

## AUDIT TOOL FOR POLICIES AND PROCEDURES

Please give status of Procedure:		Review
<b>1.</b>	<b>Details of Procedure</b>	
1.1	Title of Procedure:	Anticoagulation Monitoring Service Standard Operating Procedure
1.2	Sponsor (Executive Director):	Penny Brooks-Cordon
1.3	Drafted By:	Laura Godden
1.4	Reason for Procedure:	Statutory/Mandatory Required to comply with the NPSA Alert 18
1.5	Who does the Procedure affect?	All clinical staff providing a Level 3, 4 or 5 anticoagulation service.
1.6	Are the National Guidelines/Codes of Practices etc issued?	Yes
1.7	Has consideration been given to equal opportunities when developing the procedure and have Human Resources been involved where appropriate?	Yes
<b>2.</b>	<b>Information Collation</b>	
2.1	Where was Procedure information obtained from?	
<b>3.</b>	<b>Procedure Management</b>	
3.1	Is there a requirement for a new or revised management structure for the implementation of the Procedure?	No
3.2	If YES attach a copy to this form.	
3.3	If NO explain why.	Existing structures can implement this procedure
<b>4.</b>	<b>Consultation Process</b>	
4.1	Was there external/internal consultation?	Yes
4.2	List groups/persons involved	Evidence Based Practice Group
4.3	Have external/internal comments been included?	The Draft document was revised to take account of comments.
4.4	If external/internal comments have not been included, state why.	N/A
<b>5.</b>	<b>Procedure Attachments</b>	
5.1	Does the Procedure have any attachment etc, if so state their function.	No

	<b>Additional Comments</b>	
<b>6.</b>	<b>Risk Management</b>	
6.1	Name/Job title of who submitted the Procedure for ratification:	Laura Godden, Clinical Practice Pharmacist
6.2	Is a review of the Procedure required by the sponsor?	Yes
6.3	Review date	November 2011

**For use only where the Procedure is for review:**

<b>7.</b>	<b>Procedure Review</b>	
7.1	Procedure Name	Anticoagulation Monitoring Service Standard Operating Procedure
7.2	Revision No: i.e., 1, 2 etc	2
7.3	Are any changes required of the Procedure?	YES
7.4	If 'YES, please state by whom, why and which sections of the Procedure have been revised. (If insufficient space, please continue on separate sheet and attach)	Section 6-anticoagulation provided at a different site to patients registered GP. Identify responsible person/carer where communication with patient is not possible Section 16.1-computersied linking of medications to indication. Section 17.22- Maximum appointment time between INRs for mechanical valves is 8 weeks. Section 17.28- advice re monitored dosage systems Section 22-frequency of IQC tests. Contact details for NEQAS. Appendix 1- Refer to Appendix 12 for management of high INR. Appendix 2-Protocol for the communication between the anticoagulation service provider and the patients registered GP Appendix 6-updated patient information 'Living with Anticoagulants'. Appendix 14- Audit proforma for providers of anticoagulation management services in primary care.

7.5	Review of Procedure undertaken by:	Laura Godden, Clinical Practice Pharmacist
7.6	Date of next review	2011
7.7	Implementation/Monitoring Arrangements	

**Date ratified by the Appropriate Sub-Committee:**

**Signature of Sub-Committee Chair:**

# ANTICOAGULATION MONITORING SERVICE

## Standard Operating Procedure For the provision of a Level 3, 4 and 5 Anticoagulation Service

Version:	2.0
Date at ET/PEC:	October 2008
Date ratified at Board:	N/A
Name and dept of originator/author:	Laura Godden, Clinical Practice Pharmacist
Name of responsible committee/individual and title:	Penny Brooks-Cordon, Director of Standards and Engagement
Date issued:	November 2008
Review date:	November 2011
Target audience:	All clinical staff

This policy/service has been reviewed in accordance with Equalities Legislation on race, disability, age, gender, sexual orientation and gender identity, faith and belief.

*Chairman Tony Pedder*

*Chief Executive Jan Sobieraj*

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## Anticoagulation Standard Operating Procedure

	<b>Contents</b>	<b>Page No</b>
1	Introduction	3
2	National Guidance and Additional Resources	3
3	Aim	4
4	Objectives	4
5	Responsibilities of Sheffield PCT	4
6	Responsibilities of Anticoagulation Service Provider	4
7	Responsibilities of the patient's GP	5
8	Target population	5
9	Secondary Care Referral Process	6
10	Actions for those patients excluded from primary care management	6
11	Actions for patients not wishing to transfer to primary care management	6
12	Primary Care – Clinic Organisation	7
13	Call and recall procedures	7
14	Clinic Appointments	7
15	Clinical Management	8
16	Documentation	9
17	Warfarin Supply, Testing and Dosing	9
18	Initiating therapy	12
19	Discontinuation	12
20	Training	13
21	Reporting near misses, incidents and serious untoward incidents	13
22	Quality Assurance	14
23	Audit	15
	<b>Appendices</b>	
1	Warfarin prescribing guidelines	16
2	Protocol for the communication between the anticoagulation service provider and the patients registered GP	21
3	Policy for appropriate transfer of patients from secondary care	23
4	STH Referral to Primary Care Provider of Anticoagulation Monitoring form	25
5	Transfer of patients previously monitored in secondary care – transfer form	26
5a	Transfer of patients monitored in primary care- post hospital discharge referral form	28
6	'Living with Anticoagulants' – patient booklet	29
7	Warfarin Drug Interactions	41
8	STH Warfarin Slow Start Protocol	47
9	Training courses	49
10	Form to report near misses, incidents and serious untoward incidents	50
11	NEQAS	51
12	Management of over-anticoagulation (including use of Vitamin K)	52
13	Patient over-anticoagulation report	54
14	Audit proforma for providers of anticoagulation management services in primary care	55
15	Useful contacts	59
16	Equality Impact Assessment	60

## **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 Locally, anti-coagulants 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 procedures for the care of patients receiving warfarin that minimises the risks associated with anticoagulation.
- 1.4 These procedures should be adopted by those providers who have been commissioned by Sheffield PCT to provide a level 3, 4 or 5 enhanced anticoagulation service.

## **2 National Guidance and Additional Resources**

Guidance in this document is produced taking into account;

- 1 Guidelines on oral anticoagulation: Third edition. British Journal of Haematology 3<sup>rd</sup> edition 1998;101,374-387

### **2 GMS Contract - National Enhanced Service- 2004**

- 3 British Committee for Standards in Haematology. Guidelines on oral anticoagulation (warfarin): third edition - 2005 update. Available at URL: [http://www.bcsghguidelines.com/pdf/OAC-guidelines\\_190705.pdf](http://www.bcsghguidelines.com/pdf/OAC-guidelines_190705.pdf) <20.07.05>
- 4 Murray et al. INRs and point of care testing. BMJ 2003; 326: 5-6
- 5 Walton R et al. Computer support for determining drug dosage: systematic review and meta-analysis. BMJ; 318: 984-990
- 6 Blann A D, Fitzmaurice D A, Lip GYH. Anticoagulation in hospitals and general practice. BMJ 2003; 326:153-156
- 7 National Patient Safety Agency – Patient Safety Alert on Actions that can make anticoagulant therapy safer, February 2007
- 8 Anon. An example standard operating procedure (SOP) for a primary care anticoagulation clinic using NPT and CDSS.

### 3 Aim

To offer therapeutic anticoagulation management to patients within Sheffield PCT who are receiving anticoagulant therapy, either via venous blood sampling or 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 Sheffield PCT

The role of Sheffield PCT is to ensure that services provided in primary care are in accordance with the service level agreement for the provision of level 3, 4 and 5 anticoagulation services including the following;

- Ensuring a system is in place for patients to receive urgent medical advice relating to anticoagulation.
- Monitoring participation of sites in national laboratory quality assurance scheme and monitoring performance (Providers of Level 4 service).
- Ensuring regular clinical audit in line with section 23 of this document.
- Ensuring anticoagulant guidelines are available for the management of under and over anticoagulation.
- Supplying Computerised Decision Support Software (CDSS) and training prior to implementation.

### 6 Responsibilities of Anticoagulation Service Provider

The provider is responsible for ensuring the service is in line with the Sheffield Anticoagulation Service Specification, including the following;

- 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 – see section 15.3 for further information.

