WARFARIN
MANAGEMENT
GUIDELINES

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# Warfarin Management Guidelines

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Acknowledgement

We would like to acknowledge the work done by Sheffield PCT in developing anticoagulation services and allowing us to use their work in producing this document.

1 Introduction

1.1 Anticoagulants have a narrow therapeutic margin and are safe only if monitored closely. In primary care anti-coagulants are one of the classes of drugs most commonly associated with fatal medication errors.

1.2 Anticoagulants are generally prescribed on a shared care basis, with treatment initiated in secondary care being continued by GP practices. Safe anticoagulant therapy relies on clear communication between the two.

1.3 This document sets out standardised and clinically effective guidelines for the care of patients receiving warfarin that minimises the risks associated with anticoagulation.

1.4 These guidelines should be used by those providers who have been commissioned by NHS Cumbria LES to provide a level 4 enhanced anticoagulation service.

1.5 The other two oral anticoagulants which require monitoring are nicoumalone (acenocoumarol) and phenindione. Both of these are rarely used, only if patients are allergic to warfarin or are particularly sensitive/resistant to warfarin.

1.6 There are newer oral anticoagulants on the market: currently dabigatran (Pradaxa®) which is a direct thrombin inhibitor and rivaroxaban (Xarelto®) which is a direct factor X inhibitor. These two drugs are not covered in this guidance as they do not routinely require monitoring.

2 National Guidance and Additional Resources

Guidance in this document is produced taking into account:


2.3 GMS Contract - National Enhanced Service.

2.4 Murray et al. INRs and point of care testing. BMJ 2003; 326: 5-6.


2.8 Anon. An example standard operating procedure (SOP) for a primary care anticoagulation clinic using NPT and CDSS.

3 **Aim**

To offer therapeutic warfarin management to patients in Cumbria who are receiving warfarin therapy, using near patient testing within the local community.

4 **Objectives**

The objectives are as follows:

- To provide standardised and clinically effective anticoagulation management to patients receiving warfarin therapy whilst minimising the risks associated with anticoagulation
- To identify patients receiving warfarin and offer transfer of care from hospital to primary care clinics for appropriate patients
- To initiate warfarin for suitable patients
- To produce optimum management of INR control
- To educate patients in understanding their treatment, in terms of their condition requiring warfarin, 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
- To maintain a register of all patients receiving warfarin 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
5 **Responsibilities of NHS Cumbria**

The role of NHS Cumbria is to ensure that services provided in primary care are in accordance with the service level agreement for the provision of level 4 anticoagulation services including the following;

- Ensuring the NPSA safety alert 18 (Actions that can make anticoagulant therapy safer) March 2007 is implemented in GP Practices
- Develop, update and review the Local Enhanced Service for Anticoagulation in Primary Care as necessary
- Developing Anticoagulation Therapy Guideline, training pack and template Standard Operating Procedures to support GP practices to provide anticoagulation services
- Ensuring anticoagulant guidelines are available for the management of under and over anticoagulation
- Ensuring regular clinical audit is undertaken in line with section 24 of this document
- Monitoring participation of sites in national laboratory quality assurance scheme and monitoring performance (Providers of Level 4 service)

6 **Responsibilities of GP Practice**

- Notify NHS Cumbria of the level of service agreement they are to provide
- Ensure NHS Cumbria Warfarin Management Guidelines are distributed and available
- To develop Practice Standard Operating Procedures or detailed policies, which are read and signed by all relevant staff and responsibilities of staff are clear and understood
- Ensuring appropriate training is undertaken by all staff involved in anticoagulation and evidence of this training is documented. All competencies must be satisfactory before undertaking the service
- Training on Computerised Decision Support Software (CDSS) is completed prior to implementation, if used
- The appropriate equipment for testing INR and vitamin K is available at the anticoagulation clinic/ GP surgery
- Training on Near Patient Test meters (NPT) must be undertaken before testing can commence
- Ensuring internal and external audit for the equipment used in anticoagulation is undertaken and results submitted to NHS Cumbria (for level 4 providers)
- Perform and record clinical audit
- Ensure a GP is available at all times when anticoagulation services are offered to patients by the practice
- Ensure reception staff are aware of the importance of patients attending within a specified period so that appointments are not unwittingly delayed without guidance from appropriate clinical staff
7 Responsibilities of the Patient’s GP

Overall responsibility for the care of the patients continues to reside with the registered GP who will be providing prescriptions for anticoagulation therapy, and includes:

• Ensuring that dose recommendations and recall are guided by approved written protocols (Appendix 1) or Computerised Decision Support Software (CDSS)
• Ensuring patients receive education regarding anticoagulant therapy (Appendix 3)
• Giving advice on duration and intensity of anticoagulation as guided by initiating clinician
• Being aware of the potential effects of additional therapy given to a patient on anticoagulants, and arranging earlier INR testing as required
• Acting promptly to patients with bleeding problems and/or INR > 8 or who are otherwise considered to be at risk of bleeding
• Dosing decisions should be made by health-care professionals (e.g. GP’s, registered Nurses or registered Pharmacists) who have undergone an approved course for practitioners undertaking anticoagulant monitoring in primary care and who are deemed competent under the NPSA competency framework
• Arranging admission to hospital if required
• Issuing warfarin prescriptions
• Ensuring that all patients receive appropriate monitoring, either with primary care anticoagulation service or in secondary care
• To stop anticoagulant when specified duration is complete
• On initiation of therapy the suitability of the patient is assessed to their ability to take warfarin safely (see risk assessment of patients for oral anticoagulation Appendix 2)
• Ensuring that patients who do not speak, read or write English or who have communication difficulties (including without limitation hearing, oral or learning impairments) are provided with appropriate assistance. A responsible person or carer should be identified who can assist patient with any dose alterations.

8 Responsibilities of Secondary Care

• Identify suitable patients for transfer in to primary care
• Able to provide urgent medical advice relating to anticoagulation
• To accept patients who are maybe not suitable for anticoagulation monitoring in primary care (examples listed in section 9.4)
• Ensuring transferring of care from secondary to primary care is seamless in terms of patients anticoagulant therapy
• To provide INR testing from venous samples
9  **Target population**

9.1 Patients who are currently on warfarin therapy in the primary care.

9.2 Patients currently in secondary care anticoagulant clinics who are ‘stable’ (i.e., had INR readings within target range for 4 consecutive readings and considered appropriate for transfer).

9.3 Patients who need slow loading with anticoagulant.

9.4 Complex high risk patients will continued to be monitored in secondary care
Including:
- A known hereditary or acquired bleeding disorder
- Patients with alcohol dependence due to instability in anticoagulation management
- Severe malnourishment due to absorption difficulties
- Mentally ill with no carer support in the community
- Dementia with no carer support in the community
- Liver failure
- Severe renal impairment
- Documented evidence of CNS haemorrhage
- Severe heart failure
- Uncontrolled severe hypertension
- Gastric-intestinal bleeding in the last 6 months
- Pregnancy (Urgent referral to appropriate Haematologist Consultant)
- Those on chemotherapy for malignant tumours
- Children under 16 years
- Homozygous protein C deficiency (risk of skin necrosis)

10  **Secondary Care Referral process**

10.1 A formal referral to primary care must be made from secondary care using the agreed transfer process. The guidelines for the appropriate referral and transfer of patients from secondary care to primary care is given in Appendix 4, and details of the documentation (Appendix 5) needs to be received and completed for:
- Existing warfarin patients who are currently monitored by secondary care
- New warfarin patients initiated by secondary care
- Existing warfarin patients who are currently monitored in primary care who are admitted to and then discharged from secondary care

10.2 Following written agreement from the primary care provider to take responsibility for anticoagulation of an individual patient, a clinic appointment in primary care must be made.

10.3 Patients unable to be seen in primary care before their next hospital-booked clinic appointment will remain with their current arrangement until an appointment can be booked with the GP surgery.
10.4 At the first patient consultation, appropriate anticoagulation documentation (see section 15) should be completed.

11 Actions for those patients excluded from primary care management

11.1 Patients who are not eligible for treatment under an approved primary care anticoagulation service will remain under their present anticoagulation care management system.

11.2 If patients fail to attend their secondary care monitoring appointments then secondary care will contact the patient’s registered GP to discuss further. Consideration may need to be made as to the patient’s suitability to continue with anticoagulant therapy.

12 Primary Care - Clinic Organisation

12.1 All patients will be seen in person either in a clinic, at a GP’s surgery or at home by a Health Professional who has undergone training approved by NHS Cumbria as detailed in section 21.

12.2 Each individual GP practice will organise their own clinics. If there are only a few patients at one practice, monitoring and dosing may be organised at another GP practice.

12.3 It is recommended to test patients INR in the mornings to allow adequate time to obtain a venous sample and to organise treatment if required for patients with a high INR. (see Appendix 8 and 9).

12.4 Each practice will need to ensure adequate cover is arranged to cover illness and holidays by suitably trained personnel.

13 Call and Recall Procedures

13.1 A systematic call and recall system should be in place, and the provider should implement appropriate strategies to ensure non-attendees are identified and monitored.

13.2 If a patient fails to attend a clinic, or is not at home (for a domiciliary visit), the provider will schedule a new appointment within one week – the timing of the next appointment will be by agreement, taking into account clinical criteria.

13.3 If the patient again fails to attend, the patient should again be offered a further appointment unless there is information to suggest this is not necessary. The registered GP may decide that continuation of therapy in the absence of monitoring is considered too risky. The patient's registered GP will then be responsible for ensuring that no further prescriptions are raised.
14 Clinical Management

Individual Management Plan

14.1 The patients registered GP in conjunction with the patient should prepare an individual management plan. The plan should outline, as a minimum, the diagnosis, planned duration of treatment and therapeutic range to be achieved.

