Primary Care
Anticoagulation Monitoring
Guidelines for Patients Taking Warfarin

POLICY NUMBER: MM 01

Approved by Medicines Management Committee 19th March 2008

Updated July 2009

Review Date March 2010

VERSION 2
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1.0 Contact Details

Please add practice staff details for your clinic

**General Practice Anticoagulant Clinic Staff and Contact Numbers**

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### General Practice Anticoagulant Clinic Times

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### Testing and Dosing Equipment

<table>
<thead>
<tr>
<th>Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche diagnostic for repair of Coaguchek XS plus</td>
</tr>
<tr>
<td>INR-star (available 9.00am to 5.30pm)</td>
</tr>
</tbody>
</table>

**Tel**

| 0808 100 1920 |
| 017367 56789 |

**UK NEQAS**

Rutledge Mews, 3 Southbourne Road, Sheffield, S10 2QN

**Tel**

| 0114 267 3300 |
| 0114 267 3309 |

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### Hospital Departments

<table>
<thead>
<tr>
<th>Department</th>
<th>Lead Consultant for Anticoagulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ashford and St Peters Haematology</td>
<td>Dr Anne Miller</td>
</tr>
<tr>
<td>Ashford and St Peters Pathology Services</td>
<td>Steve Shiel</td>
</tr>
<tr>
<td>Epsom and St Helier Haematology</td>
<td>Dr K Rice</td>
</tr>
<tr>
<td>Frimley Park Haematology</td>
<td>Jayne Hughes</td>
</tr>
<tr>
<td>Frimley Park POCT Team</td>
<td>Lynda Petley</td>
</tr>
<tr>
<td>Kingston Hospital Haematology</td>
<td>Dr Helen Sykes</td>
</tr>
<tr>
<td>Royal Surrey County Haematology</td>
<td>Dr Janet Shirley</td>
</tr>
<tr>
<td>Royal Surrey County POCT Team</td>
<td>Lynda Petley</td>
</tr>
<tr>
<td>Surrey and Sussex Pathology</td>
<td>Mark Hale</td>
</tr>
</tbody>
</table>

**Tel**

| 01932 723027 |
| 01932 723026 |
| 020 8 296 2216 |
| 01276 526009 |
| 01276 526943 |
| 020 8934 2043 |
| 01483 464027 |
| 01276 526943 |
| 01737 765511 |

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### PCT Contacts

<table>
<thead>
<tr>
<th>Position</th>
<th>Name</th>
<th>Tel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation Manager</td>
<td>Denise Rayner</td>
<td>07894 598458</td>
</tr>
<tr>
<td>Contract Accounts</td>
<td>Helen Snelling</td>
<td>01372 201633</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>Liz Clark</td>
<td>07894599638</td>
</tr>
<tr>
<td>Education and Training</td>
<td>Jane Thomson</td>
<td><a href="mailto:jane.thomson@surreypct.nhs.uk">jane.thomson@surreypct.nhs.uk</a></td>
</tr>
<tr>
<td>Clinical Governance</td>
<td>Pam Knott</td>
<td>01252 305818</td>
</tr>
<tr>
<td>Information Technology</td>
<td>Emma Jackson</td>
<td><a href="mailto:Emma.Jackson@surreypct.nhs.uk">Emma.Jackson@surreypct.nhs.uk</a></td>
</tr>
</tbody>
</table>

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Anticoagulant Information, record books and alert cards can be ordered free of charge on stationary order forms.
2.0 Aims and Objectives

2.1 Aim

To provide standardised and clinically effective anticoagulation management in GP practices to patients by means of Point of Care Testing (POCT) and Computerised Decision Support Software (CDSS).

2.2 Objectives

- To provide accessible, safe, effective anticoagulant monitoring at the point of patient care.
- Ensure the same high quality of service to patients whether accessed in primary or secondary care;
- Ensure a consistent approach to testing, sampling and dosing across practices and between primary and secondary services;
- Optimise management of INR control, decreasing the risk of a thrombo-embolic event or extension of an existing event by maintaining clients’ INRs at the optimal level of anti-coagulation therapy without producing an unacceptable risk of haemorrhage
- Enhance the confidence and develop the skills of GPs and practice staff who have an interest in anti-coagulation monitoring;
- Improve the primary/secondary care interface resulting in a streamlined service that benefits patients;

These guidelines do not replace the training programme provided by the PCT, see appendix 7
Details are available from Jane Thomson: jane.thomson@surreypct.nhs.uk

3.0 Background analytical information

Surrey PCT and their local providers of pathology services in secondary care, currently support the Roche Coaguchek XS Plus and Coaguchek S devices for use by non-laboratory staff in primary care settings. The preferred device is the Coaguchek XS Plus.

In order to achieve the objectives laid down in these guidelines it is essential that all INR analysis is carried out in accordance with National Guidelines for POCT (refs) and in line with the relevant POCT policies and service level agreements from the local hospital laboratories.

The Standard Operating Procedure (SOP) documents provided for use of the equipment must be followed.


Point of Care Testing – Requirements for Quality & Competence

Management & Use of IVD Point of Care Test Devices.
Device Bulletin March 2002 MDA DB2002(03)
3.1 BACKGROUND CLINICAL INFORMATION

Anticoagulant drugs are used to treat and prevent thrombosis (abnormal blood clots) within the veins or arteries. The most commonly used drugs in the UK are the heparins and Warfarin. All anticoagulants are associated with an increased risk of bleeding and must therefore be used with care.

WARFARIN

Warfarin is an oral anticoagulant that antagonises the effects of Vitamin K.

- 0.5mg white warfarin tablet
- 1mg brown warfarin tablet
- 3mg blue warfarin tablet
- 5mg pink warfarin tablet

Warfarin is given orally and the anticoagulant response for a given dose varies widely between individuals. This is partly due to genetic factors but other factors that influence the response to Warfarin include those that alter vitamin K levels (diet, malabsorption, and diarrhoea), liver function and hypermetabolic states (carcinomatosis, hyperthyroidism).