- Ensuring recommendations are available for review by the patient's registered GP.
- Alerting GPs to patients with bleeding problems and INR > 8 or who are otherwise considered to be at risk of bleeding. Discuss possible admission to hospital with the patient's GP. If this is not possible, arrange for the patient to be assessed at the hospital.
- Alerting the patients registered GP when the anticoagulation service is provided at a different site to the GPs practice. The protocol for communication between anticoagulation service provider and the patients registered GP should be followed (Appendix 2)
- Dosing decisions should be made by health-care professionals (e.g. registered nurses or registered pharmacists) who have undergone an approved course for practitioners undertaking anticoagulant monitoring in primary care. Health care assistants can be utilised to take the finger-prick blood test but are not deemed suitably trained to make dosing decisions.
- Ensuring that patients are not discriminated against on the grounds of gender, age, ethnicity, disability, religion, sexual orientation or any other non-medical characteristic.
- 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.

## **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:

- Being aware of appropriate advice and guidelines for anticoagulant care.
- 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 with the anticoagulation provider as required.
- Arranging admission to hospital if required.
- Issuing warfarin prescriptions.
- Advising the anticoagulation service provider when anticoagulation service no longer required by patient.
- Ensuring that all patients receive appropriate monitoring, either with a primary care anticoagulation service provider or in secondary care.
- Where the anticoagulation service is provided at a different site to the patients' registered GP practice, the protocol for communication between anticoagulation service provider and the patients registered GP should be followed (Appendix 2)

## **8 Target population**

- 8.1 Patients should not be referred to the Sheffield anticoagulation primary care service from secondary care within six weeks of initiation of warfarin.
- 8.2 Patients should be stable demonstrated by the last three previous INR results in the therapeutic range (+ / - 0.5 of target INR). However individual service providers may choose to accept patients that don't meet this criteria in agreement with secondary care.

8.3 Patients with the following conditions / problems would not normally be managed in primary care. If any of these conditions arise during monitoring further consideration needs to be given as to the appropriateness of future monitoring in primary care. Some conditions must be referred back to secondary care e.g. pregnancy.

- A known hereditary or acquired bleeding disorder
- Alcoholics 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. (To be managed by Oncologist and Haematologist)
- Children under 16 yrs. (to be managed by Paediatrician and Haematologist)
- Homozygous protein C deficiency (risk of skin necrosis)

## **9 Secondary Care Referral process**

- 9.1 A formal referral to the primary care provider must be made from secondary care using the agreed transfer process. The policy for the appropriate referral and transfer of patients from secondary care to primary care is given at Appendix 3, and gives details of the documentation (Appendix 4 or Appendix 5) that needs to be received and completed for:
- Existing warfarin patients who are currently monitored by secondary care (transfer form – Appendix 4);
  - New warfarin patients initiated by secondary care and attending clinic (transfer form – Appendix 4); and
  - Existing warfarin patients who are currently monitored in primary care who are admitted to and then discharged from secondary care (referral form – Appendix 5).

## **10 Actions for those patients excluded from primary care management.**

- 10.1 Patients who are not eligible for treatment under an approved primary care anticoagulation service will remain under their present anticoagulation care management system.
- 10.2 If patients fail to attend their secondary care monitoring appointments then the anticoagulation clinic at STHFT 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.

## **11 Actions for patients not wishing to transfer to primary care management.**

- 11.1 All eligible patients will be encouraged to receive treatment under this standard operating procedure. This will be achieved through health education supported by written information, and reinforced through follow-up telephone calls wherever feasible.
- 11.2 Patients will continue to have a choice about whether they attend secondary or primary care for monitoring, since they may have valid reasons for wishing to continue their monitoring with STHFT. However, the benefits to patients of a local primary care service should be promoted wherever possible.

## **12 Primary Care - Clinic organisation**

- 12.1 All patients will be seen in person either in a clinic, at a pharmacy or at home by a Health Professional who has undergone training approved by the Sheffield PCT as detailed in the section 20.
- 12.2 The anticoagulant dose should be determined, taking into account the patient's INR and any other changes which may be identified during the interview.
- 12.3 The provider will be responsible for appropriate liaison with the patient's registered GP and secondary care anticoagulation services when necessary.

## **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 targeted 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 provider must discuss this with the patient's registered GP. 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 Clinic Appointments**

- 14.1 Following agreement from the primary care provider in writing to take responsibility for anticoagulation of an individual patient, a clinic appointment should be made before the patient's next hospital appointment.
- 14.2 Patients unable to be seen before their next hospital-booked clinic appointment will remain with their current arrangement until an appointment can be booked with an approved Anticoagulation Service.
- 14.3 At the first consultation, anticoagulation documentation as specified in the service specification (section 16) should be completed OR a standard template completed.

## **15 Clinical Management**

### **Individual management plan.**

- 15.1 The service provider in conjunction with the patient should prepare an individual management plan. The plan should outline, as a minimum, the diagnosis, planned duration and therapeutic range to be achieved.

### **Clinical Procedures.**

- 15.2 The service provider should ensure that at initial diagnosis and on an annual basis a comprehensive review of the patient's health is undertaken to include the identification of potential complications. Additionally, regular review of the patient's own monitoring records should be undertaken. The service provider must ensure that 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.

### **Education of newly diagnosed patients.**

- 15.3 At the first appointment following transfer from secondary care, education should be reinforced (according to a counselling checklist). 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 underdose/overdose 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
- 15.4 An information booklet should also be given to the patient to reinforce the verbal counselling. A comprehensive booklet 'Living with Anticoagulants', produced by STHFT, is recommended – see Appendix 6.
- 15.5 Patients should be encouraged to carry their yellow warfarin booklet with them at all times and to show it to their GP/health practitioner whenever they seek medical or dental treatment or purchase medicines from a pharmacy. 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 Brincliffe House.

## **16 Documentation**

### **Patient Register and Patient Records**

16.1 The following records will be kept by the anticoagulation service provider:

- Patient Name
- Patient Date of Birth
- Registered GP practice
- Indication for treatment, including computerised linkage of medication to indication
- 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 effect 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

16.2 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.

16.3 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 anticoagulation service provider will contact the initiating hospital if any of these details are omitted.

### **Clinic Attendance**

16.4 A record of the number of attendees, non-attendees and home visits should be recorded for each clinic session including information re strategies adopted to inform non-attendees of new appointment.

## **17 Warfarin Supply, Testing and Dosing**

17.1 Different people require very 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 7.

17.2 Patients will be encouraged to take their warfarin daily and at a regular time.

17.3 Warfarin will be supplied from the patient's registered GP via a prescription. Wherever possible the patient should not be provided with more than 2 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.

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

<b>Strength</b>	<b>Colour</b>
0.5 mg	White
1 mg	Brown
3 mg	Blue
5 mg	Pink

17.5 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.

### **INR Testing**

17.6 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?

17.7 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.

17.8 Those practices that are providing a level 3 anticoagulation service will receive their INR results from the laboratory via a pathology messaging system or fax. Practices must ensure a named person is responsible for promptly distributing the results and ensuring they are 'owned' by a GP or nurse.

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

### **Near Patient Testing and High INR Results**

17.10 If the INR result is greater than 5.0 then repeat the patient INR using a new finger stick sample with CoaguChek S or XS and perform Internal Quality Control (see section 22.3 onwards).

17.11 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 and send a venous sample to the central laboratory.

- 17.12 The device will NOT record an INR of >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.
- 17.13 If a "test error" message is obtained the Coaguchek S or XS will not provide a reading. Repeat the test and if a second "test error" message is obtained, a sample should be sent to the central laboratory for testing.
- 17.14 If a laboratory sample is required and there is no blood collection from the provider's base within 4 hours, the patient must be sent to the walk-in-centre with a form for a sample to be taken that day. 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.
- 17.15 If an unexpected result occurs (higher or lower than expected from the patient's past history) repeat the INR test with Coagucheck S or XS.
- 17.16 If the patient has significant anaemia or polycythaemia this may lead to unreliable results and the device should not be used. (Patients who have a packed cell volume/ haematocrit in the range is 30-55% can be tested) Those few patients with a PCV outside this range should not be tested.

### **Dose adjustment of oral anticoagulants**

- 17.17 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 17.6 above).
- 17.18 Dosage of oral anticoagulants should be **guided** by using Computerised Decision Support Software (CDSS) or by approved clinical guidelines (Appendix 1).

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

- 17.19 The INR result should be inputted into the CDSS that uses a validated equation for calculation of the recommended dose and date for review.
- 17.20 The recommended dose and review date should be accepted or overridden depending on whether they are acceptable taking into account all patient factors.
- 17.21 The anticoagulation provider can alter dosage and / or reset review dates if clinically appropriate.

