1. Population Needs

1.1 National/local context and evidence base

An ageing population, increased screening and more public awareness has resulted in an increased prevalence of conditions requiring anticoagulation. The most commonly used anticoagulant is Warfarin. Warfarin, Acenocoumarol and Phenidone are all vitamin K antagonists.

Vitamin K antagonists are being used in the management of increasing numbers of patients and conditions including patients’ post-myocardial infarction, atrial fibrillation, DVT’s and other disorders. While they are very effective drugs in these conditions, they can also have serious side effects e.g. severe haemorrhage. These side effects are related to the International Normalised Ratio (INR level), which measures the delay in the clotting of the blood caused by the vitamin K antagonist. While the "normal" INR is one (1), the specific range of INR values depends on the disease and the clinical conditions. The monitoring of vitamin K antagonists aims to stabilise the INR within set limits to help prevent serious side effects whilst maximising effective treatment.

An alternative treatment now available for treating the above indications are a group of drugs called New Oral Anti-coagulants (NOACs). This group includes; Rivaroxaban, Dabigatran, Apixaban and Edoxaban. A range of NICE guidance advises the appropriate use of these drugs.

The monitoring of vitamin K antagonists for patients taking oral anticoagulants has traditionally been performed in hospital anticoagulation clinics. However, there has been a trend over the last few years for this activity to be transferred into primary care and many GP practices are setting up practice based anticoagulation clinics.

It is recognised that a proportion of the existing activity would need to stay in a secondary care setting. Though this will be the case, the majority of patients will be seen in the community setting once they are stable on their medication. In this instance ‘stable’ refers to patients with a % Therapeutic time in range less than 70%.

In patients with atrial fibrillation who are taking warfarin for the purpose of stroke prevention, evidence indicates that prevention of stroke is most effective when the TTR is 70% or above1. Patients with a TTR below 70% are not receiving the full benefits of anticoagulation and those less than 40% are receiving no benefit at all. Poorly controlled warfarin is potentially detrimental compared to no warfarin at all if good INR control cannot be achieved. For these patients, an assessment should be made as to whether warfarin is the most appropriate treatment. Furthermore, NICE recommend that any patient with a TTR below 65% should have anticoagulation reassessed.

Once a stable warfarin, acenocoumarol or phenidone dose that controls the INR has been established, changes in dose are seldom required.
2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

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

2.2 Local defined outcomes

To ensure that patients have equitable access to a convenient local primary care based service – whether through a clinic or domiciliary visits (where appropriate).

To ensure that patients are seen in the right place appropriate for their level of care i.e. primary or secondary care

3. Scope

3.1 Aims and objectives of service

The overall aim is to provide an integrated anticoagulant service across primary and secondary care.

- To offer a cost effective, standardised clinically effective monitoring system for the management of patients undergoing oral anticoagulant therapy in order to ensure good control and to reduce complications.
- To ensure that patients have equitable access to a convenient local primary care based service – whether through a clinic or domiciliary visits (where appropriate).
- To provide comprehensive and ongoing education of patients so that they better understand their therapy.
- To provide optimal management of INR control
- To ensure quality control testing and quality assurance measures on service outcomes.
- To ensure the need for continuation of therapy is reviewed regularly.
- To ensure that therapy is discontinued when appropriate

3.2 Anticoagulant Practitioner Training and Competency Standards

All staff involved in providing care for patients must have the necessary training and skills to undertake their duties safely. This should be reviewed annually (ideally as part of the appraisal process) against the standards for work competencies set out by the National Prescribing Safety Agency (NPSA) and the British Committee for Standards in Haematology (BCSH).

A GP Clinician must retain clinical responsibility for ensuring appropriate monitoring of patients occurs under this Service. This must not be delegated to non-clinical staff.

Before working in an unsupervised capacity the Practitioner will have received appropriate training, to enable them to demonstrate the following competencies:

- Operation of analyser / software
- Determination of quality control results
- Obtaining of adequate blood sample
- Determination of INR results
- Clinical guidance taught by trainer
- Understanding of range of problems likely to be encountered in interpreting INR results.
- Making dosage adjustments
- Recognition of instances where it is necessary to seek further advice
- The giving of information and advice to patients
- Documenting information in both patient and clinic held records

All Practitioners will be required to demonstrate good practice through audit and participation in peer review. The provider will keep records of completion of training for all anticoagulant practitioners participating in the service.

