safe use of anticoagulants. The results will be compiled and sent to the Commissioner by the end of May each year of the life of the contract.

An internal review of the service delivered will be carried out at least annually by all members of the oral anticoagulation therapy team. The review should consist of any relevant items

detailed in Appendix D and any relevant interim issues raised by members of the team or Commissioners.

The services delivered by this specification will be subject to annual review by the Commissioner. Circumstances may arise when a more frequent review is deemed necessary. All reasonable information required in order to carry out the review will be made available on request. At the review, any difficulties in delivering the service will be discussed.

Providers should record all the required information detailed on the Minimum Data Set (MDS) which will inform a quarterly report. The required reporting template can be found in Schedule 6A of the contract.

It is recommended that the practice use the following code when recording the delivery of this enhanced service.

Procedure	READ codes	SNOWMED codes
Anticoagulation monitoring enhanced service completed	XaKAF	166441000000104

Adverse events/incidents defined as "an untoward or adverse event that gives rise to, or has the potential to produce, unexpected or unwanted events which could be detrimental to the safety of service users, other persons, staff or the provider" and should be managed through the local risk management procedures of the provider. Reported incidents will be reported on to the ICB Federated Risk Management Team:
Cross O'Cliff Court, Bracebridge Heath, Lincoln LN4 2HN

or via email to licb.clinicalriskincidents@nhs.net

These must be reported by the service provider within one working day of the information becoming known to them.

The service provider will participate in a review of any serious incidents notified to the ICB Federated Risk Management Team and demonstrate that any learning from the incident is acted upon to minimise future risk.

3.3 Any acceptance and exclusion criteria and thresholds

Acceptance

All patients covered by Lincolnshire CCG that require Warfarin oral anticoagulation therapy and who fit the criteria below will be eligible for care under this service.

The criteria for patients receiving oral anticoagulation therapy includes but is not limited to:

Short to medium term:
- Prophylaxis
- Established Deep Vein Thrombosis (DVT) (single episode)
- Bioprosthetic Heart Valve Replacements
- Pulmonary Embolism (single episode)
- Coronary Artery Bypass Graft

Long term:
- Recurrent thrombo-embolism

- Embolic complications of rheumatic heart disease
- Prevention of stroke or systemic embolism in Atrial fibrillation
- Cardiac Prosthetic Valve Replacement
- Inherited thrombotic disorders and Anti-phospholipid Syndrome (Hughes Syndrome)
- On chemotherapy for malignant tumours
- Includes other conditions refer to BCSH guidelines
- Any other condition deemed suitable for inclusion by Consultant or General Practitioner (GP)

Exclusion

- Patients who are pregnant, under 16 years of age, patients allergic to or unable to tolerate the oral anticoagulant, also those patients with consistently unstable INR results or at risk of a major bleed should have their particular cases discussed with a specialist in anticoagulant care after which, by agreement, they may be excluded from this service. Providers may find the use of the NICE risk assessment grid useful in this process. Reference: https://www.nice.org.uk/guidance/ng196

3.4 Interdependence with other services/providers

The Provider is expected to work across the Lincolnshire Health Economy boundaries.

Providers are expected to cooperate and share information with others involved in a patient's care, treatment and support while having regard to the patients' rights to confidentiality.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

Care Quality Commission

This specification intends and expects compliance with the relevant standards of quality and safety across all provided regulated activities. This will be through registration with the Care Quality Commission. The new regulations are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 and the Care Quality Commission (Registration) Regulations 2009. These regulations replace 1) National Minimum Standards and 2) Standards for Better Health.

NICE Guidance

- National Service Framework for Coronary Heart Disease. National_Service_Framework_for_Coronary_Heart_Disease.pdf (publishing.service.gov.uk)
- British Committee for Standards in Haematology (1998, updated 2011). Guidelines on oral anticoagulation: third edition. British Journal of Haematology, **101**, 374-387.
- Interventional procedures guidance IPG349 - Percutaneous occlusion of the left atrial appendage in non-valvular atrial fibrillation for the prevention of thromboembolism
- https://www.nice.org.uk/guidance/ng196