### **Frequency of Monitoring**

- 17.22 The length of time between test dates varies, the maximum length of time being 12 weeks between tests, (BCSH Guidelines 1998). For those with mechanical heart valves, the maximum is 8 weeks. The length of time between tests will depend on the patient's stability and untoward occurrences likely to cause instability.

### **Updating the yellow warfarin booklet**

- 17.23 The provider will complete 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*).
- 17.24 Date of next test and contact numbers for advice should be recorded.

- 17.25 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. The patient themselves must be asked to write this in their yellow book.
- 17.26 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.
- 17.27 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.
- 17.28 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 over the phone. The patient must be asked to write this in their yellow book. The information will be confirmed in writing to the patient and the pharmacist.

## **18 Initiating therapy**

- 18.1 A provider 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 STH warfarin slow start protocol (Appendix 8).
- 18.2 At the first appointment to initiate warfarin, the provider must ensure that the patient is given all the relevant information and education verbally and in writing – see paragraph 15.4 onwards. The provider should also complete the relevant sections of the yellow hand-held warfarin book, and issue this to the patient. Supplies of these books are available from Brincliffe House.
- 18.3 This will be classed as a level 5 service and will be reimbursed at £50.00 per patient. Level 5 is a one-off payment, and following stabilisation the patient will then move onto the level 3 or level 4 service at the agreed rates.

## **19 Discontinuation**

- 19.1 The maximum duration of overall treatment will be documented on the initial referral form and in the patient's yellow warfarin booklet.
- 19.2 In respect of providers who are not the patient's registered GP practice, (i.e. community pharmacies) towards the end of the maximum duration of treatment, a letter will be sent to the registered GP asking for the date when anticoagulation therapy can be discontinued. Only when a reply has been received in writing will therapy be discontinued. If a reply is not received from the registered GP then the provider should contact the GP to chase this up.
- 19.3 The patient or carer will be informed in clinic, domiciliary visit or verbally by telephone and followed up by letter to confirm this.

- 19.4 Oral anticoagulants will be discontinued completely on a defined date, unless otherwise specified by the registered GP.
- 19.5 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 etc.

## **20 Training**

- 20.1 Each service provider must ensure that **all** staff involved in providing **any** aspect of care under the scheme has the necessary training and skills to do so.
- 20.2 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 9.
- 20.3 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.
- 20.4 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.

- 20.5 All external and in-house training undertaken by the provider's staff should be recorded.
- 20.6 The following educational resources are recommended to update CPD where necessary:  
[www.bmjlearning.com](http://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.  
[www.cppe.manchester.ac.uk](http://www.cppe.manchester.ac.uk) "Anticoagulation: managing patients, prescribing and problems" for pharmacists

## **21 Reporting near misses, incidents and serious untoward incidents**

- 21.1 It is a condition of participation in the service that providers will report all significant and serious untoward incidents to Sheffield PCT that relate to anticoagulation.
- 21.2 A reporting form, which can be found at Appendix 10, should be completed and faxed to the Risk Management Department of Sheffield PCT, within the following timescales:
- Near misses and incidents – 72 hours

- Serious untoward incidents – 24 hours

21.3 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 Sheffield PCT.

21.4 Support with the investigation and SEA is available from Sheffield PCT in accordance with the Serious Incident Policy.

## 22 Quality Assurance

### General

22.1 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.

22.2 The provider 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)

22.3 Those providers 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

22.4 Perform IQC when beginning any new box of strips. An IQC also needs to be performed at the beginning of every clinic or every 20 tests/ 2 weeks whichever is sooner.

22.5 IQC tests are usually supplied in a box of four vials; each batch number has a different INR range. The Coaguchek S NPT device has a very broad acceptable INR range. Therefore if practices are using Coaguchek S as their NPT device, it is recommended that a minimum of 20 IQC test vials are purchased at any one time to be able to calculate a narrower mean range for a particular batch number.

22.6 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  $\pm 0.5$  INR of the mean of the first 5 IQC results.

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

22.8 If IQC is out of limits patient testing should be **suspended** with that device/test strip batch. Roche Diagnostics should be contacted if there are concerns about the accuracy of the Coaguchek device.

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

### **External Quality Assurance**

22.10 Those providers using near patient testing equipment will be required to join an external quality assurance scheme (UK NEQAS). Further information is given at Appendix 11.

22.11 External Quality Assurance (EQA) 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 via the laboratory at the Royal Hallamshire hospital.

### **Cleaning Procedure**

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

### **Review of care pathway**

22.13 It is strongly recommend that 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 actioned;
- 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.

22.14 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.

## **23 Audit**

23.1 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 local actions to improve the safe use of anticoagulants, and will also be used as part of the performance management process of Sheffield PCT.

23.2 An audit template will be issued at an appropriate time during the period of the service agreement (Appendix 14).

## Appendix 1

### Warfarin prescribing guidelines

#### 1 General guidance

- 1.1 This protocol sets out details for the care of patients taking Warfarin. The patient should also have received advice and written information on anticoagulant therapy, normally in the form of an anticoagulant booklet.

#### 2 Background

- 2.1 Warfarin use is increasing as new indications for its efficacy have been recently identified. Nevertheless, its use is associated with adverse effects, particularly bleeding and optimum management can be achieved by shared care between hospital and general practitioner. The present indications for Warfarin, together with the presently agreed degree of anticoagulation for that indication are shown in Table 1:

**Table 1:**

	<b>Target (+/- 0.5)</b>
Prophylaxis of postoperative deep vein thrombosis [general surgery]	<b>2.5</b>
Myocardial infarction: prevention of venous thromboembolism.	<b>2.5</b>
Treatment of venous thrombosis [DVT]	<b>2.5</b>
Treatment of pulmonary embolism [PE]	<b>2.5</b>
Transient ischaemic attacks	<b>2.5</b>
Tissue heart valves	<b>2.5</b>
Atrial fibrillation	<b>2.5</b>
Valvular heart disease	<b>2.5</b>
Recurrent deep vein thrombosis and pulmonary embolism	<b>3.5</b>
Intravascular stent	<b>2.5</b>
Mechanical prosthetic valves – all patients will be discharged from the cardio-thoracic unit with a recommended target INR range	

#### 3 Dosage Regimens

- 3.1 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. (Tablet strengths are 0.5mg [white], 1mg [brown], 3 mg [blue], 5 mg [pink].)

#### 4 Duration of therapy

- 4.1 After a single episode of venous thromboembolism, 3-6 months of warfarin therapy is likely to be necessary. The duration of therapy needed after a second episode of DVT or PE is uncertain but 6-12 months' therapy, or long-term anticoagulation is normally advocated.
- 4.2 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 recall periods during maintenance therapy\*  
**\*(not initiation)**

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

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)

- 5 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 intercurrent illness, frequency of monitoring should be increased.
- 6 The following conditions cause Warfarin sensitivity [i.e. need for reduced dose]:
  - i Liver dysfunction
  - ii Heart failure
  - iii Hyperthyroidism
  - iv Some drugs
  - v Acute pyrexial episode
- 7 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
  - ii Some drugs ( Indicative list is provided in appendix 11)

## Warfarin dose adjustments

- 1 All patients being transferred into the community for INR monitoring should have been on warfarin for > 6 weeks and fulfil the criteria for community anticoagulation (Section 8).
- 2 Adjustment of the patient's anticoagulant dose will be performed by the appropriately trained pharmacist, nurse, or physician, in order to maintain the INR within the recommended range.
- 3 These guidelines are for general guidance; consideration should be given to the patient's previous INR record, pattern of response, and the individual's specific details when making dose adjustments.
- 4 Should the INR be outside the recommended range, the approved individual will first satisfy him/herself that there are **no obvious reasons** for this (e.g. drug interaction/ non-compliance/ change in diet or alcohol intake).
- 5 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 the following guidelines:
- 6 Adjustments to patient's weekly dose should be +/- 10%.
- 7 Boosting ("one off") doses should be approximately 50% greater than the patient's regular maintenance dose: therefore if daily dose 6mg, boosting dose should be 9mg. **Again, consideration should be given to patient's previous pattern of response.**
- 8 The following anticoagulation service practitioners at the RHH can be contacted for advice on 271 3820 during normal working hours:

Linda Carver (Clinical Nurse Specialist)  
Stuart Rollings (Clinical Nurse Specialist)  
Lesley Lyons (Nurse Practitioner)

If advice is required out of hours, please contact the on-call haematologist.