All staff providing the service should have appropriate indemnity cover to meet in full any claims made against them as individuals.

Practitioners will be required to demonstrate a commitment to continuing education organised through their professional body or other approved method.

Practitioners will undertake fire safety and evacuation procedures on an annual basis and will receive training in cardio-pulmonary resuscitation and treatment of anaphylaxis.

Practitioners should be fully immunised against Hepatitis B.

**3.2.1 Minimum Required Activity**

The minimum required activity for the provider to keep their skills up to date is review of 5 INR tests per month plus dosing.

**3.3 Service description/care pathway**

This service specification requires primary care anticoagulant monitoring service providers to provide a GP delivered service. Providers will be expected to provide a ‘one-stop’ service including near patient testing, dosing, prescribing and next appointment given within one consultation. The Practitioner will exercise all professional skill and care in providing the anticoagulant monitoring service. The service will be delivered under the direct supervision of the GP.

New patients will follow the New Patients Pathway as detailed in Appendix (i) and patients already undertaking Anti-Coagulant monitoring will follow the pathway described in Appendix (ii). Anticoagulant practitioners would see existing patients who have been initially stabilised in Secondary Care and are suitable (based on robust clinical criteria produced by secondary and primary care clinicians) to be treated in a primary care setting (Appendix (iii)).

In order to meet local needs these clinics would be arranged at various locations around the Greater Preston and Chorley & South Ribble Locality with patients being invited to attend a venue close to their home.

The service will provide optimal therapeutic control for patients prescribed oral anticoagulants, whilst minimising the risks associated with such therapy. The Anticoagulant Practitioner will undertake all blood tests and make all dosing decisions.

The management of patients should be facilitated using point of care monitoring devices.

Computerised decision support software which automates the dosing of patients should be used. This should include:

- Facility for tracking individual patients
- User friendly recording of clinical information
- Alert system for missed appointments/discontinuation of treatment
- Provision of audit information

The service will also offer domiciliary visits to housebound patients and patients in residential or a
nursing home setting requiring anticoagulant therapy and this will include near point testing. Housebound patients are defined as those who are genuinely unable to travel to clinics for reasons of mobility, rather than transport difficulties alone. The provider will confirm housebound status with the patients’ GP before agreeing to undertake domiciliary visits. In the case of a home visit, the provider is expected to take all necessary equipment with them to provide the full service at this location.

The service provider also has a responsibility for ensuring that the relevant person (patient, carer, pharmacist or support worker) is aware of the dose change and the implication for use of compliance aids.

The Provider must not discriminate in the provision of services on the basis of race, gender, religion, age or disability.

Providers will be expected to have cover for absence due to sickness, annual leave etc. for all staff involved in the anticoagulation service. This could be provided by reciprocal arrangements with other provider/s including recharging arrangements where necessary.

3.3.1 Equipment / Premises

The lead professional is responsible for storage of machine and test strips as per manufacturer’s guidelines and provider protocol.

Electronic Analyser
- After each use / session clean with alcohol wipes
- Always carry in supplied padded bag when travelling
- Test strips
- Do not freeze
- Keep in surgery fridge at a temp 2-8 degrees

Be responsible for the appropriate care and planned replacement of each piece of equipment.

Ensure that the maintenance of each analyser is in accordance with the manufacturer’s recommendations.

3.3.2 Quality Assurance and Control

Quality must be assured across all aspects of the service, including clinical supervision, INR testing, dosage advice, record keeping; patient held records and quality control records and testing, information giving and education. The anticoagulant practitioner must complete all documentation required and record any action taken which is outside the service protocol.