Many drugs interact with the absorption, metabolism and clearance of Warfarin and can also lead to an increased bleeding risk through other mechanisms.

Warfarin takes at least 3 days to affect the levels of clotting factors with the longest half-lives. This is why patients with acute thrombosis are started on heparin before Warfarin is introduced. Protein C and S are natural anticoagulants with relatively short half-lives and are also vitamin K dependant and so initiating Warfarin can induce a transient pro-coagulant state. It is therefore essential that heparin is given for the first five days of initiating anticoagulation for a thrombotic event.

The long half-life of Warfarin and some of the clotting factors means that any changes in dose can take about 3 days to be effective.

When Warfarin is stopped the INR may take several days to return to 1.0.

The effect of Warfarin may be overcome by the administration of vitamin K.

Therapeutic indications

- Prophylaxis of embolism in rheumatic heart disease and Atrial fibrillation
- Prophylaxis and treatment of venous thrombosis and pulmonary embolism
- Transient ischaemic attacks if patient has atrial fibrillation (otherwise Aspirin is used)
- Prophylaxis of thrombo-embolism after insertion of prosthetic heart valve

Contraindications

- Pregnancy
- Hypersensitivity to warfarin
- Within 2 days of surgery
- Bacterial endocarditis
- Severe renal or hepatic disease
- Documented evidence of CNS haemorrhage in the previous 6 months
- Gastric-intestinal bleeding in the past 6 months

Warfarin Monitoring

This is done by measuring the prothrombin time of the anticoagulated patient either with a venous or capillary blood sample. This is then expressed as a ratio called the International Normalised Ratio (INR).

The INR is obtained by measuring the prothrombin time (PT) of the patient, dividing this figure by a geometric normal mean normal prothrombin time (GMNPT) and raising the result to the power of the ISI value of the thromboplastin used for testing.
\[
\text{INR} = \left( \frac{\text{patient PT}}{\text{GMNPT}} \right)^{\text{ISI}}
\]

This calculation is necessary because every coagulometer used to measure a PT will give a different result for a given patient depending on the thromboplastin used but it is obviously important that the INR is the same, wherever the patient happens to be tested. Each coagulometer must be calibrated with a set of plasmas with known values to establish an ISI relevant to that particular instrument. Each batch of reagent will come with its own ISI and this must be taken into account when calculating the results. Some manufacturers will have calibrated their instruments at source and provide the ISI value to be used with each batch of reagents.

**Special Precautions**

**General**
Changes in the patient’s clinical condition especially associated with inter-current illness or liver disease will require more frequent INR monitoring.

The following may exaggerate the effect of warfarin and may necessitate a dose adjustment and more frequent INR monitoring:

- Loss of weight
- Elderly
- Acute illness
- Deficient renal function
- Decreased dietary intake of vitamin K
- Administration of some drugs (see interactions)

The following may reduce the effect of warfarin and may require a dose adjustment and more frequent INR monitoring:

- Weight gain
- Diarrhoea
- Vomiting
- Increased dietary intake of vitamin K, fats and oils
- Administration of some drugs

More frequent monitoring of INR levels are necessary if any new medication (including non-prescription) is added or withdrawn from the regimen of a patient stabilised on warfarin, or if the dose of a concurrent medication is changed.

**Pregnancy**
Oral anticoagulants should not be used in pregnancy because of possible teratogenicity and foetal haemorrhage near term.

Women of childbearing age who are taking warfarin should be cautioned about the teratogenicity of warfarin. Stopping warfarin before the sixth week of gestation may largely avoid the risk of foetal abnormality. Referral to secondary care is required if any patients are pregnant or have plans to become pregnant.

**Lactation**
Warfarin is excreted into breast milk in extremely small quantities and is therefore considered compatible with breast-feeding.

**Elderly**
The elderly may be more susceptible to the effects of warfarin which may result in an increased risk of haemorrhage. Lower maintenance doses, weight for weight than those usually recommended for adults may be required for this group of patients.
### 3.2 Warfarin Indications and INR targets

The indications for warfarin treatment including target INR and an estimation of the length of therapy can be found in table 1.

#### Table 1 Warfarin indications

<table>
<thead>
<tr>
<th><strong>Indication</strong></th>
<th><strong>Target INR</strong></th>
<th><strong>Anticipated length of treatment</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary embolus</td>
<td>2.5 (2.0-3.0)</td>
<td>1st event with temporary risk factor 3 months. With identified or permanent risk factor 6 months</td>
</tr>
<tr>
<td>Proximal deep vein thrombosis</td>
<td>2.5 (2.0-3.0)</td>
<td>Same as above</td>
</tr>
<tr>
<td>Calf vein thrombosis</td>
<td>2.5 (2.0-3.0)</td>
<td>Post op without risk factors 6 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Otherwise 3 months</td>
</tr>
<tr>
<td>Recurrence of venous thrombo-embolism when no longer on warfarin therapy</td>
<td>2.5 (2.0-3.0)</td>
<td>Long Term</td>
</tr>
<tr>
<td>Recurrence of venous thrombo-embolism whilst on warfarin therapy</td>
<td>3.5 (3.0-4.5)</td>
<td>Long term</td>
</tr>
<tr>
<td>Symptomatic inherited thrombophilia</td>
<td>2.5 (2.0-3.0)</td>
<td>Long term</td>
</tr>
<tr>
<td>Antiphospholipid syndrome with venous thrombosis</td>
<td>2.5 (2.0-3.0)</td>
<td>Long term</td>
</tr>
<tr>
<td>Antiphospholipid syndrome with arterial thrombosis</td>
<td>3.5 (3.0-4.5)</td>
<td>Long term</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2.5 (2.0-3.0)</td>
<td>Long term</td>
</tr>
<tr>
<td>Cardioversion</td>
<td>2.5 or 3.0 *</td>
<td>3.0 for 4 weeks pre-cardioversion; 2.5 for a minimum of 4 weeks post-cardioversion</td>
</tr>
<tr>
<td>Mural thrombosis</td>
<td>2.5 (2.0-3.0)</td>
<td>Long term – whilst documented as present</td>
</tr>
<tr>
<td>Cardiomyopathy</td>
<td>2.5 (2.0-3.0)</td>
<td>Long term</td>
</tr>
<tr>
<td>Mechanical prosthetic heart valve - aortic</td>
<td>3.0 or 2.5</td>
<td>Long term</td>
</tr>
<tr>
<td>(see table 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mechanical prosthetic heart valve - mitral</td>
<td>3.5 or 3.0</td>
<td>Long term</td>
</tr>
<tr>
<td>(see table 2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bioprosthetic valve</td>
<td>2.5 (2.0-3.0)</td>
<td>Short term</td>
</tr>
<tr>
<td>Ischaemic stroke without Atrial fibrillation</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>Retinal vessel occlusion</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>Peripheral arterial thrombosis</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>Arterial grafts</td>
<td>2.5 (2.0-3.0)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery thrombosis</td>
<td>2.5 (2.0-3.0)</td>
<td></td>
</tr>
<tr>
<td>Coronary artery graft</td>
<td>Not indicated</td>
<td></td>
</tr>
<tr>
<td>Coronary angioplasty and stents</td>
<td>Not indicated</td>
<td></td>
</tr>
</tbody>
</table>