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

### Sub-therapeutic

		Dose adjustment	Next Appointment
Slight	1.8 - 1.9	Increase dose if consistently low	2-4 weeks
Moderate	1.6 - 1.8	Increase dose	1-2 weeks
Significant	< 1.6	Consider boosting dose(s), and increase dose.	Within 1 week

If VTE patient and two or more INR results < 1.6 consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range. If advice is required on starting LMWH contact the on-call Haematology registrar at STHFT.

### Over-anticoagulated

		Dose adjustment	Next Appointment
Slight	3.0 - 3.2	Decrease dose if consistently high.	4-6 weeks
Moderate	3.4 - 3.9	Decrease dose.	1-2 weeks
Significant	4.0 - 4.9	Omit dose for 1 day, decrease dose.	max 1 week
Severe	5.0 - 5.9	Omit doses for 2 days, decrease dose	max 1 week
Very Severe	6.0 - 8.0	*Stop warfarin/phenindione/nicoumalone, restart when INR <5.0 at reduced dose. Consider Vitamin K as advised by haematologist (see appendix 12)	Next day

Evidence of bleeding will require a change in this schedule, and 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 (either by hospital or District Nurses) and that the results are acted on.

**High risk patients:** Age>70; hypertension; diabetes; renal failure; previous myocardial infarction, stroke or gastrointestinal bleed.

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

### *Sub-therapeutic*

		Dose adjustment	Next Appointment
Slight	2.8- 2.9	Continue as before	2-3 weeks
Moderate	2.0 - 2.7	Consider boosting dose + increase dose	2-4 weeks
Severe	< 2.0	Consider boosting doses + increase dose <sup>†</sup>	1 weeks

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.

<sup>†</sup>**Patients' with prosthetic valves in the mitral position, or a history of previous systemic emboli may require heparin therapy until warfarin becomes effective. Discuss with the cardiothoracic surgical team.**

<sup>†</sup>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. If advice is required on starting LMWH contact the on-call Haematology registrar at STHFT.

### *Over-anticoagulated*

		Dose adjustment	Next Appointment
Slight	4.0- 4.9	Decrease dose if consistently high	2-3 weeks
Moderate	5.0 – 5.9	Omit dose for 1day + reduce dose	1 week
Significant	6.0 - 6.9	Omit for 1-2 days and reduce dose	1 week
Severe	7.0 - 8.0	*Stop warfarin, restart when INR <5.0. Consider Vitamin K as directed by haematologist (see appendix 12)	next day

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 (either by hospital or District Nurses) 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

### Protocol for the communication between the Anti-coagulation service provider and the patients registered GP

To comply with the Sheffield Standard Operating Procedure for Anti-coagulation monitoring in Primary Care a robust communication channel must be in place, when the service provider is not the patient's GP.

#### **Responsibility of anti-coagulation service provider**

The responsibilities of the anti-coagulation service provider are to ensure the service is in line with the Sheffield SOP, which states:

1. The service provider must ensure completeness and accurate documentation of the clinic process
2. Ensure recommendations are available for review by the patients registered GP
3. Alert GP's to patients with potential problems e.g. bleeding
4. Primary Care clinic organisation – The provider will be responsible for appropriate liaison with the patients registered GP and secondary care anti-coagulation services when necessary

#### **Process to be followed by anti-coagulation service provider**

At the end of every clinic, a summary sheet printed by INR Star, should be sent to the patient's GP practice. A summary sheet is to be sent for all the patients who have attended clinic that day. This gives the practice all the information they will need. It also gives them a lot more information than the hospital clinic could provide.

The summary sheet can also be used, to write any non-urgent messages to the patient's GP or to alert the GP of any suspected problems etc.

For urgent matters, the practice must be telephoned either whilst the patient is still in clinic or at the end of the clinic.

#### **Responsibility of patients GP practice**

To ensure this works, each week a GP or designated person from the practice must go through the summary sheets and record the information on the computer or in the patients' notes. The GP must record on the patients' medical record the responsible provider of anticoagulation.

#### **Joint Responsibilities for the patient**

For the anti-coagulation clinic to be a success, the communication channel between service provider and patients GP must be a two way process and the GP must be prepared to communicate freely with the service provider any relevant information about the patient, e.g. any medication changes etc.

Secondary care must also be made aware of the service provider of anti-coagulation services for each GP practice. This must be confirmed in writing to Dr Rhona McClean Consultant Haematologist. This is then logged onto the hospital computer system, and when any warfarin patients are admitted to hospital, the service provider can be contacted, with discharge dates and follow up appointments can be made.

**Anticoagulation service provision by another provider other than the patients registered GP**

This agreement is between *(insert anticoagulation service provider)* and *(insert medical centre name and lead partner name)*. The agreement covers the period *(insert dates from and to)*. From here in the two parties to this agreement agree to follow the agreed Sheffield PCT protocol regarding the communication of the agreed anticoagulation service provider and the patients registered GP.

Only one of these signed forms is required to cover one GP practices patient set, NOT ONE PER PATIENT

**Signature Sheet**

This document constitutes the agreement between the two parties, both accepting their responsibilities as set out in the attached Protocol.

**Signature on behalf of Anticoagulation service provider:**

Signature	Name	Provider name and address	Date

**Signature on behalf of patients registered GP Practice:**

Signature	Name	Practice Name and address	Date

**When signed please return to Lisa Shackleton, PBC Secretary,  
722 Prince of Wales Road, Darnall, Sheffield S9 4EU**

## Appendix 3

### Policy for the appropriate transfer of patients from STH Anticoagulation Clinics to Sheffield Primary Care Anticoagulation Service

#### 1. Existing patients

- 1.1 The Anticoagulation Clinic faxes the transfer request form (Appendix 4) with the patient's details to the anticoagulation service provider.
- 1.2 On receipt of the transfer request form, the primary care provider will contact the patient to explain the new service. If the patient agrees to the transfer the primary care provider will arrange a first appointment for INR monitoring.
- 1.3 When the primary care monitoring appointment has been arranged, the primary care provider signs the bottom of the transfer request form and faxes this back to the secondary care anticoagulation clinic. The primary care provider 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 All patients referred for transfer but not accepted by the primary care provider will continue to be managed by secondary care. In these cases the provider must complete the bottom of the transfer form stating that they do not accept the patient for primary care monitoring and fax back to the secondary care anticoagulation clinic.
- 1.5 If there is a time delay between the secondary care clinic first sending the referral form and the patient being accepted by the primary care provider, 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 aim to transfer all patients as per 1.1 -1.5 above, who are not excluded from the primary care provision to the patient's anticoagulation provider, once the patient has had six weeks INR monitoring and three stable INRs.
- 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. In these cases the primary care provider will decide whether it is appropriate for the patient to transfer.

#### 3 Existing Primary Care Anticoagulation patients - post discharge

- 3.1 Patients who were being managed by the primary care anticoagulation service prior to a hospital admission will be referred back to the primary care service post discharge. However, if the patient has developed one of the specified exclusions (Section 8 – Page 5) the primary care provider should consider if it is still appropriate to manage the patient in primary care, and if not the primary care provider should refer back to secondary care.
- 3.2 The responsible doctor in secondary care will fill in the STH anticoagulation referral form (Appendix 5). This will be faxed with a copy of the patient's warfarin prescription chart to the primary care provider along with an 'STH Referral to Primary Care Provider of Anticoagulation Monitoring' form (Appendix 5a).

- 3.3 On receipt of this, the primary care provider will arrange an appropriate appointment for the patient and complete the second part of the 'STH Referral to Primary Care Provider of Anticoagulation Monitoring' form before faxing it back to the referring ward, **on the same day as receipt**. A copy of this form will be given to the patient on discharge so that they have a record of their INR appointment date. The patient must have an appointment for their next INR check with the primary care provider before leaving hospital. However if the patient has left hospital before being given this, the ward staff will be responsible for contacting them about their next appointment.
- 3.4 Should discharge occur on a weekend, referral to the primary care provider will be made in line with 3.2 above. On Monday morning the primary care provider will arrange an appointment for the patient and fax the completed referral form back to the ward. 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.