The Anticoagulant Service provider will be responsible for the monitoring of:
- Quality Assurance of stored reagents
- Analytical quality control
- Compliance with clinical management protocols
- Maintenance of staff competencies

The Anticoagulant Service Provider will:
- Ensure that practitioners are documenting the batch numbers and shelf life of test strips used.
- Ensure that the analytical process is subject to both internal and external quality control in accordance with national guidelines and all procedures will be fully documented by the Anticoagulant Service Provider.

The provider needs to ensure the accuracy of the near patient testing machine readings by submitting a blood sample to the laboratory for testing. This is to be a minimum of one per quarter.

It is recommended that the Provider uses Computerised Decision Support Software and must:
- Ensure the most up to date clinical version of the software in used
- Ensure that all staff using the software receives training and are competent to do so
• Ensure all data stored on the computer system is subject to the requirements of a comprehensive data protection policy

3.3.3 Audit

The services delivered by this enhanced service will be subject to annual audit.

The provider will be responsible for registering with the National External Quality Assurance Scheme (NEQAS) and must participate in all audits in this scheme and make all results available to the Commissioners annually or upon request.

The Anticoagulant Service Provider will ensure the following are evaluated through internal and external audit on a regular basis:
- Clinical outcomes
- Frequency of patient reviews
- Acceptability of service for patients using patient satisfaction surveys on an annual basis
- Quality of INR control

3.3.4 Patient and Public Involvement

The service provider shall undertake an annual patient satisfaction survey that covers issues such as patient experience, wait times and education which are the responsibility of the provider.

3.3.5 Complaints and untoward incidents

It is a condition of participation in this service that practitioners will provide notification to the Commissioners and to the referring GP practice of all significant events, including emergency admissions or deaths of patients using this service, where such admission or death is or may be due to usage of the warfarin, acenocoumarol or phenidone. Deaths must be reported within 48 hours of the information becoming known to the practitioner and admissions notified within one week. This is an addition to the practitioner’s statutory obligations. If a GP practice has referred a patient into the service and is aware of a significant related event then all efforts should be made to keep the INR monitoring doctor aware of the events.

The provider shall provide the Commissioners with a written review of the incident to include actions taken to prevent further incidents and to include lessons learned.

The Commissioners will support the provider in reviewing any significant event and in serious case reviews the Commissioners will be present for these case reviews to assist in lessons learned.

3.4 Referral Process

Locally agreed guidelines will be set up between practices in the event that patients will be referred to another provider:

- New patients pathway – Appendix (i)
- Transfer of existing patients’ pathway – Appendix (ii)
- Referral form – Appendix (iii)

All patients, who meet the inclusion criteria, will be given the choice as to whether they wish to attend a primary/community clinic or a secondary care clinic.

All patients’ currently under the care of secondary care and who meet the inclusion criteria will be offered the option of moving to a primary care clinic.

3.5 Referral process to secondary care in the event of complications

If a patient presents to clinic with a complication that requires urgent treatment it is the responsibility of the clinical provider to refer the patient to secondary care immediately.
For routine referrals the provider should write to the patients’ registered GP practice and patient to notify them of the referral to secondary care.

For patients with high INR >5 and >8 guidance in appendix (iv) should be followed. All practices providing an anticoagulation monitoring service should maintain a stock of Vitamin K.

3.6 Failure to attend appointments

In the event of a patient failing to attend a single clinic appointment or to provide a sample of blood, as arranged, the service provider will contact the patient within one working day of the missed appointment to arrange a further appointment.

If this attempt is unsuccessful, three additional attempts should be made to contact the patient/carer over the next two weeks. The service provider should attend to contact the patient by the most suitable method for the patient.

The service provider will inform the patient’s registered GP practice within two days of the patients’ failure to attend.

If the patient is under the care of mental health services a named healthcare professional will be contacted if the patient fails to attend.

Management and outcomes of patients failing to attend appointments will be monitored by the Commissioner and detailed under monitoring.

3.7 Population covered

All patients registered with a General Practice who is a member of either Chorley & South Ribble or Greater Preston Clinical Commissioning Group.