#### Table 2 Recommendations for valve-location-specific target INR's

<table>
<thead>
<tr>
<th><strong>Valve type</strong></th>
<th><strong>Position</strong></th>
<th><strong>Target INR</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Bi-leaflet</td>
<td>Aortic</td>
<td>2.5 (2.0-3.0)</td>
</tr>
<tr>
<td>Tilting disk</td>
<td>Aortic</td>
<td>3.0 (2.5-3.5)</td>
</tr>
<tr>
<td>Bi-leaflet</td>
<td>Mitral</td>
<td>3.0 (2.5-3.5)</td>
</tr>
<tr>
<td>Tilting Disk</td>
<td>Mitral</td>
<td>3.0 (2.5-3.5)</td>
</tr>
<tr>
<td>Caged ball or caged disk</td>
<td>Aortic or mitral</td>
<td>3.5 (3.0-4.5)</td>
</tr>
</tbody>
</table>
4.0 Patient Selection

4.1 Selection criteria

It has been agreed locally that patients should start oral anticoagulants in secondary care until such a time as primary care clinics have developed sufficient expertise to take on this role. Once the INR is stable (at least 3 consecutive INRs within 0.5 of target INR), patients in the following categories may be transferred to primary care:

- Atrial Fibrillation
- Prophylaxis and treatment of venous thrombosis and pulmonary embolism
- Artificial Heart Valves
- Long-term anticoagulation for recurrent venous thrombosis (except antiphospholipid syndrome)
- Mural Thrombus
- Cardiomyopathy

Transfer should be arranged by written request between the general practitioner and the lead clinician for the hospital based anticoagulant service. This allows formal review of the patient’s A/C records before transfer as some patients in the above categories may be best served by remaining with the secondary care service.

In established primary care clinics, where the staff have experience in INR monitoring and have demonstrated competences, anticoagulation may be initiated in selected patients (e.g. atrial fibrillation) as deemed appropriate by the lead clinician.

For information on loading doses see appendix 9.

4.2 Exclusion criteria

The decision of which patients should remain under the care of the hospital haematology department is made according to the judgement of the lead clinicians for primary care clinic and the secondary care service.

Practices new to anticoagulant monitoring services may choose to exclude the following patients:

- Patients taking Phenindione or Acenocoumaral
- Patients with poor control or consistently unstable or high INR results
  - Alcohol problems
  - IV drug use
  - Severe Heart Failure
  - Chemotherapy for malignant tumours
  - LMWH may be required long term in malignancies
- Patients who have had a DVT/PE in the past month
- Children under 16 years (refer to Paediatrician)
- Patients undergoing Cardioversion
- Patients with prosthetic heart valves
- Other conditions the Consultant Haematologist considers should exclude the patient from management in primary care
5.0 Practice Protocol

5.1 INR clinic procedure

1. Preparation of CDSS, Coagucheck XS Plus (document serial number of machine used) and any internal or external quality control required
2. Documentation of any internal or external quality control and reporting of name, batch numbers and expiry date of test strips used
3. Ensure any relevant clinic protocols are to hand (e.g. health and safety protocols)

For each patient seen, the following procedure should be followed:

4. Confirm name and DOB of patient and reason for attending clinic
5. Inform the patient of the clinic process and gain full informed consent before procedure (verbally is acceptable)
6. Identify patient on CDSS and ask initial questions regarding:
   • unusual bleeding or bruising
   • missed doses
   • medication changes -stopped/started (inc. OTC and herbal)
   • changes in diet or lifestyle
   • planned surgery
   Inform GP of any positive responses
7. Perform blood test using capillary blood sample according to standard operating procedures.
8. Download INR result into CDSS to obtain dosing and date of next appointment. Ensure this is appropriate. Clinical responsibility for the dose is with the registered health care professional (Nurse, Pharmacist or Doctor) who is signing the yellow book. CDSS does not replace clinical judgement.
9. Inform GP of any out of range results. (Lead GP may determine which results an experienced anticoagulant nurse or pharmacist need inform them of)
10. Write the INR, dose regime and date of next appointment into the patient’s yellow book. Dose should be written as mg rather than number of tablets.
11. Verbalise this to the patient ensuring they know what dose to take.
12. Provide the patient with any relevant education or advice,
   • All new Patients should have a copy of the yellow book from the National Patient Safety Agency (NPSA) and contact numbers for advice.
   • Check they have their yellow alert card and carry it with them at all times ensuring they have their yellow book available when seen by a health care professional, in particular when visiting the dispensing pharmacist.
   • Ensure they know what to do in the event of bleeding.
   • Check that any women of childbearing age are taking adequate contraceptive precautions and know to inform the clinic if planning to get pregnant, document this information provided.