**THE ANTICOAGULATION SERVICE****RHH SITE:** Tele: 2713820

Fax: 2268690

**NGH SITE:** Tele: No. 2714399 Fax: 2715454**REQUEST FOR TRANSFER OF THIS PATIENT'S ANTICOAGULATION  
MANAGEMENT TO HIS/HER G.P.PRACTICE.**

Patient's name: Joe Bloggs

D.O.B. 27/06/1896

Hosp No.

NHS No.

**Address****G.P.** DR. HILDITCH, FL, TRAMWAYS MEDICAL CENTRE, 54A HOLME LANE, SHEFFIELD, S6 4JQ**Referring Consultant** DR SAMANIEGO, NC**Reason for anticoagulation** DVT **Anticoagulant** WARFARIN MIXED TABLETS WEEKLY**Date started** 13/10/2006 **Target INR RANGE** 2.0 - 3.0 (2.5 Target)**Length of treatment.** 26 weeks. Long Term **For Consultant review before stopping treatment?** Yes  No **Last 3 INR's and doses Dosage in milligrams per day**07/11/2006 INR 2.40  
Mon Tue Wed Thu Fri Sat Sun  
**9 9 9 9 9 8 8**31/10/2006 INR 2.20  
Mon Tue Wed Thu Fri Sat Sun  
**9 9 9 9 9 8 8**26/10/2006 INR 2.30  
Mon Tue Wed Thu Fri Sat Sun  
**9 8 9 8 9 8 9****Next Appointment** 22/11/2006**Please sign and date below:****I ACCEPT this patient for management of his/her anticoagulation from this date onwards**

Date: \_\_\_\_\_ Sign. \_\_\_\_\_

**I DO NOT ACCEPT this patient for management of his/her anticoagulation**

Date: \_\_\_\_\_ Sign \_\_\_\_\_

Reason: \_\_\_\_\_

# Appendix 5

## ANTICOAGULATION REFERRAL FORM

Sheffield Teaching Hospitals 

NHS Foundation Trust

**Referrals will not be accepted unless this form is fully completed by the referring doctor and accompanied by the current warfarin prescription chart. SEE OVERLEAF FOR REFERRAL INFORMATION**

Patient's Tele. No. _____ GP _____ GP FAX number _____ Referring Consultant _____	Name: _____ DoB: _____ (Affix Patient Label Here) Hosp No.: _____ NHS No.: _____
--	---

Anticoagulation monitoring and prescribing to be provided by: RHH  NGH  GP   
 (if new DVT/PE to be monitored at STH anticoagulation clinic for 6 weeks)

Reason for anticoagulation & any other significant medical or surgical problems \_\_\_\_\_  
 \_\_\_\_\_

Is the patient on anti-platelet drugs? Yes  specify \_\_\_\_\_ No

If yes, are these to continue? Yes  stop when INR in target range  No

Other medication \_\_\_\_\_  
 \_\_\_\_\_

Name and dose of current anticoagulant \_\_\_\_\_

Date anticoagulation started \_\_\_\_\_

INR target range 2-3  3-4  3-4.5  Other (please specify) \_\_\_\_\_

Anticoagulation duration: 6 weeks  3 months  6 months  long term

Anticoagulation to be discontinued:

after stated period  N/A (longterm)  only after consultant medical review

Baseline bloods of FBC, U & Es and clotting screen done on \_\_\_\_\_ (date)

Date required for first appointment in anticoagulation clinic \_\_\_\_\_ (If required appointment not available, monitoring of the patient's anticoagulation remains the responsibility of the referring medical / surgical team until the patient is seen in clinic).

Transport (if RHH/NGH follow-up): Own  Medicar  2 man ambulance

Signature \_\_\_\_\_ Print name \_\_\_\_\_

Status \_\_\_\_\_ Bleep No. \_\_\_\_\_ Date \_\_\_\_\_

Faxed by \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

Received by \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_

**For referral to anticoagulation clinic, fax form AND WARFARIN PRESCRIPTION CHART to the Anticoagulation Clinic Clerk:**

**Anticoagulation clinic RHH phone ext: 13820, fax: 68690,  
NGH phone ext: 14399, fax: 15454**

**For referral to GP fax form and WARFARIN PRESCRIPTION CHART to GP surgery**

## ***GUIDELINES FOR ANTICOAGULATION***

### **INITIATING TREATMENT**

**Loading regime:** see STH "Warfarin Treatment Management Guidelines" August 2004.

**Slow start regime for AF ONLY:** 2 mgs of warfarin daily for 2 weeks until seen in clinic.

<u>Reason for anticoagulation</u>	<u>INR target</u>	<u>INR target ranges</u>	<u>Duration</u>
Deep vein thrombosis (DVT)	2.5	2 – 3	Calf vein 3 months Proximal vein 6months
Pulmonary embolus (PE)	2.5	2 – 3	6 months
Recurrent DVT/PE	2.5	2 – 3	Long term
Recurrent DVT/PE whilst on anticoagulants	3.5	3 - 4	Long term

**For recurrent pulmonary embolus / deep vein thrombosis consider haematology referral**

Atrial fibrillation Atrial flutter Cardiomyopathy Mural thrombus Valvular disease Congenital heart disease	All these require 2.5 as a target 2 - 3 as the target range	.....Long term
---	--	----------------

Mitral bioprosthetic heart valve	2.5	2 – 3	3 months
Mechanical prosthetic heart valve	3.5	3 – 4	Long term
Vena cava filters	2.5	2 - 3	Long term
Antiphospholipid syndrome	3.5	3 - 4	Long term

**Where there is uncertainty or specific guidance is required, this can be obtained from the Registrar on call for haematology.**

(The guidelines above are based on the "Guidelines on Oral Anticoagulation". British Journal of Haematology 3<sup>rd</sup> Edition 1998. 101 p 374 – 387).

Ref SRLC/RM ref 3 doc March 2004

**STH REFERRAL TO PRIMARY CARE PROVIDER OF ANTICOAGULATION MONITORING**

**FROM:** Hospital Ward .....at Hospital .....  
Contact Name .....Tel No: .....  
Fax No: .....

**Re:** Patient Name: ..... DO.B.....  
NHS No. ....

**TO: Primary Care Provider:** .....

We are discharging this patient on .....(date) and we request that you resume the monitoring of his/her anticoagulation therapy. We are faxing the referral form and Warfarin dosing chart and await your reply.

**FROM: Primary Care Provider:** .....

I have received your referral for ongoing monitoring of this patient's anticoagulation therapy and have given him/her an appointment for his/her INR test on.....(date) at .....(time).

If the patient is unable to attend this appointment he/she should contact the surgery or pharmacy that he/she attends for INR monitoring as soon as possible to arrange another appointment for their next INR test.

**Signed:** .....

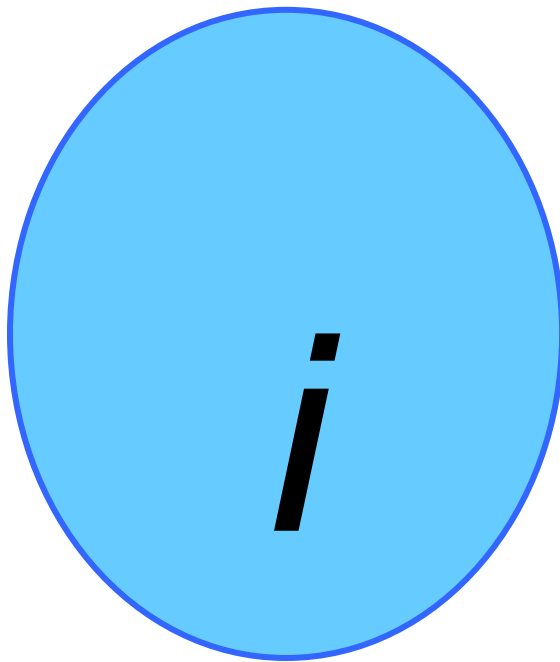
**Position:** .....

**Date:** ..... **Contact Tel. No.** .....

**Discharging team to give the patient a copy of this letter (with both sections completed) before he/she leaves the clinical area or if the patient has already left – post it to him/her.**

---

# Living with Anticoagulants



***Information for patients***

Anticoagulation  
Service

Name .....

Hosp. No .....

D O B .....

Address .....

.....

.....

Telephone .....

Name of anticoagulant .....

Reason for anticoagulation .....

Target range .....

Date treatment started .....

Duration of treatment .....

**Please note:**

If you experience any bleeding or extensive bruising you should seek advice from your GP or attend the nearest Accident and Emergency Department.