3.8 Any acceptance and exclusion criteria

Inclusion Criteria
The clinics will treat patients established on Warfarin, Acenocoumarol or Phenidone for the treatment or prevention of a thromboembolic disorder. These include:

- Atrial fibrillation
- Replacement heart valves
- Pulmonary embolism
- Deep vein thrombosis

Exclusion criteria

Absolute Contraindications:
- Active peptic ulcer, oesophageal varices, aneurysm, and proliferative retinopathy
- Epistaxis and Haematuria
- Recent organ biopsy
- Recent trauma or surgery to the head, orbit, or spine
- Recent stroke
- Confirmed intracranial or intraspinal bleed
- Uncontrolled hypertension >180/110
- Infective endocarditis.
- Pregnancy
- Allergy to Warfarin, Acenocoumarol and Phenidone
- Blood borne Viruses
- Antiphospholipid syndrome

These patients should be referred via Haematology to the hospital clinic
Relative Contraindications:
- History of gastrointestinal bleeding
- Liver disease
- Renal failure
- Alcoholism
- Mental impairment including dementia
- Thrombocytopenia
- Coagulation disorders
- Interacting drugs, in particular non-steroidal anti-inflammatory drugs
- Poor concordance
- Poor attendance for regular blood tests.

These patients may be referred but provider needs to be informed

3.9 Documentation

The Service Provider shall hold an up to date register of all anti-coagulant patients. There must be adequate systems in place to ensure that computer records are backed up regularly and maintain strict confidentiality of patient records at all times in compliance with data protection legislation. Suitable arrangements should be demonstrated to enable this, as well as to ensure emergency access in the interests of patient safety.

Service Providers must have a systematic call and recall system in place and should be able to provide data to demonstrate the effectiveness of the system. It is particularly important that service providers implement appropriate and effective strategies for monitoring and targeting non-attendees.

In addition the service provider must inform the patient’s GP with regard to the patient’s dosing and most recent INR within 48 hours of the patient being seen. The patient’s registered GP must inform the service provider within 48 hours if there is any change to the patient’s medication which may interfere with warfarin, Acenocoumarol or Phenidone.

A Standard Operating Procedure for monitoring of anticoagulation should be in place,

3.9.1 Clinic held patient records

A patient record will be maintained for each patient. The record will be updated at each clinic visit and will contain.
- The original referral information and prescription
- The INR result at each visit
- The dose of anticoagulant
- The number of weeks to next appointment
- The duration of the therapy
- Target INR
- Correspondence concerning the individual patient
- Provide a record of missed appointments

The service should ensure that each patient has an up to date patient held booklet and information pack and this should be completed by the clinician at each monitoring appointment.

If this is not available a temporary record booklet must be completed and given to the patient. NO patient should leave the clinic without written instructions on their therapy.

3.9.2 Clinic Summary Records

The Service Provider will record the following information for each clinic session
- The number of INR tests performed
- The number of patients with appointments who did not attend the session
- The percentage of INR tests falling within 0.5 and 0.75 INR units from the target
• The number of patients with INR >5 (NPSA)
• The number of patients with INR >8 (NPSA)
• The number of patients with INR <1 below range (NPSA)
• The average number of weeks since the last appointment

3.10 Interdependencies with other services
Lancashire Teaching Hospitals NHS Foundation Trust
Lancashire Care NHS Foundation Trust
GP Practices within Chorley & South Ribble and Greater Preston CCG

3.11 Activity Reporting
The provider is required to submit their activity to the Commissioning Support Unit (enhancedserviceslcsu@nhs.net) using the services spreadsheet, within one month of the date on which the new patient was accepted or of the anniversary date.

3.12 Finance
All costs of the service including staffing, equipment, software, on-going training and premises are included within the payments made.

Payment - £339.31 per patient per annum (this includes the cost of annual NEQAS Registration & equipment costs)
GP practice sample, GP practice testing, GP practice dosing for own registered patients and those from other practices, near patient testing.

There must only be one claim per patient per year.

£31.00 for each domiciliary visit to a housebound patient or patient in a residential care or nursing care setting.

All domiciliary visits must be carried out by a qualified staff member who is employed by the provider to meet the requirements for payment. No payment will be made in respect of activity detailed in this specification undertaken by staff not directly employed by the practice.