An example patient pathway can be found in Appendix 2

5.2 INR OUT OF RANGE

First check that the patient is taking the dose you think they are. Ask in terms of tablet colours as well as dose.

• Check for missed doses either deliberately (i.e. for surgery) or accidentally
• Check for changes in medication (i.e. stopping/ starting interacting drugs)
• Check if using over the counter or herbal medications
• Significant changes to diet- either increase or decrease in salad, vegetables or cranberry juice
• Changes in pattern of alcohol consumption
• Check that patient is following instructions correctly.
• If poor compliance is suspected, this needs to be documented and the clinic doctor and general practitioner should be informed.
5.2.1 Dealing with Low INRs

For low INRs the CDSS may be overcautious and bring the patients back in one week rather than change the dose. Unless there is an obvious reason for the low INR, a dosage adjustment with two or three weeks to the next test may be preferred. Clinical judgement should be used in these cases.

**Use of low molecular weight heparin for low INRs**

An INR persistently below the therapeutic range increases the thrombotic risk. This risk is greatest in patients with:

- DVT or PE within last 4 weeks
- Mechanical heart valve replacements
- Antiphospholipid syndrome
- Previous DVT/PE with known antithrombin deficiency; protein C or protein S deficiency; homozygosity for FV Leiden; homozygosity for prothrombin gene mutation; double heterozygosity for any two inherited thrombophilias.

Discuss use of therapeutic LMWH with haematologist if INR < 2.0 in patient from above groups

There is little evidence for the efficacy of heparin in atrial fibrillation.

LMWH does not need monitoring apart from the need for FBC if patient is on it > 5 days

LMWH is difficult to reverse and, because it is given subcutaneously and has a long half-life, may be released into the circulation for up to 24 hrs after administration.

LMWH will not affect the INR

5.2.2 Dealing with high INRs

The main adverse effect of oral anticoagulants is haemorrhage. Abnormal bleeding is the main sign of warfarin overdose and may be manifested by blood in the stools, haematuria, malaena, petechiae, excessive menstrual bleeding, excessive bruising or persistent oozing from superficial injuries.

Checking the INR and omitting doses where appropriate is essential. If the oral anticoagulant is stopped but not reversed, the INR should be measured 2-3 days later to ensure that it is falling. The following guidance comes from the recommendations of the British Society for Haematology and is based on the result of the INR and whether there is major or minor bleeding/bruising in patients taking warfarin.

An INR >5.0 is associated with an increased risk of bleeding, although patients may of course bleed at therapeutic INR especially if there is an underlying lesion such as a bladder carcinoma or peptic ulcer.

- Check that patient is following instructions correctly
- Check for changes in medications (i.e., starting on interacting drugs or stopping a drug that reduced the effects of Warfarin)
- Check alcohol consumption
- Check for signs of bleeding &/or bruising
The following may act as a guide to practical dosing in cases of high INR, clinical judgement must also be used:

<table>
<thead>
<tr>
<th>TARGET INR 2.0 – 3.0</th>
<th>Dosage Change</th>
<th>Next Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0 – 5.9 (without bleeding)</td>
<td>Omit for 2 days then reduce Warfarin by 10-15%</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>6.0-7.9 (without bleeding)</td>
<td>Omit for 3 days then reduce Warfarin by 15-20%</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>&gt;8.0 (without bleeding)</td>
<td>Give Vitamin K at 0.5mg – 2.5mg orally Stop Warfarin &amp; restart warfarin at lower dose when INR &lt;4.5</td>
<td>1-2 days</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TARGET INR 3.0-4.0</th>
<th>Dosage Change</th>
<th>Next Visit</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0-5.9 (without bleeding)</td>
<td>Omit for 1 day then reduce Warfarin by 10-15%</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>6.0-7.9 (without bleeding)</td>
<td>Omit for 2 days then reduce Warfarin by 15-20%</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>&gt;8.0 (without bleeding)</td>
<td>Give Vitamin K at 0.5mg – 2.5mg orally Stop Warfarin &amp; restart warfarin at lower dose when INR &lt;4.5</td>
<td>1-2 days</td>
</tr>
</tbody>
</table>

ALL PATIENTS WITH ACTIVE BLEEDING TO BE REFERRED DIRECTLY TO THE ACCIDENT AND EMERGENCY DEPARTMENT ASAP
A&E may need to give vitamin K 5-10mg by slow IV injection and give pro-thrombin complex concentrate or fresh frozen plasma

5.3 Referrals out of Primary Care

Patients should be referred to the Haematology department where the anticoagulation provider feels that the management of a patient is outside his/her sphere of competence or falls under exclusion.

Patients should be referred to secondary care if there are complications which do not require emergency treatment via A&E.

This should be done by written referral from the lead clinician for anticoagulant service.

5.4 Patient education.

Patients attending for anticoagulation monitoring in primary care should have been provided with NPSA information pack. They should also have received education on the management of and prevention of secondary complications of their condition. This should be documented in the patient notes and reviewed with them at every visit regardless of the duration of warfarin therapy.

In addition to this, at every visit, all patients should be given up to date information to ensure they are aware of and understand the following:

- Name of drug and current dose.
- Target INR.
- Reason for and objectives of treatment.
- Anticipated length of treatment.
- What to do in the event of a missed dose.
- Symptoms of under and overdose and what to do if these occur.
- Drug and food interactions including lifestyle factors.
- To tell healthcare professionals they are taking warfarin and show their yellow book whenever they receive treatment or advice.
- Need to take yellow book when requesting warfarin prescriptions from GP and to collect from pharmacy.
- What to do if dental treatment or surgery is required (warfarin does not usually need to be stopped for dental treatment. It is usually stopped or reduced for surgery).
- Contact details for the provider in case of concerns.
5.5 Record keeping

Practices will be required to keep a record for each patient under their care. This information must be updated at each visit and will include:

- Patient name and address
- Date of Birth
- Indication for treatment
- Length of treatment
- Target INR
- Relevant notes supporting the dose decision, counselling and self management
- Time spent within target range
- Frequency of missed appointments
- Medical conditions, hospital admissions likely to affect anticoagulation such as increased risk of haemorrhage.
- Bleeding episodes and adverse events
- Discontinuation date
- Name of initiating Consultant or GP
- Any actions taken other than dosing and retest dates.