---

Your anticoagulation will be monitored at one of the following places  
*[Tick in appropriate box]*

---

Anticoagulation clinic, Room C 51

**Royal Hallamshire Hospital** Tel: 0114 2713820  
(This is located opposite the blood testing reception in  
The Outpatient Building on C Floor)

---

Anticoagulation Clinic, Outpatients 2

**Northern General Hospital** Tel: 0114 2714399  
(This is the second building on your left when you  
enter the hospital at the Herries Road entrance.)

---

Your GP Practice at:

.....

An appointment has been made for you to attend the clinic/GP Practice identified above  
on:

.....(date) at ..... (time)

**Please inform the clinic of FP practice dealing with the management of your  
anticoagulation if you are unable to attend for your next appointment.**

---

**\* See next page to complete dose instructions**

Until your appointment you dose of .....  
will be as follows:

---

Daily dose in milligrams per day:

Date							
Date							

Signed by ..... Date .....

Print Name .....

Position .....

Ward/Department ..... Hospital .....

**This section needs to be completed before you are discharged and the anticoagulant dosing instructions completed and signed by a doctor.**

## What are anticoagulants?

Anticoagulants are medicines used to prevent harmful blood clots. The most commonly used medicine is **Warfarin** but there are others such as **nicoumalone** (sinthrome) or **Phenindione** (dindevan). In this booklet, the advice applies to all three anticoagulants but we will refer only to warfarin in the text,

### **Warfarin is used mainly in two situations:**

- To prevent further clotting (or thrombosis) when a blood clot has already caused a problem - such as when a clot has formed in the legs (a deep vein thrombosis) or has travelled to the lungs (a pulmonary embolus)
- To prevent clotting when you are at risk of forming a blood clot - such as if you have a have an artificial heart valve. In this situation a clot forming on the valve may clog up the valve causing heart failure.

If you have an irregular heartbeat you are at risk of forming a blood clot in the heart. If this were to happen the clot may break off, travel in the blood supply to the brain, and cause a stroke by blocking a small artery.

The aim of anticoagulant treatment is therefore to prevent any problems which might be caused by clots forming where they can cause damage.

### **Why does the blood clot?**

When a blood vessel is damaged by a cut or injury, a blood clot forms to seal the hole and stop the bleeding. Without this action the bleeding would not stop. So the ability of the blood to clot is life saving.

However clots can be life threatening if they occur in places where they should not develop. Blood clots (or thromboses) developing inside a vein or artery when there is no injury can be life threatening. In this circumstance the clot can block the blood vessel cutting off the blood supply to the surrounding tissue or preventing blood from flowing through the vessel thereby causing swelling and pain. Sometimes the clot can move to the lungs or brain. Here, the clot may cause serious problems such as a pulmonary embolus or a stroke.

### **When do harmful blood clots occur?**

A blood clot can develop suddenly and unpredictably, or as a consequence of certain conditions. For example, if you have an irregular heart beat, then blood clots are more likely to form in your heart; or if you are confined to bed after an operation then blood may pool in the veins of the legs causing a deep vein thrombosis. There are times when clots can form in areas where they are harmful and we have little idea as to what has caused them.

## How can you stop or treat harmful blood clots?

There are certain medicines that reduce the clotting tendency of the blood. These are called **anticoagulants**. Anticoagulant medicines are given either to prevent blood clots forming or to treat them when they have formed.

The drug most commonly used is called warfarin- you may have heard of it before because it has been used in very large doses as a rat poison. Warfarin prevents clots forming when there is a risk of this occurring and prevents the growth of a clot when it has already formed.

Warfarin does not dissolve clots. There is a chemical process in everyone's body which breaks clots down over a period of time. Warfarin protects you from further clot development while this process takes place. It is important to regularly monitor your blood clotting ability when taking anticoagulants to ensure that you are taking the right amount to reduce the blood's ability to clot, without exposing you to a risk of bleeding. It is for this reason that you will need to have regular blood tests.

## How does warfarin work?

Warfarin works by altering the way the liver makes the proteins which produce clots. Many factors can alter the way warfarin works such as illness, other medicines and alcohol. If you have liver disease you will be very sensitive to warfarin. The amount of warfarin needed to change the clotting ability of the blood to the correct level varies from person to person - there is no standard dose of warfarin.

We have to find the right amount for you and that can only be determined by frequent blood testing and adjustment of your dose.

### Warfarin Tablets.

It is because we need to give different doses of warfarin that it is manufactured in four strengths:

0.5 milligram	White tablet	○
1 milligram	Brown tablet	○
3 milligram	Blue tablet	○
5 milligram	Pink tablet	○

You may be asked to take a combination of these strengths to achieve the correct dose for you. Generally most patients will be issued with 2 types - the **3mg blue** tablets and the **1mg brown** tablets. Only in exceptional cases will the other strengths be issued.

If warfarin doesn't suit you (and this is very unusual) other medicines which do the same job are available. These are called called nicoumalone (sinthrome) and phenindione (dindevan).

To find the correct dosage your blood needs to be monitored regularly. However the amount of warfarin you need may also change due to changes in your condition, other medications prescribed, or your diet. So it is **important** that blood checks are made at regular intervals although these should become less frequent than they were when you first started the treatment.

## How is the blood tested?

The laboratory based clotting test of the blood is called **I.N.R. (International Normalised Ratio)**. This is a test that compares the time for a sample of blood to clot when taken from a person not taking warfarin with a sample from a person who is taking warfarin. For example, if your INR is 2.0 this means that it takes approximately twice as long for your blood to clot compared with a blood sample taken from a person who is not taking warfarin. Even though your blood takes twice as long to clot as the normal blood sample this difference is still only a matter of seconds.

## How often must I have blood tests?

When you begin taking warfarin your blood tests will be frequent. When the correct dose is found the intervals between the blood tests should increase until you may need to have your blood checked only once every 8-12 weeks. However the frequency of blood tests required will depend on the stability of your blood results and this cannot be predicted at the outset. Generally speaking the more stable your results the less often you will need your blood testing. You can help by always taking the correct alcohol. However, some factors which upset stability, will be out of your control such as illness and the need for new medicines.

**It is very important you attend for blood tests when required. This will help us to find the correct dose for you and keep your blood results stable.**

## What should my INR be?

The degree to which your blood clotting ability needs to be reduced will depend on the condition for which you are being treated. Below are some examples of INR ranges and the conditions for which they are appropriate:

INR	2.0-3.0	Atrial Fibrillation (Irregular heart beat) Deep Vein Thombosis (clot in leg) Pulmonary Embolus (clot in lung)
INR	2.5-3.5 or 3.0-4.5	Mechanical Heart Valve Replacements

*These are general ranges. Occasionally your doctor may decide on a slightly different range that is appropriate for your condition.*

## For how long must I take warfarin?

The length of time you must take warfarin depends upon your diagnosis.

Here are some examples:

Deep Vein Thombosis (DVT)	3-6 months
Pulmonary Embolus (PE)	6 months
Atrial Fibrillation	Lifelong
Heart Valve Replacements	Lifelong
Recurrent DVT and PE	Lifelong

## What happens when I start warfarin?

When you begin warfarin therapy, all aspects of the treatment will be explained to you. A booklet called **Anticoagulant Therapy Record** will be given to you. The book provides an ongoing record of your blood tests and warfarin dosage. Remember to take this book with you when you visit whoever is monitoring your warfarin or any other health professional such as your doctor or dentist. You will also be given an **Alert Card** which says that you are taking warfarin and names the clinic which deals with your warfarin dosing. Please carry this with you at all times as it will be important in the event of an emergency to inform any healthcare professionals dealing with your care.

## When should I take my warfarin?

The usual advice is to take your warfarin at around 6pm each evening. This is useful if your dosage has to be changed on the same day as a blood test which is usually done in the morning. However it is more important that you remember to take your tablets every day at around the same time, so if it is easier and more convenient to take your warfarin at a different time of day then that is what you should do. Try to find a system that helps you to remember to take it. For example take the warfarin half an hour before your evening meal then you will associate the taking of warfarin with eating your meal and it should help you to remember.

## What if I miss a dose?

If you forget to take your warfarin at your usual time but remember it later on the same day then take it later when you remember. If it is the following day when you remember then do not take a double dose but make a note of the date and tell whoever is monitoring your warfarin at the next visit. If you take warfarin because you have a metal heart valve you should seek the advice of your clinic when you remember you have missed a dose.