Clinical Procedures

14.2 All clinical information is recorded in the patient’s own GP held lifelong record, including completion of the "significant problem" record indicating that the patient is on warfarin and the indication for anticoagulation. At initial diagnosis and on an annual basis, a comprehensive review of the patient’s health needs to be undertaken to include the identification of potential complications. Additionally, regular review of the patient’s own monitoring records should be undertaken.

Education of Newly Diagnosed Patients

14.3 All new patients prescribed warfarin must have a counselling checklist (Appendix 3) completed to ensure the patient has received all the appropriate information required. At the first appointment following transfer from secondary care, education should be reinforced (according to a Counselling Checklist - Appendix 3). The counselling should be comprehensive to ensure that patients are fully aware of their treatment and should include:

a. The name of the drug and current dose,
b. The reason they are taking the drug,
c. Therapeutic goal,
d. The anticipated length of treatment,
e. What to do in the event of a missed dose,
f. Symptoms of under/over anticoagulation and action to take if these occur,
g. Drug/drug and drug/food interactions,
h. Clinic arrangements and how to obtain further medicine supplies,
i. What to do if dental treatment/surgery is required,
j. What to do if a surgical procedure is required/indicated,
k. Who to contact regarding any worries or concerns relating to their anticoagulation management.

14.4 Check the patient has received a yellow Anticoagulant pack. This contains a yellow record booklet which they need to show to their GP/health practitioner whenever they seek medical or dental treatment or purchase medicines from a Pharmacy. Patients should be encouraged to carry their yellow credit card style information card with them at all times. It should be ensured that all newly diagnosed patients (and/or their carers and support staff when appropriate) receive appropriate management of, and prevention of, secondary complications of their condition, including the provision of a handheld anticoagulation booklet.
Supplies of the yellow warfarin booklet are available from:
North Cumbria: Lynzie Myers, Rosehill, Carlisle.
Order by fax 01228 603612 or email pct-stores@cumbriapct.nhs.uk
South Cumbria: Contractor Distribution, LASCA Tel 01772 221308
Order by usual general stationary order form or via website (free of charge)

14.5 The patient needs to present their yellow booklet to the Pharmacist when collecting their prescription of anticoagulant. The patient may be given a print out of their results and new doses from the Computer Decision Support Software (CDSS). The patient needs to take their yellow booklet or the CDSS printout with them before the prescription can be dispensed by the Pharmacy. Their prescription cannot be dispensed without proof their INR is being monitored and in the range (NPSA safety alert).

15 **Documentation**

Patient Register and Patient Records

15.1 The following records will be kept by the patients registered GP:

- Patient Name
- Patient Date of Birth
- NHS number
- Indication for treatment
- Length of treatment
- Target INR
- Named medical practitioner initiating treatment
- Discontinuation date
- INR results, dosage instructions and review dates
- Missed days (i.e. a record of days when the patient has not taken their anticoagulant therapy in accordance with dosing instructions)
- Concurrent medication
- Medical conditions, hospital admissions likely to affect anticoagulation such as an increased risk of haemorrhage (BCSH Guidelines 1998)
- Bleeding episodes
- Any actions taken, as well as dosing and retest dates e.g. education, advice, whether the INR result is from near patient testing or central lab testing
- Occasions when the patient failed to attend an agreed clinic appointment
- Contact details for patient or for carers responsible for the administration of warfarin

15.2 The patient’s yellow warfarin booklet must be updated at each visit. If this booklet is not available, a temporary record booklet must be completed and given to the patient. A printout from CDSS is also acceptable, which must be kept with previous printouts to form the patient’s hand-held records.

15.3 The front of the yellow warfarin booklet must be completed i.e. indication, INR target range and duration of treatment, person with clinical responsibility, and emergency
contact number. The patients registered GP will contact the initiating hospital if any of these details are omitted.

15.4 For new patients who need to be initiated on warfarin, a risk assessment needs to be completed (see Appendix 2) and a counselling checklist needs to be completed (see Appendix 3)

**Clinic Attendance**

15.5 It is essential all warfarin patients keep their clinic appointments.

15.6 Non-attendees should be identified immediately. The patient should be given and informed of new appointment within one week (see section 13).

16 **Warfarin Supply**

16.1 Different people require different doses of warfarin. Some pre-existing conditions may make patients more or less sensitive to warfarin. Drugs, herbal remedies and diet also have the potential to interact dangerously with anticoagulants, and an indicative list of possible interactions is given at Appendix 6.

16.2 Patients will be encouraged to take their warfarin daily and at a regular time, usually 6pm.

16.3 Warfarin will be supplied from the patient’s registered GP via a prescription. Wherever possible the patient should not be provided with more than two strengths of warfarin. Tablets should be routinely supplied in 1mg and 3mg strengths to ensure a consistent approach across primary and secondary care and minimize the risk of confusion. In exceptional circumstances e.g. high warfarin sensitivity or high dosage requirements, warfarin may be prescribed in 0.5mg or 5mg strengths. In these instances the prescription must indicate the strength prescribed in both numbers and words (“half mg” or “five mg”) to ensure that the correct tablet is given. The patient should be supplied with the least number of different strengths of tablets possible.

16.4 The table below shows the strength and colour of the different warfarin tablets available.

<table>
<thead>
<tr>
<th>Strength</th>
<th>Colour</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.5 mg</td>
<td>White</td>
</tr>
<tr>
<td>1 mg</td>
<td>Brown</td>
</tr>
<tr>
<td>3 mg</td>
<td>Blue</td>
</tr>
<tr>
<td>5 mg</td>
<td>Pink</td>
</tr>
</tbody>
</table>

16.5 Specific dosing instructions will not normally appear on the dispensing label. All dosing instructions will be given verbally as well as written in the patient's yellow warfarin booklet or on a computerised dosing sheet.
17 **INR Testing**

17.1 Each time that a patient attends to have their INR tested, the practitioner should obtain the following information:

- Has the patient experienced any signs of bleeding or bruising?
- Is the patient planning any dental or other surgery?
- Has the patient followed their advised dosage instructions?
- Has there been a change in the patient’s other medications or dietary habits since their last test?

17.2 If the practitioner undertaking the blood test is not giving the dosing instructions, then any relevant information obtained from the patient should be passed on to the relevant clinician to inform their dosing decision.

17.3 Those practices undertaking a level 4 anticoagulation service will be using their own testing equipment to obtain an INR result.

17.4 It is recommended to test patient’s INR in the morning so if subsequent samples are needed, there is sufficient time to obtain results before the end of the day.

### Near Patient Testing and High INR Results

17.5 If the INR result is greater than 4.5, then repeat the patients INR using a new finger stick test using near patient testing device (NPT e.g. CoaguChek XS plus®)

17.6 If the second result is within 0.5 of the original result then accept the result and proceed. If the second test is more than 0.5 different from the first then disregard the results. Send a venous sample to the central laboratory and perform Internal Quality Control on NPT device (see section 23).

17.7 The device will NOT record a specific measurement when an INR > 8.0. For any INR results above 8 repeat the test. If the second result confirms the first then send a venous sample to the central laboratory for testing. This is to obtain a specific INR measurement.

17.8 If a "test error" message is obtained, the NPT device will not provide a reading. Repeat the test and if a second "test error" message is obtained, a venous sample should be sent to the central laboratory for testing.

17.9 If a laboratory sample is required because of a high INR and there is no blood collection from the provider’s base within 4 hours, arrangements for a venous sample need to be made depending on locality. Full patient contact details, including alternative telephone numbers, must be on the form in case of urgent need for out of hours providers to contact the patient.

17.10 If an unexpected result occurs (higher or lower than expected from the patient’s past history e.g. difference of > 50% of previous result where there is no good reason found), repeat the INR test.

17.11 If the patient has significant anaemia or polycythaemia, this may lead to unreliable results and the device should not be used.
17.12 If INR > 4.5 **ACTION MUST BEEN TAKEN IMMEDIATELY.**
Follow Guidelines of Treatment of Over-Anticoagulation as in appendix 9 and 10.

### 18 Dose adjustment of oral anticoagulants

18.1 The anticoagulant dose should be adjusted by the practitioner, with reference to the patient’s INR and any other changes that may be identified during the appointment (see 17.1 above).

18.2 Dosage of oral anticoagulants should be **guided** by using Computerised Decision Support Software (CDSS) or by approved clinical guidelines (example is Appendix 1).

18.3 Dosing should not be increased by more than 5-20% weekly dose.

18.4 There is no maximum dose of warfarin but most patients require 2mg to 10mg per day. A small proportion of patients (5%) are warfarin resistant and so will need higher than expected doses (e.g., over 15mg per day). It is important to determine if this could be due to noncompliance or diet rather than the genetic cause.

**Computerised Decision Support Software (CDSS):**

18.5 The INR result should be inputted into the CDSS that uses a validated equation for calculation of the recommended dose and date for review.

18.6 The recommended dose and review date should be accepted or overridden depending on whether they are acceptable taking into account all patient factors.