The computerised decision support software provided to practices will be set up to store this information. In addition to this after each consultation the following information must also be recorded:

- Patient’s INR;
- Dose of anticoagulant;
- Date of next appointment;
- Information from the patient about unusual bleeding or bruising, adherence to treatment, stopped/initiated medication (including OTC and herbal etc), changes in diet, lifestyle or planned surgery;
- Information from the prescriber (where appropriate)
- Additional information from the patient’s medical notes (where appropriate);
- Any advice given or interventions made.

The practices will also be required to ensure that all clinical information related to the service (not the routine dosing) is recorded in the patient’s own GP held lifelong record, including the completion of any ‘significant event’ record that occurs whilst the patient is on warfarin.

5.6 Medication

Prescribing

- The prescribing of medication will remain the responsibility of the patient’s own GP practice, as at present, on the advice of the anticoagulation monitoring provider whether in primary or secondary care.
- Repeat prescriptions should only be issued if the prescriber has checked that the patient is regularly attending the anticoagulant clinic, that the INR is within safe limits and the patient understands what dose to administer.
- GP’s from referring practices may be able to access their patient’s data via the web-based system.
- Prescribers should arrange additional INR monitoring within 4-7 days and alert the monitoring service if an interacting medicine is started or stopped.

Dispensing

- The practitioner who dispenses the warfarin prescription must ensure it is safe to dispense – there may have been a delay between it being written and dispensing.
- The Pharmacist should review the patient’s yellow book checking the date of last blood test, latest INR, current dose and confirming this information with the patient or carer.
- When dispensing or providing an interacting drug from the pharmacy the dispensing practitioner should check that the next test is planned within a week.

5.7 Individual annual review

Patients should undergo an annual health check as part of the management of their condition. The responsibility of this lies with the patients own GP.
5.8 Discontinuation of Warfarin

- The anticipated duration of overall treatment will be documented at the point of the initial referral.
- Whether treatment should be discontinued (including a risk/benefit comparison) should be reviewed regularly and at least annually by the clinician responsible for INR monitoring.
- Responsibility for the decision to discontinue the anticoagulant will reside with the patient's own registered GP.
- The anticoagulation provider should raise the issue when appropriate and provide written evidence.
- Oral anticoagulants will be discontinued on an agreed defined date and all people involved in the care of that patient will be informed.
- If warfarin therapy needs to be discontinued for medical reasons then the GP and the initiating consultant/clinician should be notified ASAP.

6.0 Adverse events and Incidents

An incident is any unplanned event which caused or may have caused harm or damage to either patients, staff, visitors, contractors, services or property which are the responsibility of the PCT.

Practices are required to report any adverse event to the PCT Lead within 24 hours of the information becoming known to the practitioner. This is in addition to a practitioner’s statutory obligations. The reason for this is to detect any systematic problems of quality within the service rather than performance management of individual service providers. The PCT leads will undertake root cause analysis and provide feedback as outlined in the flow chart in Appendix 3.

Examples of adverse events or incidents:
- Wrong dose prescribed but error identified and little or no harm to patient
- Wrong dose taken resulting in little or no harm
- Misfiling of patient's visit information, identified and appropriate actions taken

6.1 Non serious incidents/near misses

A ‘near miss’ is any unplanned event that does not cause injury but which has the potential to do so.

Examples of near misses include:
- a prescribing error which is picked up by the dispensing pharmacist
- defective equipment identified and taken out of use without harm to patients
- a potential slip, trip or fall which is prevented
- a needle found on the floor and picked up and disposed of without injury

6.2 Serious Untoward Incidents (SUI)

An SUI is defined as ‘an accident or incident when a patient, member of staff, or member of the public suffers serious injury, major permanent harm or unexpected death, (or the risk of death or injury), on hospital, other health service premises or other premises where health care is provided and where actions of health service staff are likely to cause significant public/media concern.’

Examples of serious incidents include:
- extensive bleeding while taking warfarin requiring treatment with blood products or causing significant harm or death
- Patient provided with inadequate anticoagulation therapy resulting in thrombosis or extension of existing thrombosis
- Loss or breach of confidentially where person/patient or service user’s are identified.
7.0 Quality Control

Practices will be expected to follow clear internal and external quality control procedures. This is to ensure the accuracy of the INR readings. Quality control guidance can be found in Appendix 4 and is summarised in Table 3 for the Coaguchek XS Plus. Full details will be found in the Standard Operating Procedure for the relevant device.