## **What if I take the wrong dose?**

If you make a mistake and find that you have been taking the wrong dose or you accidentally take too much warfarin then you should contact the anticoagulation clinic or your GP as soon as possible.

## **Where do I get supplies of warfarin?**

You should always obtain further supplies of warfarin from your GP before you run out of tablets. Take your record book to the surgery and the doctor will provide you with a prescription. Your community pharmacist will also want to see your record book when dispensing your warfarin tablets. If your prescription is collected for you, please ensure that the person dealing with this has your warfarin dosing record with them. If you pay for prescriptions and are taking additional medication as well as warfarin you may save money by using a Pre-Payment Certificate. Instructions on how to obtain this certificate can be obtained by telephoning **0845 8500030**.

## **Are there any side effects from warfarin?**

The most important side effect of warfarin is a tendency to bruise and bleed. By careful monitoring with blood tests we can control the bleeding tendency. Nevertheless, if you knock yourself you will probably bruise more easily. If you feel the bruising is excessive then ask your GP or Clinic Nurse for advice.

If the bleeding is continuous then you should attend Accident and Emergency as there may be a reason for the bleeding which requires urgent medical attention.

### **If you observe:**

- blood in urine or faeces
- excessively heavy periods (obviously in women)
- nose bleeds
- coughing up blood

**you should seek advice from your anticoagulation clinic or your GP.**

You should also inform whoever is monitoring your warfarin dose. Warfarin can have other side effects such as rash, hair loss, nausea, diarrhoea and headaches. These are extremely rare but if they do occur they frequently disappear within a short time of starting the drug. It is important to note that there may be other reasons for such effects and it would be unwise to assume they are caused by warfarin without considering other possibilities. It is best to seek the advice of your GP.

## **How can I help to avoid bleeding?**

You should make every effort to safeguard against cutting or injuring yourself:

Some useful advice:

- If you shave - use electric or battery razors
- Use a soft toothbrush for cleaning teeth
- Wear gloves for gardening
- Always wear shoes or slippers to protect your feet
- Seek advice on the kind of sport you wish participate in

## What do I do if I cut myself or have a nose bleed?

If you should cut yourself, apply a clean cloth and press on the wound for at least 5 -10 minutes. If after twenty minutes you are still bleeding you should consult your GP or Accident and Emergency Department. If you experience a nose bleed; apply ice and nip the soft part of nose whilst sitting up in a comfortable position. If the bleeding still hasn't stopped in fifteen minutes you should seek advice from the nearest Accident and Emergency Department.

## Do other illnesses affect my warfarin?

When you are ill it will generally have an effect on your warfarin requirement and you should inform the clinic or your GP. Certainly if you become ill with fever, vomiting or diarrhoea, which lasts more than 48 hours you should seek advice from your clinic or GP as this may change your sensitivity to warfarin and require your dose to be adjusted. This can best be decided by doing a blood test.

## What about other medication?

Many medicines will affect the action of warfarin. Here is a short list of those that are well known to affect warfarin:

**Antibiotics:** e.g. amoxicillin, metronidazole, erythromycin.

**Antifungals:** e.g. terbinafine, miconazole, fluconazole.

**Anti-epileptic/Anti-spasmodics:** e.g. phenytoin, carbamazepine, gabapentin.

**Heart Medication:** e.g. amiodarone.

**Cholesterol lowering drugs:** e.g. simvastatin

**Pain relief (analgesics)** e.g. morphine, dihydrocodeine, tramadol

**Thyroxine:** e.g. levothyroxine

**Gastric Medication:** e.g. omeprazole, lansoprazole.

**Sex hormones:** including the contraceptive pill and HRT

**Alternative medicines:** e.g. ginko biloba, ginseng.

Because these medicines might affect your warfarin dose this does not mean that you should not have them. If a doctor has prescribed them for you then you need them.

**Whenever you are either prescribed a new medicine or a doctor stops one of your regular medicines you must inform whoever is managing your warfarin dosing as soon as possible. You will probably need**

Don't worry about any medications you are already taking prior to starting warfarin, given that whoever is monitoring your warfarin is aware of them. If any doctor prescribes a new drug for you, remember to tell him that you are taking anticoagulants and also inform whoever is monitoring your warfarin. If you want to take any over the counter medicines including alternative remedies, you should first discuss this with your local pharmacist and tell them you are taking warfarin.

## What medicines should I avoid?

Aspirin also helps to prevent clotting and on rare occasions a doctor may advise you to take both aspirin and warfarin but this is unusual. **So you should not take aspirin and warfarin together unless your Doctor or Hospital Consultant advises you to do so.**

Anti-inflammatory drugs used to treat arthritis, e.g. ibuprofen or diclofenac, can inflame the stomach lining which can cause bleeding. This bleeding may become quite serious when you are also taking warfarin so you should only take them if they are prescribed by a doctor. Some of these medicines can be bought over the counter with different names such as Nurofen (ibuprofen) so **please take care.**

## What pain killers can I take?

You can safely take paracetamol or cocodamol - up to 4 tablets each day. If you require 6-8 tablets a day you should inform whoever is managing your warfarin dose.

Some paracetamol and codeine based pain killers, which you can buy over the counter at the pharmacist, can also contain aspirin. You should always check before you buy them as, generally speaking, aspirin should be avoided if you are taking warfarin. If you are ever prescribed stronger pain-killers than paracetamol/co-codamol then please inform whoever is managing your warfarin dose immediately.

## What about vaccination?

Some vaccines may increase or decrease the action of warfarin. This does not mean you should not be vaccinated but that some alteration in your warfarin dosage may be necessary. You must inform whoever is managing your warfarin dose of any vaccinations you require. If you plan to have a flu vaccine you should inform the clinic so that you can have your blood tested within a week of receiving it.

## What can I eat and drink?

You should eat a well-balanced diet, one which ideally should be high in fibre and include some fruit and vegetables each day. The best advice is that you should not eat or drink excessive amounts of any one kind of food or drink. Certain foods, if consumed in **large amounts** can certainly affect your blood results. These are, green leafy vegetables, liver, egg yolks, blue cheeses, avocado and olive oil. This does not mean that you cannot eat them if you are careful to avoid large quantities.

Cranberry juice may have an effect on warfarin and should be avoided. Chamomile Tea has also been reported to affect warfarin control.

Anticoagulants can be affected by special slimming diets e.g. Slimming World or Weight Watchers mainly because you change the amounts of fruit and vegetables that you eat. Please inform your Anticoagulation Clinic if you intend to change your diet or lose weight.

## Can I drink alcohol?

Yes, you can still enjoy a drink! Alcohol increases the effect of warfarin but a daily ration of 2 units is acceptable.

Don't save it all up for one or two nights, but spread it out over the week.

**1 unit = ½ pint beer or lager or cider or**

**1 small glass of wine or**

**1 pub measure of spirit**

If you change greatly the amounts of alcohol you take on a daily basis it will be difficult to find a stable dose for you and you will require more blood tests.

Alcohol contributes to heart disease so it is advisable to reduce the amount you drink to about 14 units per week.

## **What happens when I go on holiday?**

Before you go on holiday it is advisable to have a blood test just before you go especially if your holiday is abroad. Take enough warfarin with you to last the entire holiday and a bit extra! If you need to have vaccinations or take malaria tablets, make sure that whoever prescribes them is aware you are taking anticoagulants and also inform whoever is monitoring your anticoagulation that you are taking them.

If you are flying, don't sit for the whole flight - stretch your legs from time to time, avoid alcohol and drink plenty of water and soft drinks. Wear support stockings and do gentle leg exercises whilst sitting. Whilst on holiday eat a healthy balanced diet, don't indulge in excess alcohol and ensure you have adequate amounts of fluid to prevent you from becoming dehydrated.

## **What if I am planning a pregnancy?**

Warfarin can affect the development of a baby in early pregnancy. Women, who are on warfarin, should discuss plans for future pregnancy with their doctor before trying to conceive. If you think you have become pregnant while on warfarin you should have a pregnancy test as soon as possible and if this is positive make an urgent appointment with your doctor. There are methods of reducing the risks of developing clots during pregnancy which are different to warfarin although they usually require injections.

### **Don't Forget**

By following a few simple rules warfarin treatment will become part of your daily routine. Remember if it has been prescribed for you then it is beneficial for you. A large amount of medical research has shown it helps to improve your condition, and quality of life and may help you live for longer!

**Let us know of any changes to your medications, address or telephone number.**

If you have any questions the nurse at your Outpatient Clinic or your GP practice is there to help you.