All patients being treated by the provider are counted as active (whether they attend for treatment that month or not). A patient will become inactive when they:
• move out of the area
• begin treatment in secondary care
• stop treatment
• die

For monitoring purposes, a patient will become inactive at the beginning of the month following the above.

Finance claims are to be submitted to enhancedserviceslcsu@nhs.net by 10th of each month for processing.

Claims should be submitted not later than 3 months after the date of the activity (for example, March claim can be submitted in April, May or June). Claims submitted after the 3 month period will not be approved for payment. At year end the final processing date for claims for the previous year is 10th July, (i.e. claims for 2019/2020 must be submitted by 10th July 2020)

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)
CMG (Commissioning Guide) 49: Support for Commissioning: anticoagulation therapy

National Institute for Health and Care Excellence, 14 May 2013


David Keeling, Trevor Baglin, Campbell Tait, Henry Watson, David Perry, Caroline Baglin, Steve Kitchen and Michael Makris – British Committee for Standards in Haematology


4.1.1 Infection Prevention

Further to the conditions set out in Service Conditions 2 the service provider is required to adhere to all current infection prevention guidance including the Health and Social Care Act 2012 and NICE Guidance CG139 or relevant guidance which supersedes these detailed.

4.2 Applicable standards set out in Guidance and/or issued by a competent body

National Institute for Clinical Effectiveness (NICE)
British Committee for Standards in Haematology (BCSH)
National Patient Safety Agency

4.3 Applicable local standards

5. Applicable quality requirements and CQUIN goals

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

The quality monitoring for this enhanced service is summarised in the table below:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
<th>Threshold</th>
<th>Evidence required</th>
<th>Source of Evidence</th>
<th>Consequence of breach</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinically Effective</td>
<td>Number of patients who record an out of range INR result</td>
<td></td>
<td>Figures to be submitted</td>
<td>Provider</td>
<td>Commissioners visit to agree on any developmental support / action</td>
<td>Annual Audit</td>
</tr>
<tr>
<td>3.9.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.9.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equitable Access</td>
<td>Number of patients who are satisfied with ease of access / making appointments / getting through on the phone</td>
<td>&gt;90%</td>
<td>Patient Survey to be carried out with 10% of patients quarterly</td>
<td>Provider</td>
<td>Commissioners practice visit to agree on any developmental support / action</td>
<td>Annually</td>
</tr>
<tr>
<td>5.1.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Control</td>
<td>Calibration of Coaguchek machine - Blood taken from patient at same time as near patient testing and sent for laboratory testing</td>
<td>One sample each quarter</td>
<td>Evidence sampling has taken place and reporting by exception</td>
<td>Provider</td>
<td>Cease provision of service until accurate check is carried out</td>
<td>Annual Audit</td>
</tr>
<tr>
<td>Quality Control 3.12</td>
<td>External quality audit on Coaguchek machine</td>
<td>Each machine to be registered One audit to be carried out four times a year</td>
<td>Audit results</td>
<td>Provider / NEQAS</td>
<td>Cease provision of service until Coaguchek machine has been registered / monitored</td>
<td>Audit four times per year for NEQAS Annual audit report</td>
</tr>
<tr>
<td>---------------------</td>
<td>---------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td>--------------</td>
<td>------------------</td>
<td>---------------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Quality Control 5.1.1</td>
<td>Internal quality audit on Coaguchek machine</td>
<td>One audit using control solutions to be carried out monthly as a minimum</td>
<td>Audit results</td>
<td>Provider</td>
<td>Cease provision of service until Coaguchek machine is operating correctly</td>
<td>Annual audit</td>
</tr>
<tr>
<td>Quality Control 3.2.1</td>
<td>Providers are to undertake a minimum number of tests and dosing per month</td>
<td>Tests and dosing on a minimum of 5 patients per month</td>
<td>Activity submitted</td>
<td>Provider</td>
<td>Providers managing 5 patients or less per month for 3 months will be expected to terminate their contract and refer their patients to another GP Anti-coagulant service</td>
<td>Monthly claim form</td>
</tr>
</tbody>
</table>

5.2 Applicable CQUIN goals (See Schedule 4 Part E)

6. Location of Provider Premises

Patients should have the choice of attending an anti-coagulation clinic near to their home. Clinics should be located equitably across Greater Preston & Chorley and South Ribble.