Table 3

<table>
<thead>
<tr>
<th>Quality Control</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coaguchek XS Plus</td>
<td>Integrity check QC included in every strip/test</td>
</tr>
<tr>
<td>Liquid control</td>
<td>The liquid control must be analysed routinely on a monthly basis, each time a new batch of strips is used, and whenever patient results are not as expected.</td>
</tr>
<tr>
<td>UK National External Quality Assessment Scheme (NEQAS)</td>
<td>The PCT will fund participation in NEQAS. Each Practice is registered individually. Practices will be sent a sample to test approximately four times per year to externally monitor the performance of coagulo-meters. All EQA results must be made available for hospital laboratory inspection.</td>
</tr>
<tr>
<td>Hospital venous sampling</td>
<td>This needs to be carried out:</td>
</tr>
<tr>
<td></td>
<td>• Before starting warfarin</td>
</tr>
<tr>
<td></td>
<td>• If the INR is above 4.0</td>
</tr>
<tr>
<td></td>
<td>• If the INR is below the patient’s therapeutic range</td>
</tr>
<tr>
<td></td>
<td>• If the result is unexpected</td>
</tr>
<tr>
<td></td>
<td>NB: A second capillary sample and quality control check should be performed before undertaking venous sampling.</td>
</tr>
</tbody>
</table>

References

A. BNF September 2007 and subsequent

Acknowledgements

The following are thanked for their valuable input into these guidelines
Alex Bennett Cardiac Network
Subo Emmanuel GP Integrated Care Partnership, Epsom
Gwen Atkinson Primary Care Learning Facilitator
Liz Clark Primary Care Pharmacist
Staff of Sutton and Merton PCT, Epsom and St Helier NHS Trust, Frimley Park Hospital, Ashford and St Peters NHS Trust, Royal Surrey County Hospital
Appendix 1

Protocol for Dealing with DNAs

1st DNA

If a patient DNAs the provider practice must

- Contact the patient by telephone to ascertain reason for DNA
- Arrange another appointment as soon as possible
- Notify non-provider GP

Subsequent DNAs

If the patient fails to attend for further appointments the provider GP must notify the patients GP.

The non-provider GP should

- Contact the patient to ascertain reason
- Check that they have not attended elsewhere
- Inform the patient of the importance of continued monitoring and therapy
- Follow practice DNA procedure
- Complete incident report and fax to PCT?
Appendix 2

Patient Pathway

Patient arrives in practice

If patient is new, patient is given pt information;
- Yellow NPSA booklet
- Local leaflet

Patient name and address confirmed. Patient asked re bleeding/bruising, compliance with dose, hospital visits and initiated/discontinued medication (including herbal and OTC)

Patient completes questionnaire or clinician enters onto computer template

Capillary blood sample taken and INR measured using Coagucheck XS Plus

Results downloaded into INRstar

Results documented in INRstar

Results recorded into patients yellow book

Copy of dosing sheet left with Practice

Patient leaves practice with result of INR, date of next appointment and current dose instructions in their yellow book, plus verbal or written education if appropriate
Appendix 3

INR Adverse Event Flow Chart

1. Adverse event occurred
2. Practice send incident form to PCT clinical governance lead 24 hours – email pam.knott@surreypct.nhs.uk
3. PCT clinical governance lead to disseminate incident forms to INR PCT lead
4. PCT leads to meet quarterly to undertake root cause analysis and collate incidents
   - Quarterly feedback to the North Surrey Locality subcommittee to the Surrey PEC
   - Quarterly feedback to practices on reported incidents
5. PCT to identify and address any training needs or service issues
Appendix 4

Quality Control of the Coaguchek

Quality control procedures on the Coaguchek are integral to providing quality assurance for the anticoagulant monitoring service. Quality control data must be recorded after every test, on the form provided, to ensure adequate audit trail.

INTERNAL CONTROL

- Coaguchek XS Plus strips – These strips incorporate an on board integrity check. They contain a compound which is sensitive to ambient factors such as light, humidity and temperature, which could cause test strip deterioration. Any resulting chemical changes are detected electrochemically by the Coaguchek XS Plus and patient results will only be displayed if the test strip integrity is intact.
  NB: Coaguchek S strips do not have this integrity check.

- Liquid control – Roche give no clear guidance on the frequency of liquid QC testing with the Coaguchek XS Plus meter but have advised the PCT that this should be performed routinely on a monthly basis; each time a new batch of strips is used, if you suspect the strips have been incorrectly stored or handled, if the machine is dropped or incorrectly stored or if you obtain an implausible patient result.

EXTERNAL QUALITY CONTROL


It is recommended that every device is registered with NEQAS.
It may be possible to use the same EQA sample on more than one machine (probably not more than 2 devices due to delays affecting the result) which could save a bit of money.

The scheme

The purpose of the Near Patient Testing programme is to provide external quality assessment as a part of the overall quality assurance for tests of blood coagulation carried out on an instrument designed for near patient or point of care testing whether within or remote from hospital laboratories. The aim of the programme is to promote high standards of performance and practice achieved with the UKNEQAS primary aim of education by the provision of independent, objective and impartial information.

Registration

The participant registered should be the centre responsible for performing the tests. If the daily testing is carried out by a GP surgery then the surgery should be registered. Results and associated data from participants will be treated with strict confidentiality. Each registered participant will be given a unique participation number which should be quoted in all correspondence. Use of this number will assist in maintaining confidentiality in survey correspondence.

Participation

Participating centres will be sent at least four surveys per year each comprising of two samples for INR determination. The samples will consist of lyophilised human plasma which has been screened for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C and human immunodeficiency virus types 1 and 2 (anti-HIV-1+2).

Participants will be provided with instructions on reconstitution and testing of the samples. A closing date for return of the results will be given and results will be analysed and reports sent back to participants approximately one week after the closing date of the survey.

Performance Analysis

Approval has been given by the UK National Quality Assurance Panel for Haematology for the following performance criteria:

A median result will be calculated for each reagent/instrument group, and the percentage deviation of individual laboratories from this median will be determined. The figure will indicate how close to the ‘consensus’ result individual results are from other users of the test system and performance ‘without consensus’ is defined as a result greater than 15% deviation from the reagent group median.
If the result is out of range the practice must notify the PCT Lead, the local laboratory and also Roche Diagnostics. Reasons for unacceptable EQA results include problems with the QA material, poor operator technique and faulty equipment. Follow up of such results may require additional training sessions, investigation of EQA sample storage/processing or machine maintenance.

An overall report on the operation of the scheme will be distributed on an annual basis. UK NEQAS for blood coagulation and the near patient testing EQA scheme are fully accredited by Clinical Pathology Accreditation (CPA (UK) Ltd) in the EQA Scheme Accreditation programme.