18.7 The clinician can alter dosage and / or reset review dates if clinically appropriate.

**Frequency of INR Monitoring**

18.8 The length of time between INR test dates varies, the maximum recommended length of time allowed between INR tests is 12 weeks (BCSH Guidelines 1998). For those with mechanical heart valves, the maximum recommended length of time is 8 weeks. The length of time between INR tests will depend on the patient’s INR measurement stability and untoward occurrences likely to cause instability. [http://www.cks.nhs.uk/knowledgeplus/test_of_the_week/anticoagulant_monitoring/warfarin_monitoring](http://www.cks.nhs.uk/knowledgeplus/test_of_the_week/anticoagulant_monitoring/warfarin_monitoring)

18.9 There are shorter periods recommended between INR tests elsewhere in the world. In USA it is 4 weeks and in New Zealand it is 8 weeks.

**Communicating Dose Changes**

18.10 The provider will need to update the yellow warfarin booklet giving dosage instructions to include:
- details of dose,
- frequency,
- colour and number of tablets,
- e.g. 7mg once a day (2 x 3mg – blue tablets and 1 x 1mg – brown tablets).
A printout of new doses from CDSS will be acceptable to give to the patient, but these need to be kept to form the patient’s hand held records, in accordance with the NPSA alert.

18.11 Date of the next INR test and contact numbers for advice should be recorded.

18.12 If dosing decisions are not given to a patient in an appointment, then appropriate arrangements should be made to ensure that results, dosage instructions and the next review date are given to the patient.

18.13 If results are given over the phone, then practices should ensure that a named person is responsible for this. Verbal instructions should be followed up by a posted written instruction. Where practices identify patients for whom it is not appropriate to give results over the phone, then alternative arrangements should be made to ensure that information is received in a timely manner by the patient. Practices are strongly recommended to develop a protocol for this.

18.14 Particular care should be taken when communicating dose changes to patients in social care settings (e.g. nursing or residential care homes). The nurse in charge should be informed of the warfarin dose and next review date over the phone. This information should be confirmed in writing by fax or by post as appropriate. Practices are strongly recommended to develop a protocol for this.

18.15 Particular care should be taken when communicating dose changes to patients using Monitored Dosage Systems (e.g. NOMADs). Both the patient and the Pharmacist filling the monitored dosage system should be informed of the warfarin dose and next review date. The information will be confirmed in writing to the patient and the Pharmacist.

It is recommended that a risk assessment is done on patients on MDSS and warfarin. It may not be the most appropriate method of helping with medicine compliance.

19 Initiating therapy

19.1 A GP may choose, or be asked, to initiate warfarin for suitable patients who require non-urgent anticoagulation e.g. in atrial fibrillation. Warfarin should be initiated according to the warfarin slow start guidelines (Appendix 7).

19.2 At the first appointment to initiate warfarin, it is essential that the provider must ensure that the patient is given all the relevant information and education verbally and in writing – (see section 14.3 onwards). The provider should also complete the relevant sections of the yellow hand-held warfarin book and issue this to the patient.

20 Discontinuation

20.1 The maximum duration of overall treatment will be documented on the initial referral form and in the patient’s yellow warfarin booklet.
20.2 Oral anticoagulants will be discontinued completely on a defined date as specified by the registered GP.

20.3 The patient or carer will be informed in clinic or domiciliary visit and followed up by letter to confirm this.

20.4 Consideration may need to be given to the early discontinuation of therapy in situations where the risks outweigh the benefits of continued treatment, e.g. patients not attending regular monitoring, those unable to follow the dosing regime.

21 Training

21.1 Each GP surgery must ensure that all staff involved in providing any aspect of care under the scheme has the necessary training and skills to do so.

21.2 Before a non-GP practitioner (e.g. Practice Nurse, Practice or Community Pharmacist) can provide an anticoagulation service, he/she must demonstrate suitable qualification and experience to comply with the specification and must have completed an approved course for practitioners undertaking anticoagulant monitoring in primary care – see Appendix 12.

21.3 GPs who have previously provided an anticoagulation service similar to this enhanced service shall be deemed professionally qualified to do so. However, it is strongly recommended that GPs attend one or more days on an approved course to update their skills and knowledge as required.

21.4 For any healthcare professional involved in warfarin dosing and prescribing, the minimum requirement is to complete and pass the two BMJ e-learning modules on anticoagulation.

21.5 The key competencies that must be demonstrated are as follows:

- Obtaining adequate blood samples
- Determination of INR results
- Compliance with established clinical management protocol for action of INR results by use of computerised decision support software and/or approved clinical guidelines
- Understanding of range of problems likely to be encountered in interpreting INR results
- Giving dosage instructions
- Recognition of instances where it is necessary to seek further advice
- The giving of information and advice to patients

In addition, those using near patient testing equipment must be able to operate the analyser and determine / interpret INR and quality control results.

21.6 All external and in-house training undertaken by the GP surgery staff must be recorded and sent with the annual audit (see Appendix 11 for training log).
21.7 The following 2 educational resources are mandatory and certificates will need to be sent in with the training log for the annual audit (see Appendix 11): www.bmjlearning.com

“Starting patients on anticoagulants: how to do it”

“Maintaining patients on anticoagulants: how to do it” for GPs, practice nurses and other healthcare professionals.

22 Reporting near misses, incidents and serious untoward incidents

22.1 It is a condition of participation in the service that providers will report all significant and serious untoward incidents to NHS Cumbria which relate to anticoagulation.

22.2 A reporting form should be completed and faxed to the Risk Management Department of NHS Cumbria Partnership within the following timescales:

- Near misses and incidents – 72 hours
- Serious untoward incidents – 24 hours

22.3 Serious untoward incidents would include patients that required hospital admission or have died as a result of mismanagement of the patient. Significant event analysis (SEA) should be conducted with all relevant persons involved, and a report with actions sent to Risk Management, NHS Cumbria Partnership.

22.4 Support with the investigation and SEA is available from NHS Cumbria in accordance with the Serious Incident Policy.

22.5 The reporting form (Lilac Form) can be obtained from NHS Cumbria and is available to download at: http://www.intranet.cumbria.nhs.uk/RiskManagement/LilacForm.pdf

22.6 All documentation should be returned to: Laura Holmes, Provider Governance Dept, NHS Cumbria Partnership, Tenterfield, Brigsteer Road, Kendal LA9 5EA.

23 Quality Assurance

General

23.1 Quality must be assured across all aspects of the service including INR testing, dosage advice, record keeping, documentation (patient and quality control records), patient education and patient satisfaction.

23.2 The GP surgery must complete all relevant documentation pertinent to providing the service and record any action taken which is outside the service protocol.
Internal Quality Control (IQC) of Near Patient Testing (NPT)

23.3 Those GP surgeries using near patient testing must perform internal quality control procedures as per the manufacturer’s instructions. These are used to establish whether the particular technique is performing consistently over a period of time, to ensure day-to-day consistency. Many manufacturers of Near Patient Testing (NPT) monitors and test strips for INR determination have control materials or electronic devices available for the purpose of IQC.

Frequency of IQC tests

23.4 Performing IQC will vary from GP practice to GP practice depending on the level usage of the meter. As a minimum requirement for every GP practice, an IQC needs to be performed at the beginning of every month. However this may need to be more frequent if there are a large number of INR tests. If a new test strip box is started that has a different lot number from the previous batch, an IQC needs to be performed.

23.5 IQC tests are usually supplied in a box of four vials; each batch number has a different INR range.

23.6 IQC results should be within a range of 1.0 INR units (not the wider range quoted by the manufacturer) for one particular batch of test strips; i.e. within ±0.5 INR of the mean of the first 5 IQC results.

23.7 IQC results should be recorded with the batch number of IQC, and test strips and the identity of the operator.

23.8 If IQC is out of limits patient testing should be suspended with that device/test strip batch. The manufacturer should be contacted if there are concerns about the accuracy of the device.

23.9 All IQC results, together with the batch/lot number of test strips employed at each clinic/surgery should be recorded to create an audit trail. These details will be required as part of the annual audit return to NHS Cumbria.

External Quality Control (EQC) of Near Patient Test (NPT)

23.10 Those GP surgeries using near patient testing equipment will be required to join an External Quality Assurance Scheme (e.g., UK NEQAS). Further information is given at Appendix 10.

23.11 External Quality Control (EQC) is used to identify the degree of agreement between one centre’s results and those obtained by other centres. External QA is available through the UK National External Quality Assessment Scheme (UK NEQAS) for blood coagulation and is essential in ensure the INR recordings from the meter are accurate and reliable.

Cleaning Procedure
23.12 The Near Patient Testing device should be cleaned and maintained as per the manufacturer's guidance.

Managing Clinical Performance of Computer Decision Software System (CDSS)

23.13 For INR star CDSS, please register for their point prevalence feedback service. Point prevalence is a way of performing Internal Quality Control on the warfarin dosing. There is a feedback service which compares different practices results every quarter. This is the External Quality Control on the warfarin dosing recommendations given by the CDSS. [http://www.inrstar.co.uk/managing_clinical_performance/point_prevalence_feedback](http://www.inrstar.co.uk/managing_clinical_performance/point_prevalence_feedback)

### 24 Review of Care Pathway

24.1 It is strongly recommend that in each GP practice there is a nominated Anticoagulation Lead who understands the whole care pathway and reviews this periodically to identify potential problems. In particular, they should ensure:

- There is a system for identifying all INR tests, which includes patients seen on home visits (this must not rely only on the phlebotomist)
- There is a failsafe system which ensures all results are received and appropriately action taken
- The respective responsibilities of those in the pathway are clearly defined
- Patients are aware of how they will be informed of their INR result, dosing instructions and recall date
- Patients with specific needs are identified and appropriately managed, i.e. where the patient has no phone; there are communication problems; patients in social care settings; patients using Monitored Dosage Systems (e.g. NOMADs) etc.