7. Individual Service User Placement
Appendix (i)
Anti-Coagulant Monitoring Service in Primary Care – New Patients Pathway

Refer to Secondary Care Haematology Team

Decision to Commence Vit K antagonist Anti-Coagulation (Warfarin, acenocoumarol, phenidone)

Any exclusions to prevent primary care initiation?

Referrer Choice

Patient offered information on local providers

Referrer Choice

Referral form by fax or post to chosen provider

Referrer Choice

Provider receives fax and contacts patient by letter or phone

Referrer Choice

Patient gets appointment/visit

Yes

Anti-coagulant treatment commenced

No

1 further attempt to contact patient

No

3 unsuccessful attempts to contact patient

Notify GP and referrer by letter/fax

No

Yes

Location

Provider website

Practice

Downloaded from website

Sent out

Yes

No

No

No

No

No

Yes

Yes

Yes

Yes

Literature to all local stakeholders

Provider website

Literature

Downloaded from website

Sent out

Yes

No

No

No

No

Yes

Yes

Anti-coagulant treatment commenced

Yes
Appendix (ii)
Anti-Coagulant Monitoring Service in Primary Care – Transfer of Existing Patients Pathway

Patient already receiving anti-coagulant treatment – secondary care or primary care pharmacist

Meets criteria

Patient's practice contacts patient regarding possible transfer to primary care via standard letter

Patient Agrees

Write to existing provider – standard letter modelled on referral form – need to know:
- Indication
- Intended duration
- Yellow card
- Compliance

Patient Disagrees

Maintain in Secondary Care

Doesn't meet criteria

Secondary care/existing provider clinical objection

No objection/no clinical issues

Anti-coagulant treatment commences in primary care

Maintain in Secondary Care
Anticoagulant Monitoring Service Referral Form

No patient will be dosed by the service provider unless this form is completed IN FULL. Responsibility for anticoagulant rests with the referring GP practice until that time.

To: The Service provider

Practice Details

**PATIENT DETAILS**

<table>
<thead>
<tr>
<th>Patient name</th>
<th>DOB:</th>
<th>NHS Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Post code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tel (home)</td>
<td>Tel (day time)</td>
<td>Tel (Mobile)</td>
</tr>
</tbody>
</table>

Is the patient housebound – YES/NO. If yes, please provide a brief description

<table>
<thead>
<tr>
<th>Indication for anticoagulation</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Date this condition started</td>
<td></td>
</tr>
<tr>
<td>Proposed duration of anticoagulation therapy</td>
<td></td>
</tr>
<tr>
<td>Please confirm that the base line tests have been taken.</td>
<td>YES / NO</td>
</tr>
<tr>
<td>LFT/ U&amp;E/ PT/ INR</td>
<td></td>
</tr>
<tr>
<td>Yellow Anticoagulant Therapy Record Book given to patient?</td>
<td>YES / NO</td>
</tr>
</tbody>
</table>

**CURRENT MEDICATION**


**RELEVANT PAST MEDICAL HISTORY (SEE BELOW)**


Referring General Practitioner ____________________________ Date ________________
Advice for referrers:

Please note that the following are absolute contraindications:

Active peptic ulcer, oesophageal varices, aneurysm, and proliferative retinopathy
Epistaxis and Haematuria
Recent organ biopsy
Recent trauma or surgery to the head, orbit, or spine
Recent stroke
Confirmed intracranial or intraspinal bleed
Uncontrolled hypertension >180/110
Infected endocarditis.
Pregnancy
Allergy to Warfarin, Acenocoumarol or Phenidone
Blood borne Viruses
Antiphospholipid syndrome

These patients should be referred via haematology to the hospital clinic

And the following are relative contraindications:

History of gastrointestinal bleeding
Liver disease
Renal failure
Alcoholism
Mental impairment
Thrombocytopenia
Coagulation disorders
Interacting drugs, in particular non-steroidal anti-inflammatory drugs
Poor concordance
Poor attendance for regular blood tests.