For further details please contact the scheme manager, UK NEQAS for blood coagulation, Rutledge Mews, 3 Southbourne Road, Sheffield.
S10 2QN. Tel 0114 267 3300. Fax 0114 267 3309.
E-mail: negas@coageqa.demon.co.uk

Venous sampling for analysis at the central laboratory.

Venous blood sampling should be undertaken if the Coaguchek result is unexpected. Unexpected results should be verified by performing a liquid quality control and repeating the patient test before taking the venous sample.
The practice should perform random venous blood sampling to cross check results with the laboratory as part of quality assurance.
Appendix 5

Contingency Planning

All practices have business continuity plans and these should be followed for situations that arise that are covered by the plan. For the anticoagulation service itself, the following continuity plans should be followed:

Computer decision support software
In the event of INRstar software failing, the following guidance should be followed:

<table>
<thead>
<tr>
<th>INR</th>
<th>Advice to patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR within target range</td>
<td>To continue current dose.</td>
</tr>
<tr>
<td></td>
<td>To contact patient with any change within 24 hours</td>
</tr>
<tr>
<td>INR above target</td>
<td><strong>Action: To liaise with clinician</strong></td>
</tr>
<tr>
<td>INR below target</td>
<td><strong>Action: To liaise with clinician</strong></td>
</tr>
</tbody>
</table>

In the event of INRstar software not being available for more than 24 hours:

The practice needs to contact the **PCT IT service desk** to ensure that the network/hardware is working. If the problem is still present, the practice needs to contact the INRstar support desk.

If the user has lost or forgotten their password, the user with administration rights at each surgery has access to reset the passwords of colleagues. If they are unavailable or if the forgotten password actually belongs to the local administrator, the PCT administrator or the PCT IT service desk can reset the password. INRstar support desk does not normally have direct access to customer systems.

Coaguchek XS Plus

In the event of the Coaguchek XS plus meter not working, Roche should be contacted immediately to organise a repair or replacement. The machines have two years warranty (which excludes damage through misuse) and Roche promise to repair or replace the meter normally the next day providing the problem is reported before 3pm Monday to Thursday. All other times, a repair or replacement will be provided within two days. Details that will need to be provided are:

- Description of the problem
- Serial number of the monitor (located on the back)
- Strip lot number/QC lot number
- Error message (if applicable)
- Contact details if you are calling for the first time

Contingency contact details

<table>
<thead>
<tr>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roche diagnostic for repair of Coaguchek XS plus</td>
</tr>
<tr>
<td>INRstar (available 9.00am to 5.30pm)</td>
</tr>
<tr>
<td>PCT IT Department</td>
</tr>
<tr>
<td>PCT Anticoagulant Lead</td>
</tr>
<tr>
<td>Liz Clark</td>
</tr>
<tr>
<td>07894599638</td>
</tr>
<tr>
<td>Tel 0808 100 1920</td>
</tr>
<tr>
<td>Tel 017367 56789</td>
</tr>
<tr>
<td>Tel 01932 722266</td>
</tr>
<tr>
<td>Liz Clark</td>
</tr>
<tr>
<td>07894599638</td>
</tr>
</tbody>
</table>
Appendix 6

Evaluating the Service

Following the National Patient Safety Agencies advice (Guidelines April 2007) the following training is advised for any member of the team who is reviewing the safety and effectiveness of an anticoagulant service.

Legislation, regulations and guidelines

- An in-depth understanding of national and local anti-coagulant guidelines and their application.
- A working understanding of the local guidelines for patient records, their storage and confidentiality of information.
- An in-depth understanding of the national and local prescribing guidelines.
- A working understanding of the guidelines on administration of medicines.

Clinical knowledge

- An in-depth understanding about the indications and contra-indications for the proposed treatment.
- An in-depth understanding of principles and practice of prescribing anticoagulants.
- An in-depth understanding of the mode of action and side effects of anticoagulants and how to recognise and manage them.
- An in-depth understanding of the ways of monitoring safety and effectiveness of an anticoagulation service.
- A working understanding of peer reviewed literature.

Technical Knowledge

- A working understanding of different near patient testing devices and their care and maintenance requirements.
- A working knowledge of laboratory methods for measurement of clotting parameters.
- A working knowledge of local computerised patient record systems, laboratory IT systems and pharmacy IT systems.

Procedures and patient management

- A factual knowledge of the roles and responsibilities of other team members.
- A working understanding of the limits of one’s own knowledge and experience and the importance of not operating beyond these.
- An in-depth understanding of local patient care pathways.
The PCT will evaluate the service annually and will follow The National Patient Safety Agency guidelines. The evaluation will take the following into consideration:

Determine the method of review and evaluation
1. Identify the main objectives and outcomes of the service
2. Identify the purpose, range and level of the evaluation
3. Choose appropriate ways of evaluating the safety and effectiveness of the service, in accordance with local and national guidelines
4. Specify the evaluation criteria for outcomes and delivery
5. Confirm that the resources are available to carry out the evaluation
6. Agree with the appropriate people how the evaluation will be carried out
7. Specify a plan for putting the evaluation into practice

Perform the review
1. Identify the information needed to evaluate the service and where this information can be found
2. Collect relevant information using suitable methods and procedures
3. Produce samples that are sufficiently representative to give reliable results
4. Ask clear questions
5. Ensure that the evaluation causes as little disruption as possible to the delivery of the service
6. Ensure that the staff involved understand why the evaluation is being carried out and encourage them to give their views
7. Record information accurately and follow the rules of confidentiality
8. Report the results of the evaluation in a consistent and comprehensible way
9. Communicate the results of the evaluation in a timely manner to managers, staff, service providers and other relevant parties.