24.2 Key areas of risk are:

- Communications with the hospital over results, because of delays in collecting samples and breakdown of the pathology messaging system
- Induction of new administrative staff to anticoagulation arrangements
- Communication with patients

### 25 Audit

25.1 All providers will participate in an annual audit that will be based on the safety indicators identified by the National Patient Safety Agency (NPSA) and the criteria listed in the PCT Local Enhanced Service document. The audit results will inform
what local actions are needed to improve the safe use of anticoagulants, and will also be used as part of the performance management process of NHS Cumbria.

25.2 An audit template will be issued at the financial year end to cover the financial year of the period of the service agreement.
Appendix 1 - Warfarin prescribing guidelines

1 General Guidance

1.1 These guidelines are to guide the prescribing of warfarin where no computer software is available or where advice is sought in conjunction with CDSS. The patient should also have received advice and written information on anticoagulant therapy, normally in the form of a yellow anticoagulant booklet. A risk assessment and counselling checklist should have been completed for each patient initiated on warfarin.

2 Background

2.1 The present indications for warfarin, together with the presently agreed degree of anticoagulation for that indication are shown in Table 1:

<table>
<thead>
<tr>
<th>Table 1: Indication and target INR’s</th>
<th>Target (+/- 0.5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of venous thrombosis [DVT]</td>
<td>2.5</td>
</tr>
<tr>
<td>Treatment of pulmonary embolism [PE]</td>
<td>2.5</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2.5</td>
</tr>
<tr>
<td>Valvular heart disease</td>
<td>2.5</td>
</tr>
<tr>
<td>Tissue heart valves</td>
<td>2.5</td>
</tr>
<tr>
<td>Transient ischaemic attacks</td>
<td>2.5</td>
</tr>
<tr>
<td>Myocardial infarction: prevention of venous thromboembolism</td>
<td>2.5</td>
</tr>
<tr>
<td>Recurrent deep vein thrombosis and pulmonary embolism</td>
<td>3.5</td>
</tr>
<tr>
<td>Intravascular stent</td>
<td>2.5</td>
</tr>
<tr>
<td>Mechanical prosthetic valves – all patients will be discharged from the cardio-thoracic unit with a recommended target INR range (see BSCH guidelines)</td>
<td></td>
</tr>
</tbody>
</table>

3 Dosage Regimens

3.1 Individuals have different dosage requirements of warfarin. The response in individuals cannot be predicted. This is partly due to the patient’s different metabolism of warfarin and partly due to other factors such as disease states and interacting drugs.

3.2 The average dose of warfarin required daily is around 5 mg [range 1-9 mg] but may vary markedly because of several factors. Warfarin should be given once daily [5-6 pm is an ideal time] and is given as a tablet for oral administration.

4 Duration of therapy

4.1 After a single episode of venous thromboembolism, 3 or 6 months of warfarin therapy is necessary depending on the thrombus position. The duration of therapy needed after a second episode of DVT or PE is uncertain but long-term anticoagulation is normally advocated.
4.2 For patients with atrial fibrillation and heart valves, the duration is as long as the condition is present. In most cases this is long-term. Often it is a change in a patient's condition (e.g. becomes confused) that requires the cessation of therapy.

5 Frequency of INR Monitoring

For patients in whom no new factor has arisen, the frequency of monitoring can be guided by the criteria shown in Table 2 or by the use of CDSS.

Table 2: Warfarin therapy: maximum recommended recall periods during maintenance therapy (not initiation)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recall Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>One INR high</td>
<td>Recall in 7 to 14 days (stop treatment for 1 to 3 days) (maximum 1 week in prosthetic valve patients)</td>
</tr>
<tr>
<td>One INR low:</td>
<td>Recall in 7 to 14 days</td>
</tr>
<tr>
<td>One INR therapeutic:</td>
<td>Recall in 1 to 2 weeks</td>
</tr>
<tr>
<td>Two INRs therapeutic</td>
<td>Recall in 2 to 3 weeks</td>
</tr>
<tr>
<td>Three INRs therapeutic</td>
<td>Recall in 3 to 4 weeks</td>
</tr>
<tr>
<td>Four INRs therapeutic</td>
<td>Recall in 4 to 5 weeks</td>
</tr>
<tr>
<td>Five INRs therapeutic</td>
<td>Recall in 6 to 8 weeks (maximum of 8 weeks for prosthetic valve patients)</td>
</tr>
<tr>
<td>More than 5 INRs therapeutic</td>
<td>Recall period can be increased in a step-wise fashion to a maximum of 12 weeks between appointments if stable.</td>
</tr>
</tbody>
</table>

NB Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks. (Based on data from Ryan et al [1989] British Medical Journal 299, 1207-1209)

6 Factors affecting Warfarin Dosing

6.1 When a condition known to cause alteration in the dose requirement of warfarin occurs (e.g. a potentially interacting drug), or the patient has an acute concurrent illness, frequency of monitoring should be increased and dose of warfarin may need to be changed.

6.2 The following conditions cause warfarin sensitivity [i.e. need for reduced dose]:
   i. Liver dysfunction
   ii. Heart failure
   iii. Hyperthyroidism
   iv. Some drugs (Indicative list is provided in appendix 6)
   v. Acute pyrexial episode

6.3 Some conditions cause warfarin requirements to be increased [i.e. need for greater than normal dose]:
   i. Hypothyroidism
   ii. Vitamin K containing remedies, e.g. some herbal remedies and enteral feeds
   iii. Some drugs (Indicative list is provided in appendix 6)
7 Warfarin Dose Adjustments

7.1 It is recommended that computer dosing decision software be used for dosing. If dosing is performed manually, and a dose adjustment is required, then it will be based on: Adjustments to patient’s weekly dose should be +/- 10% of total weekly dose.

7.2 If INR is low, boosting (“one off”) doses should be approximately 50% greater than the patient’s regular maintenance dose e.g. if daily dose is 6mg, boosting dose should be 9mg. Again, consideration should be given to patient’s previous pattern of response.

8 Suggested Dose Adjustments Regimens

8.1 Sub-therapeutic INR

Table 3: For lower therapeutic range (target INR 2.5):

<table>
<thead>
<tr>
<th>INR</th>
<th>Dose adjustment</th>
<th>Next Appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>1.8 - 1.9</td>
<td>Increase dose if consistently low, 2-4 weeks</td>
</tr>
<tr>
<td>Moderate</td>
<td>1.6 - 1.8</td>
<td>Increase dose, 1-2 weeks</td>
</tr>
<tr>
<td>Significant</td>
<td>&lt; 1.6</td>
<td>Consider boosting dose(s), and increase dose, Within 1 week</td>
</tr>
</tbody>
</table>

If VTE patient and two or more INR results < 1.6 consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range.

Table 4: For upper therapeutic range (target INR 3.5):

<table>
<thead>
<tr>
<th>INR</th>
<th>Dose adjustment</th>
<th>Next Appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>2.8- 2.9</td>
<td>Continue as before, 2-3 weeks</td>
</tr>
<tr>
<td>Moderate</td>
<td>2.0 - 2.7</td>
<td>Consider boosting dose + increase dose, 2-4 weeks</td>
</tr>
<tr>
<td>Severe</td>
<td>&lt; 2.0</td>
<td>Consider boosting doses + increase dose†, 1 weeks</td>
</tr>
</tbody>
</table>

If INR low due to reversible reason (e.g., missed warfarin), it may be reasonable to administer a stat dose, but not alter the maintenance dose.

†Patients’ with prosthetic valves in the mitral position, or a history of previous systemic emboli may require heparin therapy until warfarin becomes effective.

††Those with recurrent VTE or Protein C/S deficiency and two or more INR results < 1.6 consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range.
### 8.2 Over-anticoagulated

#### Table 5: For lower therapeutic range (target INR 2.5):

<table>
<thead>
<tr>
<th>INR</th>
<th>Dose adjustment</th>
<th>Next Appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>3.0 - 3.2 Decrease dose if consistently high.</td>
<td>4-6 weeks</td>
</tr>
<tr>
<td>Moderate</td>
<td>3.4 - 3.9 Decrease dose.</td>
<td>1-2 weeks</td>
</tr>
<tr>
<td>Significant</td>
<td>4.0 - 4.9 Omit dose for 1 day, decrease dose.</td>
<td>max. 1 week</td>
</tr>
<tr>
<td>Severe</td>
<td>5.0 - 5.9 Omit doses for 2 days, decrease dose</td>
<td>max. 1 week</td>
</tr>
<tr>
<td>Very Severe</td>
<td>6.0 - 8.0 Stop warfarin. Restart</td>
<td>Next day</td>
</tr>
</tbody>
</table>

#### Table 6: For upper therapeutic range (target INR 3.5):

<table>
<thead>
<tr>
<th>INR</th>
<th>Dose adjustment</th>
<th>Next Appointment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slight</td>
<td>4.0 - 4.9 Decrease dose if consistently high.</td>
<td>2-3 weeks</td>
</tr>
<tr>
<td>Moderate</td>
<td>5.0 - 5.9 Omit dose for 1 day + reduce dose.</td>
<td>1 week</td>
</tr>
<tr>
<td>Significant</td>
<td>6.0 - 6.9 Omit for 1-2 days and reduce dose.</td>
<td>1 week</td>
</tr>
<tr>
<td>Severe</td>
<td>7.0 - 8.0 Stop warfarin. Restart when INR &lt;5.0. Consider Vitamin K (see appendix 8&amp;9)</td>
<td>Next day</td>
</tr>
</tbody>
</table>