Venous thromboembolism

- NICE guidance on VTE as set out in the NICE pathway on venous thromboembolism including quality standards for VTE prevention and diagnosis and management of venous thromboembolic diseases (https://www.nice.org.uk/guidance/qs201)
- Further NICE guidance is also in development on rivaroxaban for pulmonary embolism (https://www.nice.org.uk/guidance/ta287) and dabigatran etexilate for venous thromboembolic events. (https://www.nice.org.uk/guidance/ta327)

Other

- Stroke pathway: fast, easy summary view of NICE guidance on stroke, including primary and secondary prevention of stroke
- Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence. NICE clinical guideline 76 (2009)

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

- See 4.3.5 Accreditation and Training

4.3 Applicable local standards

4.3.1 Facilities

The location of clinics should be chosen to promote accessibility to patients both in terms of the availability of public transport links and ease of parking.

Consulting rooms must promote privacy, dignity and support confidentiality. They should be Disability Discrimination Act (DDA) compliant with an adequate reception and waiting area. They should provide appropriate facilities to store controls and reagents.

Adequate and appropriate equipment should be available for the clinician to provide the service – this should comply with relevant local and national standards including health and safety legislation and infection control standards.

The environment will promote effective care and optimise health outcomes by being well designed and well maintained with appropriate cleanliness levels in clinical and non-clinical areas.

The equipment and facilities required to undertake the service will be supplied and maintained by the provider at their own cost. The provider will cover the cost of all consumables (e.g. test strips).

4.3.2 Equipment

In order to provide Point of Care Testing (POCT) to determine patient INR levels providers must use a monitor and associated equipment which is approved by MHRA.

Each separately approved monitor will be registered with NEQAS.

The POCT monitoring equipment internal quality assurance checks will be performed in accordance with the manufacturer's guidelines and at least weekly. Records should be kept showing the results/dates of testing/operator ID and lot numbers of reagents/test strips.

The Service Provider will participate in the NEQAS programme for external quality assurance checks which monitors the performance of coagulometers.

Following any failure to provide an acceptable result of either the internal or external quality assurance check the monitor should cease to be used until the problem has been resolved. The provider is responsible for maintaining the usual level of service throughout this period. In order to ensure such continuity of service the provider should have in place contingency plans to cover such an occurrence. Consideration may be given to an agreement with another provider to share the use of monitoring equipment or the purchase of a second coagulometer.

Monitoring equipment should be appropriate and adequate and should be maintained to appropriate infection control standards.

Computer Assisted Decision Support Software

NICE mandates the use of computer dosing software, which must be registered with the MHRA as a medical device, for decision support and audit requirements. See current NICE guidance.

4.3.3 Staffing

The staff providing the service must have access to a named clinician who is trained and available to offer support and advice in such circumstances as, but not limited to:

- patients where the INR level falls outside defined parameters
- more complex clinical therapy related decisions
- administration of Vitamin K

The Service Provider must identify a Service Manager or Lead Clinician, who is responsible for:

- Managing the operational aspects of the service
- Managing all staff
- Ensuring that all staff involved in the service are appropriately trained and competent to provide the specified service
- Ensuring the continued development of the service and staff involved in delivering the care
- Ensuring service contingency plans are developed and in readiness for implementation should the need arise.
- Evaluating the efficacy of the service through the systematic monitoring of quality indicators, thereby ensuring the service meets the requirements of the patients
- Reviewing in conjunction with the Clinical Lead, and where appropriate, updating procedures and clinical protocols for oral anticoagulant services to ensure that they reflect safe practice and that staff are trained in these procedures.
- Overseeing, in conjunction with the Clinical Lead, the audit of the oral anticoagulant services using (as a minimum) the NICE audit tool (Appendix C) as part of the annual medicine's management audit programme.
- Ensuring that the audit results are used to inform local action to improve the safe use of oral anticoagulants and sharing the results with the Commissioner Contract lead on an annual basis.
- Ensuring that all equipment is safe and appropriately maintained, that national and local safety alerts are acted on; software licenses maintained; and systems in place to assure the appropriate management of data in line with the statutory Information Governance responsibilities.
- Delivering as requested the contract monitoring reports outlined within this specification to the contract lead of Lincolnshire CCG.

4.3.4 Protocol

Providers must be able to evidence to commissioners that they have an approved protocol in place.