These patients may be referred but please inform the provider
Appendix (iv)
Guidelines for using vitamin K for the management of over-anticoagulation

For those providers using NPT, instructions on appropriate further testing when high INR results are recorded is given at paragraph 18.10 onwards, page 12.

Always ask patient about signs of bleeding:

<table>
<thead>
<tr>
<th>Issue</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>bruising</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>fresh blood in stools</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>haematuria</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>epistaxis</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>melaena</td>
<td>☐</td>
<td>☑</td>
</tr>
<tr>
<td>any other signs of bleeding</td>
<td>☐</td>
<td>☑</td>
</tr>
</tbody>
</table>

INR > 8.0 with no bleeding manifestation

All patients

If using near patient testing, send a venous sample to the central laboratory for testing to obtain INR estimation.
Discuss with the on-call haematology doctor
Omit warfarin;
Give oral vitamin K (Konakion® MM Paediatric 2mg in 0.2ml); 1-2mg as advised by haematologist;
Repeat INR test following day.
If this falls on a weekend or bank holiday it is the responsibility of the prescribing GP to ensure the test is done and the results acted upon.

INR 6.0 – 8.0 (with no bleeding or minor bleeding, e.g. epistaxis)

High risk1 patients

Omit warfarin;
Consider giving oral vitamin K (Konakion® MM Paediatric 2mg in 0.2ml); 1-2mg as advised by haematologist
Repeat INR test following day.
Restart warfarin as per guidelines

Low risk patients

Omit warfarin;
Restart warfarin as per guidelines

1 High risk: age > 75 years; diabetes; renal failure; stroke; previous gastro-intestinal haemorrhage. The GP will use his or her own judgement in managing the risk for an older person living alone.

A patient over-anticoagulation report should be completed in the patients notes.

How to administer Vitamin K (Konakion® MM Paediatric 2mg in 0.2ml) orally:

- Check expiry date of ampoule and ensure the product is in date before use
- Break ampoule
- Using the oral dispenser withdraw the solution to the appropriate mark (0.1ml = 1mg, 0.2ml = 2mg);
- Hold dispenser in patient’s mouth (at the back of the tongue) and press plunger;
- Offer patient a glass of water as the solution has a very bitter taste.

How to obtain Konakion® MM Paediatric

All providers of the anticoagulation monitoring service must purchase this product on initiation of the service.

Practices may purchase this from a local community pharmacist on receipt of a signed order.

When two ampoules remain or the product is out of date stock should be re-ordered.
Clinical governance

Ensure the expiry date of Konakion MM Paediatric™ is checked regularly as per practice protocol for checking expiry dates of drugs.

Any near misses or adverse incidents should be recorded.

Using this guidance to administer vitamin K to manage a high INR should trigger the practitioner to consider whether a Significant Event Analysis needs to be undertaken.
APPENDIX (iv)

**Annual Clinical Audit – General Practice Monitoring of Chorley & South Ribble and Greater Preston Anti-Coagulation Service**

**Aim:** to ensure Chorley & South Ribble and Greater Preston General Practice Monitoring of patients on coagulation therapy reflects the quality set out in the Service Specification

**Year (e.g. 2019/2020)**

| Practice Name: |

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Near Patient Testing</td>
<td>Date last blood test sent to laboratory</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Were readings correct in line with the near patient testing machine? Yes / No</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If no, please give more information e.g. action taken</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date of last NEQAS registration date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Date of last NEQAS audit</td>
<td></td>
</tr>
<tr>
<td>Clinical Effectiveness</td>
<td>Number of patients with INR result in the last 12 months of:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;8</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;1</td>
<td></td>
</tr>
<tr>
<td>Patient experience survey</td>
<td>Total number of patients who took part in the survey</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of patients who are satisfied with the ease of making appointments</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of patients who are satisfied with the level of education provided about their condition / monitoring / treatment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>% of patients who are overall satisfied with the service provision</td>
<td></td>
</tr>
</tbody>
</table>

Please return this audit by email to enhancedserviceslcsu@nhs.net by 30th April the following year.