Evidence of bleeding may require a change in this schedule, or referral to the responsible physician, at any INR. Consideration should be given to correction of the INR in ‘high risk’ patients whose risk of bleeding is higher (see below).

| * Alert physician responsible for anticoagulant control. |
| If high INR occurs on a Friday or weekend it is the responsibility of the prescribing GP to ensure the next INR is done and that the results are acted on. |

**High risk patients:** Age>70; hypertension; diabetes; renal failure; previous myocardial infarction, stroke or gastrointestinal bleed.
**Appendix 2 - Risk Assessment for Anticoagulation**

The following points must be considered prior to initiating anticoagulation therapy. These points are for guidance only and ticking "yes" in any section is not necessarily an absolute contraindication to anticoagulation, but should help you balance the risks. The decision to anticoagulate or to continue anticoagulation is the responsibility of the prescriber.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Action/ Date</th>
<th>Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the patient &gt;75 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient have a history of uncontrolled hypertension (systolic &gt;180 and diastolic &gt;100mmHg)?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of alcohol excess?</td>
<td></td>
<td></td>
<td>Consider aspirin</td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of liver disease? Are the LFT's abnormal?</td>
<td></td>
<td></td>
<td>Contraindicated</td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of active bleeding lesions?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient have any bleeding tendencies, including coagulation defects and thrombocytopenia?</td>
<td></td>
<td></td>
<td>Discuss with Consultant Haematologist</td>
<td></td>
</tr>
<tr>
<td>Is the patient taking antiplatelet drugs?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a commitment to use non-steroidal anti-inflammatory drugs and antibiotics?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the patient being investigated for, or receiving treatment for cancer?</td>
<td></td>
<td></td>
<td>Use LMWH not warfarin</td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of previous trips or falls?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the patient have poor literacy skills?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>If the patient has previously been on anticoagulant therapy, is there any evidence of non-compliance or instability of INR control?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there any evidence of Alzheimer's or other dementia?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision to anticoagulate</td>
<td>Yes</td>
<td>No</td>
<td>Indication</td>
<td></td>
</tr>
<tr>
<td>Target INR range</td>
<td>2-3</td>
<td>2.5-3.5</td>
<td>other_________</td>
<td>Anticipated duration</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>_________months/ Lifelong</td>
<td></td>
</tr>
<tr>
<td>Name / designation</td>
<td></td>
<td></td>
<td>Sign/ date</td>
<td></td>
</tr>
</tbody>
</table>

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### Appendix 3 - Counselling Checklist

This patient has been counselled on the following areas of warfarin therapy, by a Doctor, Pharmacist or other appropriately trained Health Care Professional in accordance with the guidance overleaf.

<table>
<thead>
<tr>
<th>Counselling point</th>
<th>Signature</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Use of the Anticoagulant Therapy Record (yellow book) and alert card</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Standard dispensing labels (<em>i.e. take strictly as directed by the anticoagulant clinic</em>)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Basic mode of action of warfarin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Indication for therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Expected duration of therapy</td>
<td></td>
<td>Specify duration if known ………………</td>
</tr>
<tr>
<td>6. Tablet identification – colour of the different tablet strengths</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Dose:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varied dosing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of day to take warfarin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How to use the different tablet strengths to make up the dose</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action to take if dose missed; NOT to take extra doses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Compliance and ways of remembering to take the tablets e.g. using a calendar</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Monitoring:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target INR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Where to go for monitoring (and importance of attendance)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10 Side effects of warfarin and poor control of anticoagulation (and what to do if experienced)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signs /symptoms of excess anticoagulation: bleeding or bruising</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recurrence of thromboembolism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11 Potential for drug interactions: aspirin, ibuprofen (paracetamol is the preferred analgesic), antibiotics , herbal remedies etc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 Diet (vitamin K containing foods, importance of avoiding major fluctuations in dietary intake; cranberry juice interaction)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13 Alcohol intake</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 Contraception, pregnancy and hormone replacement therapy (if relevant)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15 Surgical procedures (inc. day surgery/dental treatment &amp; hospital admission)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 Acute illness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>17 Hobbies and leisure activities (including flying)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18 Injections (including immunisation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19 How to obtain further supplies of warfarin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Who to contact for advice/further information</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Counselling by: (Signature): ……………………………………………………

Print name and Designation…………………………………………………. Date………………
1&2. Use of the Anticoagulant Therapy Record (yellow book) and alert card. Show the patient the yellow book and go through it with them filling in the details on pages 1 & 2 if available. If unsure of any sections, check with the doctor. Explain that the anticoagulant therapy record is the only record of dosing information available for the patient, since (2) the dispensing labels on the warfarin boxes/bottles will be labelled as “Take strictly as directed by your doctor or anticoagulant clinic”. Therefore it is important to keep the record book up to date at all times and for the patient to understand the dosing instructions.

Go through the booklet with the patient, highlighting the information it contains and ensuring that the points below are covered.

3. Basic mode of action of warfarin – “reduces the bloods ability to form clots”

4. Indication for therapy – explain why the patient is taking warfarin. Common examples (list not exhaustive) and patient explanations include:

- **DVT/PE** – “to prevent the clot getting bigger or returning

- **AF** – “when the heart is not beating regularly the blood will not flow smoothly. Therefore there is a risk of getting a clot which may travel through the body and cause damage e.g. a stroke”

- **Pre & post DC cardioversion for AF**

- **Heart valves** – “there is a risk of getting clots around the valve, which may float through the body and cause damage; also to prevent valve damage”

- **Some cancer patients who are receiving thalidomide in combination with chemotherapy and dexamethasone – “to reduce the risk of getting a clot which is sometimes associated with this group of patients”

5. Expected duration of therapy (if known) – if unsure, check with Doctor. Do not assume or guess.

- **DVT/PE** – may be a short course (3 – 6 months) or life long if recurrent

- **AF/heart valves** – treatment will be lifelong

- **DC cardioversion** – e.g. at least 4 weeks before and 4 weeks after, the latter depending on success of DC cardioversion (may be longer in practice – 8 weeks)

- **Cancer patient receiving thalidomide in combination with chemotherapy and dexamethasone** – until end of treatment

6. Tablet identification

- Explain colour of the different tablet strengths and that they will always be the same colour for each strength even if the supplier is different.

- White 500 micrograms/Brown 1mg tablets/Blue 3mg tablets/Pink 5mg tablets. It is unusual for patient to get all 4 strengths.

7. Dose

- Varied dosing according to blood result/INR

- Warfarin should be taken at same time of day, every day (which is often around teatime / (6-7pm)). If patient decides to take it in the morning, tell patient to inform hospital staff if (s)he is ever admitted to reduce the risk of getting a double dose (since many hospitals prescribe in-patient warfarin at 6pm).

- How to use the different tablet strengths to make up the dose intended

- If a dose is missed, OK to take on the same day within 6 hours of when dose was due. NEVER double up on a dose but carry on as normal on next day if dose is missed. Make a note of the date the dose was missed in the yellow book and let anticoagulant clinic/doctor know. If unsure then it is better to miss the dose rather than risk taking a double dose

8. Compliance and ways of remembering to take the tablets e.g. using a calendar to mark off whether a dose has been taken.

9. Monitoring

- INR is monitored regularly initially (daily/every few days) and gradually less often once dose and INR settles (monthly or up to 12 weekly)

- Outpatient monitoring clinics / GP practice (and importance of attendance)/ District Nurse

10 Side effects of warfarin and poor control of anticoagulation (and what to do if experienced)

- Recurrence of thromboembolism: contact GP if original symptoms recur

- Signs/symptoms of excess dosing: severe bleeding or multiple bruising with or without high INR is the most common side effect: contact doctor immediately if unusual or severe

- Contact GP if these occur: bloody stools or urine, nose bleeds (if lasting for >5mins or if pt does not usually suffer from nose bleeds), bloodshot eye, coughing or vomiting blood, excessive vaginal bleeding, cuts that take longer that 5 mins to stop bleeding

- Bleeding from gums (use a soft toothbrush)

- Any other side-effects: discuss with GP

11. Potential for drug interactions: may be affected by many medicines, therefore:

- Patient should always let doctor/dentist/pharmacist know that (s)he is on warfarin

- Not to take aspirin unless prescribed by doctor. Care with OTC painkillers (e.g., Ibuprofen/aspirin preparations). Paracetamol is preferred

- Caution with antibiotics and always check with pharmacist/anticoagulant clinic before taking herbal remedies

- Inform GP/anticoagulant clinic of any drugs stopped started or if doses are changed

12. Diet: some foods contain high levels of vitamin K which may interfere with warfarin action (e.g. broccoli, brussels sprouts, cauliflower, cabbage, chickpeas, kale, spinach, turnip greens, beef liver, pork liver + all pork products) Patient may have these foods in moderation but important to avoid major changes in regular diet or crash diets. Report any major changes in diet to anticoagulant clinic.

- Cranberry juice may raise INR – avoid or limit intake of cranberry juice whilst on warfarin.

13. Alcohol intake: check patient’s current alcohol intake and basic LFT’s/clotting. If patient a heavy drinker (known alcoholic, or drinks > recommended units/wk), discuss with Dr re plan for alcohol reduction and also warfarin implications/suitability. Ideally keep intake to a
Small to moderate amounts (e.g. 1 glass of wine/ half pint beer/lager per night or 2 – 3 x per week) should not affect warfarin control in otherwise healthy individuals with no liver problems. Avoid binge drinking.