This protocol should include the need for the Clinician to ask the patient at each monitoring appointment about any medication changes, lifestyle changes or other significant event such as treatment in secondary care for a non INR related condition, therefore allowing for an adjustment in the monitoring regime. Confirmation of patient identity must also be made at each clinic appointment and patient contact.

It will be the responsibility of the patient's registered GP to record any relevant information regarding medication changes, lifestyle changes, or any other significant event, such as treatment in secondary care for a non INR related condition as soon as it becomes known to

them. It is recommended that the patient's registered GP put a note in the patient's yellow book for presentation at their next appointment.

It is vital that the patients GP educate the patient on the importance of looking after the yellow book and of sharing this information with the Service Provider.

4.3.5 Accreditation and Training

Staff involved in the delivery of this service should be appropriately trained and have appropriate competencies to enable them to undertake their duties safely. Annual updated training for staff involved in the delivery of the service should be evidenced. Ongoing assessment / training and support should be provided to staff to ensure that their competency level remains appropriately high during the course of their work within the service. Any gaps in competency must be addressed.

The service provider is responsible for ensuring a system of clinical supervision in circumstances where senior staff oversee and assess work competency of less experienced staff testing INR. Only qualified staff who are appropriately trained should provide anticoagulation dosing.

Training should be provided to the multi professional team involved in managing the anticoagulant service, commensurate with their duties and area of responsibility.

The provider should ensure that this training includes, but is not be limited to, the following:

- An introduction to oral anticoagulation therapy including NOACs
- An understanding of the test to be performed
- Description of INR and how it is derived
- An understanding of specific Point of Care Testing (POCT) method for deriving INR
- An understanding of the relevant provider Standard Operating Procedures.
- The setting up the testing equipment
- The correct use of the decision support software.
- The target INR:
  - How it relates to the diagnosis
  - Action if result is outside range
- Recording of results and quality assurance materials:
  - All results must be fully recorded with patient's ID and operator ID
  - Batch number of reagents and quality control material
  - POCT logbook to record faults, maintenance and repair
- Health & Safety – disposal of sharps, Control of Substances Hazardous to Health (COSHH) regulations
- Awareness of Medications and Health Care Products Regulations Agency (MHRA) and National Patient Safety Agency (NPSA) guidance for oral anticoagulation.
- Continuous professional development should be undertaken.
- Basic CPR

Specifically, the provider must ensure that all staff who prescribe; adjust dosage; dispense, prepare, administer, monitor and discharge patients on anticoagulant therapy) have attained the necessary NPSA competencies related to:

- Maintaining anticoagulant therapy
- Managing anticoagulants in patients requiring dental surgery
- Dispensing oral anticoagulants
- Reviewing the safety and effectiveness of an anticoagulant service.
- Initiating anticoagulant therapy

There is a minimum requirement for attendance by the clinical/service lead at a national MSc accredited anticoagulation monitoring training course with regular updates. Both reviews and training should be documented by the service.

As a minimum, such training must be completed by the Clinical Lead, within six months of commencement of service delivery (for those providers not currently providing an anticoagulation service commissioned by Lincolnshire CCG) and within twelve months of commencement of service delivery (for those providers who are currently providing an anticoagulation service commissioned by Lincolnshire CCG).

5. Applicable quality requirements and CQUIN goals

5.1 Practices which take part in the scheme must:

Demonstrate that service provision is of high quality, evidence based, safe and effective, with robust governance systems and safeguards in place, staff have received appropriate training and equipment is maintained to the highest standard. Practices may be required to provide commissioners with assurance that services provided are within the criteria of the contract general conditions, service conditions and particulars.

5.2 CQUIN goals will not be applied.

6. Location of Provider Premises

It is the obligation of the provider to secure premises for service delivery. The provider has the opportunity to use their own facilities within a practice or access current NHS accommodation in Lincolnshire managed and accessed through NHS Property Services (to include premises owned by Lincolnshire Community Health Services, United Lincolnshire Hospital Trust and certain GP practices).

7. Appendices

Appendix A – Sample Standard Operation Procedure
Appendix B – Sample referral form
Appendix C – Minimum audit dataset
Appendix D – Suggested Annual review
Appendix E – Sample patient satisfaction survey

PLEASE NOTE: - these Appendices will be constantly reviewed and updated. Providers should access the most current version of Appendices at the policies and guidance page below - Lincolnshire Prescribing and Clinical Effectiveness