Make improvements to the service
1. Set up the objectives that will be achieved by making improvements
2. Discuss how practical the proposed improvements are with staff and managers
3. Prioritise improvements according to their cost/benefit
4. Identify the resources needed to make improvements to the service
5. Ensure that plans to make improvements are practical and realistic
6. Speak to the people who will put the plans into practice and take account of their views in the final plan
7. Give the people affected by the plan clear information about the changes and opportunities to ask for explanations on anything they do not understand
8. Identify and deal with obstacles and problems when putting the plans into practice and report them to the appropriate people
9. Collect enough information to monitor how successful the plans are
Appendix 7

INR Training requirements

Training will be organised by the PCT to ensure all provider staff or those contracted by the practice to provide the service have the necessary skills and knowledge to conduct anti-coagulation monitoring and use the equipment successfully. Training will involve point of care testing and haematology specialists.

The National Patient Safety Agency (NPSA) has issued guidance on the training and competency requirements for those involved with anticoagulation.

The clinical leads are responsible for ensuring that all members of the provider staff have attended the PCT and Roche training. This includes all practice staff involved in near patient testing and/or dosing for anticoagulation clinics.

All staff involved in monitoring patients under the anticoagulation service must attend an annual update provided by the PCT and commit to continual professional development related to INR monitoring each year.

The clinical leads for each practice will engage in local networking to develop close contact with local consultants, pharmacists and others providing this care to the patients.

The training will cover theoretical aspects of anticoagulation monitoring and aims to ensure that all staff involved has:

- The ability to safely manage a primary care based anticoagulation clinic using point of care testing for INR measurement, interpreting INR results and assessing the dose of oral anticoagulation in order to maintain results within their appropriate therapeutic ranges
- A comprehensive understanding of the conditions requiring oral anticoagulation therapy and target ranges for warfarin therapy;
- An understanding of the pharmacology of warfarin and determine the relevance of; dosing, side effects, antidotes, interacting medication and lifestyle factors.
- The ability to critically analyse all aspects of anticoagulation management and therefore evaluation aspects for safe practise.

The practical aspects of the training will involve providing evidence for set competencies.
Appendix 8

Managing patients requiring dental surgery in primary care

Oral anticoagulants should not be discontinued in the majority of patients requiring out-patient dental surgery including dental extraction.

The risk of significant bleeding in patients on oral anticoagulants and with a stable INR in the therapeutic range 2-4 (i.e. <4) is very small and the risk of thrombosis may be increased in patients in whom oral anticoagulants are temporarily discontinued.

For patients stably anticoagulated on warfarin (INR 2-4) and who are prescribed a single dose of antibiotics as prophylaxis against endocarditis, there is no necessity to alter their anticoagulant regimen.

For patients who are stably anticoagulated on warfarin, a check INR is recommended 72 hours prior to dental surgery.

Patients taking warfarin should not be prescribed non-selective NSAIDs and COX-2 inhibitors as analgesia following dental surgery.
Appendix 9

Initiation of warfarin

Treatment of thrombosis (DVT or PE)

Warfarin should not be given without heparin in presence of current thrombosis.

Warfarin Dose

Loading schedule for heparinised patients:

<table>
<thead>
<tr>
<th>Day</th>
<th>Full dose schedule</th>
<th>Modified Schedule*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10mg</td>
<td>6mg</td>
</tr>
<tr>
<td>2</td>
<td>10mg</td>
<td>6mg</td>
</tr>
<tr>
<td>3</td>
<td>5mg</td>
<td>3mg</td>
</tr>
<tr>
<td>4</td>
<td>Check INR and give further doses according to table below</td>
<td></td>
</tr>
</tbody>
</table>

Day 4 INR

<table>
<thead>
<tr>
<th>Full dose schedule</th>
<th>Modified Schedule*</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1.4</td>
<td>10mg</td>
</tr>
<tr>
<td>1.4-1.7</td>
<td>8mg</td>
</tr>
<tr>
<td>1.8-2.6</td>
<td>5mg</td>
</tr>
<tr>
<td>2.7-3.5</td>
<td>4mg</td>
</tr>
<tr>
<td>3.6-4.0</td>
<td>3mg</td>
</tr>
<tr>
<td>4.1-4.5</td>
<td>2mg</td>
</tr>
<tr>
<td>4.6-10.0</td>
<td>Omit warfarin for 2 days then check the INR.</td>
</tr>
<tr>
<td>&gt;10.0</td>
<td>Reversal with Vitamin K (1-2mg oral or IV) should be given. No further Warfarin recommended until cause of extreme sensitivity established.</td>
</tr>
</tbody>
</table>

Re-check after 2-4 days and adjust dose according to clinical judgement. Transfer to using INR star for dosing when dose settled.

Prevention of thrombosis in Atrial Fibrillation (AF)

Heparin is not required when initiating warfarin in AF.

Warfarin Dose

Patients may be started on 3mg of warfarin daily with an INR test after 5 to 7 days.
In the very elderly or patients taking potentially interacting medicines a dose of 2mg daily may be used.
In a young and otherwise fit individual with AF a dose of 5mg daily for 5 days is sometimes used.

Test on day 5 to 7 and adjust dose according to clinical judgement.
### Anticoagulation Service

**Please answer the following questions before you go in to see the nurse**

**Name:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you had any bleeding problems or excessive bruising since your last visit?</td>
<td></td>
<td></td>
<td>If yes, please give details:</td>
</tr>
<tr>
<td>Have any of your other medicines been changed since your last visit?</td>
<td></td>
<td></td>
<td>Name of drugs and date started:</td>
</tr>
<tr>
<td>Have you been in hospital since your last visit?</td>
<td></td>
<td></td>
<td>If yes, please give details:</td>
</tr>
<tr>
<td>Are you taking the dose of Warfarin as stated on the yellow book?</td>
<td></td>
<td></td>
<td>If not, what dose are you taking?</td>
</tr>
<tr>
<td>Do we have your current address?</td>
<td></td>
<td></td>
<td>Please write any changes here:</td>
</tr>
<tr>
<td>Do we have your current telephone number?</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Please write any other comments or questions here:**

**Dates to avoid for next appointment:**

---

*Appendix 10*