14. Contraception, pregnancy and hormone replacement therapy (if relevant): this should be discussed in detail in the anticoagulant clinic according to separate guidance. Basic points: if patient is still on HRT/OCP then discuss with the clinician re: stopping/appropriate choice (generally avoid oestrogen-containing preparations – progesterone only ones are preferred). Check that there is no possibility of the patient being pregnant at the time of starting warfarin therapy and that she understands the importance of effective contraception. Pregnancy should be planned following discussion with anticoagulant clinic/GP. Urgently refer women who may be pregnant and are on warfarin.

15. Surgical Procedures (including dental treatment) and hospital admission: patient must inform Doctor/dentist that s/he is on warfarin

16. Inform treating Doctor (e.g. GP) of acute illness, as more regular INR check may become necessary

17. Hobbies and leisure activities (including flying): avoid contact sports (e.g. boxing) and other higher risk sports (e.g. skiing and horse riding), as increased risk of bruising/bleeding. Inform Dr/anticoagulant clinic if flying in the near future

18. Injections (including immunisations): patient must inform GP/practice nurse that s/he is on warfarin

19. Obtain further supplies of warfarin from your GP. Make sure never to run out of warfarin tablets, especially when on holidays

20 Further advice/ information GP surgery or patient information leaflets
Appendix 4 - Policy for the Appropriate Transfer of Patients from Secondary Care Clinics to Primary Care Clinics

1. Existing patients

1.1 The Anticoagulation Clinic in secondary care identifies suitable patients for transfer of care into primary care. The clinic faxes the transfer request form (Appendix 5) with the patient’s details to the patient’s registered GP.

1.2 On receipt of the transfer request form, the GP surgery will arrange a first appointment for INR monitoring.

1.3 When the primary care monitoring appointment has been arranged, the patient’s GP signs the bottom of the transfer request form and faxes this back to the secondary care anticoagulation clinic. The GP takes responsibility for the monitoring arrangements of that patient from the date that the transfer form is signed. At this point the patient will be deemed to have been discharged from secondary care.

1.4 If there is a time delay between the secondary care clinic first sending the referral form and the patient being accepted by the GP practice and the patient has attended secondary care for further monitoring, updated documentation on latest dosing and INR results must be sent to the primary care provider.

2. New patients

2.1 The secondary care anticoagulation clinic will transfer all patients as section 1.1-1.5 above.

2.2 The secondary care anticoagulation clinic may decide to request transfer in situations where the patient's INR is not stable, but where it would be beneficial for the patient to be monitored in primary care.

3. Existing Primary Care Anticoagulation patients - post discharge

3. Patients who were being managed by a primary care anticoagulation service prior to a hospital admission will be referred back to the primary care service post discharge.

3.2 The responsible professional in secondary care will fill in the Anticoagulation Transfer form (Appendix 5). This must be sent to the GP surgery.

3.3 An appointment must be made for the patient for their next INR check.

3.4 Prior to discharge, the patient must have details of their next INR check. However if the patient has left hospital before being given this, the ward staff will be responsible for contacting them about their next appointment.

3.5 Should discharge occur on a weekend, referral to the GP surgery will be made in line with 3.2 above. On Monday morning the GP surgery will arrange an appointment for the patient. If there is sufficient time before the appointment date, the ward will post out a copy of the referral form to the patient, otherwise the ward will contact the patient by phone to give them the appointment details.
Appendix 5 - Transfer of Care Anticoagulation Referral Form

ANTICOAGULATION REFERRAL FORM

Referrals will not be accepted unless this form is fully completed and accompanied by the current warfarin prescription chart.

Name of current anticoagulant: warfarin □ other □ please specify………………

Date anticoagulation started:

<table>
<thead>
<tr>
<th>✓</th>
<th>Tick as appropriate</th>
<th>Target</th>
<th>Duration</th>
<th>✓</th>
<th>Tick as appropriate</th>
<th>Target</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Calf DVT</td>
<td>2.5</td>
<td>12 weeks</td>
<td></td>
<td>AF</td>
<td>2.5</td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>Proximal DVT</td>
<td>2.5</td>
<td>26 weeks</td>
<td></td>
<td>TIA</td>
<td>2.5</td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>Recurrent DVT</td>
<td>2.5</td>
<td>long term</td>
<td></td>
<td>CVA</td>
<td>2.5</td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>Recurrent DVT whilst On warfarin</td>
<td>3.5</td>
<td>long term</td>
<td></td>
<td>Cardiomyopathy/ Mural thrombus</td>
<td>2.5</td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>PE</td>
<td>2.5</td>
<td>26 weeks</td>
<td></td>
<td>Mitral/aortic valve Disease</td>
<td>2.5</td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>Recurrent PE</td>
<td>2.5</td>
<td>long term</td>
<td></td>
<td>Tissue prosthetic heart valve</td>
<td>2.5</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Recurrent PE whilst On warfarin</td>
<td>3.5</td>
<td>long term</td>
<td></td>
<td>Mechanical Prosthetic heart valve</td>
<td></td>
<td>Long term</td>
</tr>
<tr>
<td></td>
<td>Prophylactic</td>
<td>2.5</td>
<td>long term</td>
<td></td>
<td>Other- please specify</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please specify if post – op Yes/ No

Current dose of anticoagulant:

Date and result of last INR:

Significant medical or surgical problems

Is the patient on any anti-platelet drugs? □ Yes Specify…………………….. □ No
If yes, are these to continue? □ Yes □ Stop when INR is in target range □ No

Other Medication:

Date Risk assessment completed
Date Counselling checklist completed
Next INR appt Made
Yellow book issued
Referring Persons Name and Signature

Signed : Name: Date

Please sign and return to …………………………..to confirm receipt and ongoing management of patient

I accept transfer of care for this patient. Signature

Name: Date
# Appendix 6 - Warfarin Drug Interactions

This guide is intended as a quick reference to highlight significant interactions between warfarin and commonly prescribed medicines or complimentary medicines. It is not intended to be exhaustive or give detailed information. Prescribers should refer to the SPC or the BNF for further information or contact NHS Cumbria Medicines Management Team for advice.

<table>
<thead>
<tr>
<th>Interacting Drug</th>
<th>Potential problem</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Fluctuations in prothrombin time in heavy drinkers or patients with liver disease.</td>
</tr>
<tr>
<td>Allopurinol</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Uncommon but unpredictable interaction – monitor INR more closely when allopurinol started.</td>
</tr>
<tr>
<td>Aminoglutethimide</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Effect appears to be related to dose of aminoglutethimide. May need up to four times the dose of warfarin.</td>
</tr>
<tr>
<td>Amiodarone</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>The onset of this interaction may be slow and may persist after amiodarone has been withdrawn.</td>
</tr>
<tr>
<td>Amitriptyline</td>
<td>Unpredictable increase or reduction in anticoagulant effect</td>
<td>Monitor INR closely. INR may be difficult to control in patients taking tricyclic antidepressants.</td>
</tr>
<tr>
<td>Anabolic Steroids (e.g. danazol, stanozolol)</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Interaction develops rapidly, possibly within 2 or 3 days.</td>
</tr>
<tr>
<td>Aspirin</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Avoid aspirin as an analgesic – use Paracetamol as a safer alternative. Low dose aspirin 75mg daily appears not to interact to any clinically relevant extent but may increase the risk of bleeding due to antiplatelet effect.</td>
</tr>
<tr>
<td>Azaproprazone</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Significant risk of bleeding. Concurrent use NOT recommended.</td>
</tr>
<tr>
<td>Azathioprine</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Warfarin dose may need to be increased when azathioprine started and reduced if azathioprine is stopped.</td>
</tr>
<tr>
<td>Barbiturates (e.g., Phenobarbital)</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>May require 30-60% increase in warfarin dose. The reduction in anticoagulant effects begins within a week, reaching a maximum after about 3 weeks and may still be evident up to 6 weeks after stopping the barbiturate.</td>
</tr>
<tr>
<td>Bezafibrate</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).</td>
</tr>
<tr>
<td>Interacting Drug</td>
<td>Potential problem</td>
<td>Comment</td>
</tr>
<tr>
<td>------------------</td>
<td>-------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Boldo</td>
<td>May increase anticoagulant effect of warfarin</td>
<td>Modest rise in INR seen in a patient taking Boldo and Fenugreek.</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Dose of warfarin may need to be increased (up to double dose). Oxcarbamazepine does not appear to interact.</td>
</tr>
<tr>
<td>Cefaclor</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Cefuroxime, cefalexin or cefradine are safer alternatives.</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Dose of warfarin may need to be increased (up to double dose). Oxcarbamazepine does not appear to interact.</td>
</tr>
<tr>
<td>Cimetidine</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Unpredictable but common interaction. Use ranitidine instead.</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>May increase the anticoagulant effect of warfarin</td>
<td>Rare and unpredictable interaction. Monitor INR. Use alternative antibiotic if possible.</td>
</tr>
<tr>
<td>Ciprofibrate</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).</td>
</tr>
<tr>
<td>Clarithromycin</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Marked increase in INR has been reported. If a macrolide is required, Azithromycin is a safer alternative.</td>
</tr>
<tr>
<td>Clofibrate</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>Mild bleeding can occur even though INRs remain stable and within range</td>
<td>Increased risk of bleeding due to antiplatelet effect. Manufacturer advises avoid concomitant use.</td>
</tr>
<tr>
<td>Colestyramine</td>
<td>Reduces anticoagulant effect of warfarin by preventing the absorption of warfarin.</td>
<td>Separating the dosages as much as possible may minimise the effects of this interaction.</td>
</tr>
<tr>
<td>Coenzyme Q10</td>
<td>Reduces anticoagulant effect</td>
<td>Monitor INR. Avoid use of products containing coenzyme Q10.</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Generally avoided in thromboembolic disorders.</td>
</tr>
<tr>
<td>Co-proxamol</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Uncommon and unpredictable. Use Paracetamol as a safer alternative.</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>Variable response</td>
<td>Low to moderate doses can increase or decrease the anticoagulant effect of warfarin. High doses have been reported to increase the anticoagulant effects. Monitor INR.</td>
</tr>
<tr>
<td>Interacting Drug</td>
<td>Potential problem</td>
<td>Comment</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cranberry Juice</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Avoid use in patients taking warfarin.</td>
</tr>
<tr>
<td>Cytotoxics</td>
<td>Increases anticoagulant effect of warfarin reported with some cytotoxics</td>
<td>Refer patients on concurrent cytotoxic agents to secondary care for management of anticoagulation.</td>
</tr>
<tr>
<td>Danshen</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Advise patients not to use Danshen whilst taking warfarin.</td>
</tr>
<tr>
<td>Devil’s Claw</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding disorders visible on the skin (purpura) have been reported.</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>Cases of bleeding reported with concomitant use.</td>
<td>Unpredictable – monitor INR &amp; adverse effects. Avoid if possible. Ibuprofen or Naproxen are less likely to interact with warfarin.</td>
</tr>
<tr>
<td>Diflunisal</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Unpredictable – monitor.</td>
</tr>
<tr>
<td>Dipyridamole</td>
<td>Mild bleeding sometimes occur even though INRs remain stable and within range.</td>
<td>Increased risk of bleeding due to antiplatelet effect.</td>
</tr>
<tr>
<td>Disulfiram</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Review concurrent use of warfarin in patients requiring Disulfiram.</td>
</tr>
<tr>
<td>Dong quai (Angelica sinensis)</td>
<td>Reports of marked increases anticoagulant effect of warfarin</td>
<td>Advise patients not to use Dong quai whilst taking warfarin. Increased bleeding time &amp; bruising.</td>
</tr>
<tr>
<td>Erythromycin</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Serious but unpredictable. The elderly are at greater risk. Monitor closely.</td>
</tr>
<tr>
<td>Esomeprazole</td>
<td></td>
<td>Monitor INR if adding or stopping esomeprazole.</td>
</tr>
<tr>
<td>Fenofibrate</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).</td>
</tr>
<tr>
<td>Feverfew</td>
<td>Altered bleeding time reported</td>
<td>Advise patients not to use Feverfew whilst taking warfarin. Monitor INR.</td>
</tr>
<tr>
<td>Fluconazole</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Monitor and reduce warfarin dose accordingly.</td>
</tr>
<tr>
<td>Flurbiprofen</td>
<td>Cases of bleeding reported with concomitant use.</td>
<td>Unpredictable – monitor INR &amp; adverse effects. Avoid if possible.</td>
</tr>
<tr>
<td>Flutamide</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Monitor and reduce warfarin dose as necessary.</td>
</tr>
<tr>
<td>Garlic</td>
<td>Case reports of increased anticoagulant effect of warfarin</td>
<td>Advise patients NOT to take garlic supplements. Regular ingestion of foods containing garlic should not pose a problem.</td>
</tr>
<tr>
<td>Interacting Drug</td>
<td>Potential problem</td>
<td>Comment</td>
</tr>
<tr>
<td>----------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Gemfibrozil</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).</td>
</tr>
<tr>
<td>Gingko Biloba</td>
<td>Isolated reports of increased risk of bleeding</td>
<td>Advise patients not to use Gingko Biloba whilst taking warfarin.</td>
</tr>
<tr>
<td>Ginseng</td>
<td>Reports of spontaneous bleeding in patients using Ginseng without anticoagulants</td>
<td>Ginseng contains antiplatelet components, so avoid use in patients taking warfarin.</td>
</tr>
<tr>
<td>Grapefruit juice</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>May cause a modest rise in INR.</td>
</tr>
<tr>
<td>Glucagon</td>
<td>Large doses (&gt;50mg over 2 days) increase anticoagulant effect of warfarin</td>
<td>Reduce dose of warfarin &amp; monitor INR closely. Smaller doses (total of 30mg) are reported not to interact.</td>
</tr>
<tr>
<td>Glucosamine</td>
<td>Reports of increases in INRs</td>
<td>Patients on warfarin are recommended not to take Glucosamine.</td>
</tr>
<tr>
<td>Glucosamine / Chondroitin</td>
<td>Increased risk of bleeding</td>
<td>Chondroitin has anticoagulant activity and should be avoided in warfarin patients.</td>
</tr>
<tr>
<td>Griseofulvin</td>
<td>Reduces anticoagulant effect of warfarin</td>
<td>Unpredictable (effects some but not all patients) – monitor INR.</td>
</tr>
<tr>
<td>Indometacin</td>
<td>Indometacin inhibits platelet aggregation and so prolongs bleeding</td>
<td>Avoid NSAIDs in patients taking warfarin if possible. If concurrent use essential, monitor INR closely.</td>
</tr>
<tr>
<td>Influenza vaccine</td>
<td>Usually safe &amp; uneventful, but small numbers of bleeding episodes reported</td>
<td>Evidence shows that influenza vaccination in those taking warfarin is normally safe &amp; uneventful. Advise patient to report any unexplained bleeding.</td>
</tr>
<tr>
<td>Itraconazole</td>
<td>Case report of increased anticoagulant effect of warfarin</td>
<td>Monitor and reduce dose if necessary. Advise patients to report any unexplained bruising or bleeding.</td>
</tr>
<tr>
<td>Ketoconazole</td>
<td>Case reports of increased anticoagulant effect of warfarin</td>
<td>Monitor and reduce dose if necessary. Elderly at greater risk. Advise patients to report any unexplained bruising or bleeding.</td>
</tr>
<tr>
<td>Ketorolac (oral)</td>
<td>Serious risk of gastrointestinal bleeding</td>
<td>Oral Ketorolac is contra-indicated in patients taking warfarin.</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>If concurrent use cannot be avoided, reduce the warfarin dose by between one-third and one-half and monitor closely.</td>
</tr>
<tr>
<td>Miconazole</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Avoid -Potentially serious interaction. Use Nystatin instead.</td>
</tr>
<tr>
<td>Interacting Drug</td>
<td>Potential problem</td>
<td>Comment</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Non-Steroidal Anti-inflammatory Drugs (NSAIDs)</td>
<td>NSAIDs irritate stomach lining and reduce platelet aggregation</td>
<td>Avoid where possible. If concomitant use cannot be avoided, monitor INR and adverse events. Ibuprofen or Naproxen are less likely to interact with warfarin.</td>
</tr>
<tr>
<td>Omeprazole</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>A small change in INR may be seen. Occasionally clinically significant interactions occur. Use Lansoprazole as an alternative.</td>
</tr>
<tr>
<td>Papaya</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Avoid use in patients taking warfarin. Monitor INR.</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>Increases anticoagulant effect of warfarin when large doses are used over a prolonged time</td>
<td>Intermittent use (&lt;2.5g/week) unlikely to effect INR. A reduction in warfarin dose may be needed for regular paracetamol users.</td>
</tr>
<tr>
<td>Penicillins</td>
<td>Increases and decreases in the anticoagulant effect of warfarin have been seen</td>
<td>Uncommon and unpredictable effect. Close monitoring of INR recommended.</td>
</tr>
<tr>
<td>Phenytoin</td>
<td>Can increase or reduce anticoagulant effect of warfarin</td>
<td>Monitor INR and adjust dose of warfarin accordingly.</td>
</tr>
<tr>
<td>Piroxicam</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Avoid NSAIDs in patients taking warfarin if possible. If concurrent use essential, monitor INR closely and reduce dose of warfarin if necessary. Ibuprofen or Naproxen are less likely to interact with warfarin.</td>
</tr>
<tr>
<td>Rifampicin / Rifabutin</td>
<td>Markedly reduces anticoagulant effect of warfarin</td>
<td>Monitor closely. Reduces anticoagulant effect within 5-7 days. Warfarin dose may need to be double or trebled and reduced on stopping Rifampicin or Rifabutin.</td>
</tr>
<tr>
<td>Simvastatin</td>
<td>Generally small, clinically irrelevant increase in anticoagulant effects</td>
<td>Monitor initially or after dose increases of Simvastatin.</td>
</tr>
<tr>
<td>St John’s Wort</td>
<td>Moderate reduction in the anticoagulant effects of warfarin</td>
<td>CSM advises stopping St John’s Wort and adjusting the dose of warfarin as necessary.</td>
</tr>
<tr>
<td>Sulindac</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Uncommon and unpredictable – monitor INR. Avoid NSAIDs where possible. Ibuprofen or Naproxen less likely to interact.</td>
</tr>
<tr>
<td>Tamoxifen</td>
<td>Markedly increases anticoagulant effect of warfarin</td>
<td>Monitor and reduce warfarin dose as necessary – may need to reduce dose by half.</td>
</tr>
<tr>
<td>Interacting Drug</td>
<td>Potential problem</td>
<td>Comment</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Thyroid hormones</td>
<td>Increases anticoagulant effect of warfarin</td>
<td>Monitor and adjust warfarin dose as necessary. Warfarin dose may need to be changed as thyroxine doses are altered.</td>
</tr>
<tr>
<td>Vitamin K</td>
<td>Anticoagulant effects of warfarin are reduced or abolished</td>
<td>Vitamin K may be present in enteral feeds, health foods, food supplements, some green vegetables, green tea. If patients are “warfarin resistant” consider this interaction.</td>
</tr>
</tbody>
</table>

References:
Drugs to watch with WARFARIN. NHSSB Prescribing Team, May 2004.
Appendix 7 - Warfarin Slow Start Regimen

This warfarin induction regimen¹ should be used for both primary and secondary care initiation of warfarin for suitable patients (see indications and exclusions below).

Background

Patients not requiring rapid anticoagulation can be safely managed using a slow loading regimen which results in therapeutic anticoagulation within 3 to 4 weeks in the majority of patients¹,². This appears to avoid over-anticoagulation and bleeding associated with rapid loading. There is no need to cover with heparin as no procoagulant state occurs when slow loading the patient.

This regimen allows for induction of anticoagulation therapy requiring only weekly monitoring.

Indications: For use in patients for whom immediate anticoagulation is not required. These include:
- chronic or paroxysmal atrial fibrillation;
- selected patients with left ventricular thrombus;
- selected patients with mitral stenosis;
- stroke outpatients in sustained AF who have waited 14 days following the acute event with a CT head scan that has excluded haemorrhage;
- selected patients with pulmonary hypertension.

Exclusion Criteria: Patients requiring immediate anticoagulation. These include:
- deep vein thrombosis and / or pulmonary embolus;
- mechanical prosthetic cardiac valve insertion;
- arterial embolus;
- selected patients with atrial fibrillation, left ventricular thrombus, mitral stenosis;
- pulmonary hypertension associated with venous thromboembolic disease.

Regimen:

1. Ensure the patient has no contraindications to warfarin and confirm with a senior member of the medical team that the slow start regimen is appropriate. Generally if a patient is taking aspirin, this should be continued until the INR is therapeutic then STOPPED.
2. Ensure baseline bloods (FBC, U&E, LFT, coagulation screen) are satisfactory.
3. Explain to the patient the indication for warfarin treatment and the risks and benefits of it. Complete risk assessment and counselling checklist.
4. Prescribe 2mg of warfarin daily at 6pm for 1 week.
5. Reduce dose to 1mg if patient has concurrent illness or medication which will increase warfarin’s effectiveness.
6. Repeat INR after a further 7 days of warfarin therapy.
7. Adjust dose as per nomogram or using CDSS.

References
NOMOGRAM FOR WARFARIN SLOW START REGIMEN

Day 1

Baseline INR < 2.0
Start 2mg warfarin/day at 6pm
Repeat INR in 7 days

Day 8

INR <2
Continue present dose warfarin.
Repeat INR in 7 days.

INR >2
Warfarin sensitive.
Action depends on level of INR

Day 15

Check INR
Adjust dose according to table below.
Predicted maintenance dosage of warfarin based on the sex of the patient and the INR after 2 weeks of warfarin 2mg/day

<table>
<thead>
<tr>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR at week 2</td>
<td>Maintenance dose</td>
</tr>
<tr>
<td>1.0</td>
<td>6mg/day</td>
</tr>
<tr>
<td>1.1-1.2</td>
<td>5mg/day</td>
</tr>
<tr>
<td>1.3-1.5</td>
<td>4mg/day</td>
</tr>
<tr>
<td>1.6-2.1</td>
<td>3mg/day</td>
</tr>
<tr>
<td>2.2-3.0</td>
<td>2mg/day</td>
</tr>
<tr>
<td>&gt;3.0</td>
<td>1mg/day</td>
</tr>
</tbody>
</table>

If INR >4.0 omit warfarin for 2 days and reduce daily dose by 1mg

Day 21

INR <2
Increase daily Warfarin dose by 1mg.
Repeat INR in 7 days.
Continue in this fashion until INR >2.0

INR 2-3
Continue present dose warfarin.
Repeat INR in 7 days.
Fine tune warfarin dose if INR fluctuates.

INR >3
Fine tune warfarin dose/ omit doses if necessary.
## Major Bleeding

<table>
<thead>
<tr>
<th>Patients</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>Treat as a medical emergency and admit to hospital</td>
</tr>
</tbody>
</table>

## INR > 8.0 with no bleeding manifestation

<table>
<thead>
<tr>
<th>Patients</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td>If using near patient testing, send a venous sample to the central laboratory for testing to obtain INR estimation. Omit warfarin. Give oral Vitamin K 1 to 5mg (Konakion MM Paediatric™ 2mg in 0.2ml) Repeat INR test following day. <em>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.</em> Restart Warfarin when INR &lt;5.0 Reduce maintenance dose and investigate cause of high INR</td>
</tr>
</tbody>
</table>

## INR 4.5 – 7.9 (with no bleeding or minor bleeding, e.g. epistaxis)

<table>
<thead>
<tr>
<th>Patients</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>High risk patients</td>
<td>Omit warfarin. Consider oral Vitamin K 1mg (Konakion MM Paediatric™ 2mg in 0.2ml) Repeat INR test following day. Restart Warfarin when INR &lt;5.0 Reduce maintenance dose and investigate cause of high INR</td>
</tr>
<tr>
<td>Low risk patients</td>
<td>Omit warfarin. Restart warfarin when INR &lt;5.0 Reduce maintenance dose and investigate cause of high INR</td>
</tr>
</tbody>
</table>

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.

## References

**Vitamin K Administration**

Konakion MM Paediatric™ (phytomenadione 2mg in 0.2ml) 0.2ml ampoules should be used to manage high INRs in the community. Although this product is licensed for several routes of administration this protocol refers to oral use, which is off licence.

**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 (1mg = 0.1ml or 2mg = 0.2ml);
- 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 practices providing an anticoagulation enhanced service must purchase this product on initiation of the service.

Your local community pharmacist can supply this 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 9 - Northern Region of Haematologist Group Guide to Warfarin Reversal

Reference
http://www.transfusionguidelines.org.uk/docs/pdfs/rtc-ne_audit_ffp.pdf (page 9)
Appendix 10 - National External Quality Assessment Scheme (NEQAS)

NHS Cumbria requires all providers to join an external quality assurance scheme, to identify the degree of agreement between one centre’s results and those obtained by others.

Registration
To participate in the NEQAS scheme a registration form should be completed and returned to NHS Cumbria’s anticoagulation contact. The practice should complete the practice details on the left hand side of the form, and the analyser information further down the page. Please leave the payment details blank to be completed by NHS Cumbria for the first year.

Surveys
Participating centres will be sent four surveys per year each comprising two samples for INR determination. In the case of UK NEQAS, this will be lyophilised human plasma that has been screened for hepatitis B surface antigen; for antibodies to hepatitis C virus and human immunodeficiency virus types 1 and 2.

Participants will be provided with instructions on reconstitution and testing of the samples. Results will be analysed, and individual reports sent to participants approximately one week after the closing date for each survey.

Results
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.

Performance analysis
Approval has been given for performance ‘out with consensus’ to be defined as a result greater than a 15% deviation.

Contact Details
UK National External Quality Assessment Scheme for Blood Coagulation
Rutledge Mews
3 Southbourne Road
Sheffield
Tel 0114 261 1689
Email: neqas@coageqa.org
Appendix 11 - Example of Training Log Required for Annual Audit

Name and designation of person in charge of anticoagulation management clinic:

Location of anticoagulation management clinic:

Name of others involved in anticoagulation management clinic:

<table>
<thead>
<tr>
<th>GPs:</th>
<th>Practice Nurses:</th>
<th>Other (state designation):</th>
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<tbody>
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</table>

TRAINING

Please give names and dates of training and education relevant to the anticoagulation management service received by practitioners and staff:

<table>
<thead>
<tr>
<th>GPs:</th>
<th>Practice Nurses:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Clinical

BMJ Learning Modules

E learning Modules

Others

Non-Clinical
<table>
<thead>
<tr>
<th>Clinical</th>
<th>GPs:</th>
<th>Practice Nurses:</th>
<th>Other:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDSS Training</td>
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<td></td>
<td></td>
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<tr>
<td>NPT Device Training</td>
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Please give details of any prior knowledge and experience:
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........................................................................................................................................................................
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Appendix 12 - Training courses

BMJ Learning
This is mandatory to all who are going to dose and prescribe anticoagulants.
www.bmjlearning.com
Two modules to undertake and complete:
1. “Starting patients on anticoagulants: how to do it”,
2. “Maintaining patients on anticoagulants: how to do it” for GPs, practice nurses and other healthcare professionals.

It is possible to register to do this module as a guest user as long as you have an NHS email address.
Evidence of undertaking the modules and passing them needs to be submitted to NHS Cumbria before dose adjustments can be made for warfarin patients

In house Training
Currently under development aimed for Nurses and other health care workers who will be dealing with patients receiving anticoagulation.

eLearning Modules
There modules on anticoagulation to be access via the training website.
www.cumbrianhslearning.org.uk
Need to register which anyone working within NHS Cumbria and North Cumbria Acute Trust can do.
More information will be distributed when modules become available (target date April 2009)

Birmingham University
This is a three-day course for GPs, Practice Nurses and other Health Care Professionals that aims to provide a theoretical and practical overview of anticoagulation management, including near-patient testing and use of computerised decision support software. At the time of going to press, the cost is £1,350. Further details are available at: www.anticoagulation.org.uk/training-info_3day.php

CPPE workbook
This is a challenging e-learning package designed for Pharmacists but has lots of good information on anticoagulants.
www.cppe.manchester.ac.uk “Anticoagulation: managing patients, prescribing and problems” for Pharmacists

Sunderland University
A two day course covering the basics of setting up an anticoagulation course. Aimed at Pharmacists interesting in setting up anticoagulant clinics.