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## Appendix 7

### 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 Sheffield Medicines Management Team for advice.

Interacting Drug	Potential problem	Comment
Alcohol	Increases anticoagulant effect of warfarin	Fluctuations in prothrombin time in heavy drinkers or patients with liver disease.
Allopurinol	Increases anticoagulant effect of warfarin	Uncommon but unpredictable interaction – monitor INR more closely when allopurinol started.
Aminoglutethamide	Reduces anticoagulant effect of warfarin	Effect appears to be related to dose of aminoglutethamide. May need up to four times the dose of warfarin.
Amiodarone	Increases anticoagulant effect of warfarin	The onset of this interaction may be slow and may persist after amiodarone has been withdrawn.
Amitriptyline	Unpredictable increase or reduction in anticoagulant effect	Monitor INR closely. INR may be difficult to control in patients taking tricyclic antidepressants.
Anabolic Steroids (e.g. danazol, stanozolol)	Increases anticoagulant effect of warfarin	Interaction develops rapidly, possibly within 2 or 3 days.
Aspirin	Increases anticoagulant effect of warfarin	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.
Azapropazone	Increases anticoagulant effect of warfarin	Significant risk of bleeding. Concurrent use NOT recommended.
Azathioprine	Reduces anticoagulant effect of warfarin	Warfarin dose may need to be increased when azathioprine started and reduced if azathioprine is stopped.
Barbiturates (e.g. Phenobarbital)	Reduces anticoagulant effect of warfarin	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.
Bezafibrate	Increases anticoagulant effect of warfarin	Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).
Boldo	May increase anticoagulant effect of warfarin	Modest rise in INR seen in a patient taking Boldo and Fenugreek.

<b>Interacting Drug</b>	<b>Potential problem</b>	<b>Comment</b>
Carbamazepine	Reduces anticoagulant effect of warfarin	Dose of warfarin may need to be increased (up to double dose). Oxcarbamazepine does not appear to interact.
Cefaclor	Increases anticoagulant effect of warfarin	Cefuroxime, cefalexin or cefradine are safer alternatives.
Celecoxib	Increases anticoagulant effect of warfarin	Rare cases of increased INR and bleeding reported.
Cimetidine	Increases anticoagulant effect of warfarin	Unpredictable but common interaction. Use ranitidine instead.
Ciprofloxacin	May increase the anticoagulant effect of warfarin	Rare and unpredictable interaction. Monitor INR. Use alternative antibiotic if possible.
Ciprofibrate	Increases anticoagulant effect of warfarin	Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).
Clarithromycin	Increases anticoagulant effect of warfarin	Marked increase in INR has been reported. If a macrolide is required, Azithromycin is a safer alternative.
Clofibrate	Increases anticoagulant effect of warfarin	Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).
Clopidogrel	Mild bleeding can occur even though INRs remain stable and within range.	Increased risk of bleeding due to antiplatelet effect. Manufacturer advises avoid concomitant use.
Colestyramine	Reduces anticoagulant effect of warfarin by preventing the absorption of warfarin.	Separating the dosages as much as possible may minimise the effects of this interaction.
Coenzyme Q10	Reduces anticoagulant effect	Monitor INR. Avoid use of products containing coenzyme Q10.
Oral contraceptives	Reduces anticoagulant effect of warfarin	Generally avoided in thromboembolic disorders
Co-proxamol	Increases anticoagulant effect of warfarin	Uncommon and unpredictable. Use Paracetamol as a safer alternative.
Corticosteroids	Variable response	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.
Cranberry Juice	Increases anticoagulant effect of warfarin	Avoid use in patients taking warfarin.
Cytotoxics	Increases anticoagulant effect of warfarin reported with some cytotoxics	Refer patients on concurrent cytotoxic agents to secondary care for management of anticoagulation

<b>Interacting Drug</b>	<b>Potential problem</b>	<b>Comment</b>
Danshen	Increases anticoagulant effect of warfarin	Advise patients not to use Danshen whilst taking warfarin.
Devil's Claw	Increases anticoagulant effect of warfarin	Bleeding disorders visible on the skin (purpura) have been reported.
Diclofenac	Cases of bleeding reported with concomitant use.	Unpredictable – monitor INR & adverse effects. Avoid if possible. Ibuprofen or Naproxen are less likely to interact with warfarin.
Diflunisal	Increases anticoagulant effect of warfarin	Unpredictable – monitor
Dipyridamole	Mild bleeding sometimes occur even though INRs remain stable and within range.	Increased risk of bleeding due to antiplatelet effect.
Disulfiram	Increases anticoagulant effect of warfarin	Review concurrent use of warfarin in patients requiring Disulfiram.
Dong quai ( <i>Angelica sinensis</i> )	Reports of marked increases anticoagulant effect of warfarin	Advise patients not to use Dong quai whilst taking warfarin. Increased bleeding time & bruising.
Erythromycin	Increases anticoagulant effect of warfarin	Serious but unpredictable. The elderly are at greater risk. Monitor closely.
Esomeprazole		Monitor INR if adding or stopping esomeprazole.
Fenofibrate	Increases anticoagulant effect of warfarin	Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).
Feverfew	Altered bleeding time reported	Advise patients not to use Feverfew whilst taking warfarin. Monitor INR.
Fluconazole	Increases anticoagulant effect of warfarin	Monitor and reduce warfarin dose accordingly.
Flurbiprofen	Cases of bleeding reported with concomitant use.	Unpredictable – monitor INR & adverse effects. Avoid if possible.
Flutamide	Increases anticoagulant effect of warfarin	Monitor and reduce warfarin dose as necessary.
Garlic	Case reports of increased anticoagulant effect of warfarin	Advise patients NOT to take garlic supplements. Regular ingestion of foods containing garlic should not pose a problem.
Gemfibrozil	Increases anticoagulant effect of warfarin	Bleeding is likely if the anticoagulant dose is not reduced appropriately (between one-third to one-half and then adjusted as per INR).

<b>Interacting Drug</b>	<b>Potential problem</b>	<b>Comment</b>
Gingko Biloba	Isolated reports of increased risk of bleeding	Advise patients not to use Gingo Biloba whilst taking warfarin.
Ginseng	Reports of spontaneous bleeding in patients using Ginseng without anticoagulants	Ginseng contains antiplatelet components, so avoid use in patients taking warfarin.
Grapefruit juice	Increases anticoagulant effect of warfarin	May cause a modest rise in INR
Glucagon	Large doses ( $\geq 50$ mg over 2 days) increase anticoagulant effect of warfarin	Reduce dose of warfarin & monitor INR closely. Smaller doses (total of 30mg) are reported not to interact.
Glucosamine	Reports of increases in INRs	Patients on warfarin are recommended not to take Glucosamine
Glucosamine / Chondroitin	Increased risk of bleeding	Chondroitin has anticoagulant activity and should be avoided in warfarin patients.
Griseofulvin	Reduces anticoagulant effect of warfarin	Unpredictable (effects some but not all patients) – monitor INR
Indometacin	Indometacin inhibits platelet aggregation and so prolongs bleeding.	Avoid NSAIDs in patients taking warfarin if possible. If concurrent use essential, monitor INR closely.
Influenza vaccine	Usually safe & uneventful, but small numbers of bleeding episodes reported.	Evidence shows that influenza vaccination in those taking warfarin is normally safe & uneventful. Advise patient to report any unexplained bleeding.
Itraconazole	Case report of increased anticoagulant effect of warfarin	Monitor and reduce dose if necessary. Advise patients to report any unexplained bruising or bleeding.
Ketoconazole	Case reports of increased anticoagulant effect of warfarin	Monitor and reduce dose if necessary. Elderly at greater risk. Advise patients to report any unexplained bruising or bleeding.
Ketorolac (oral)	Serious risk of gastrointestinal bleeding	Oral Ketorolac is contra-indicated in patients taking warfarin.
Metronidazole	Increases anticoagulant effect of warfarin	If concurrent use cannot be avoided, reduce the warfarin dose by between one-third and one-half and monitor closely.
Miconazole	Increases anticoagulant effect of warfarin	Avoid -Potentially serious interaction. Use Nystatin instead.
Non-Steroidal Anti-inflammatory Drugs (NSAIDs)	NSAIDs irritate stomach lining and reduce platelet aggregation	Avoid where possible. If concomitant use cannot be avoided, monitor INR and adverse events. Ibuprofen or Naproxen are less likely to interact with warfarin.

<b>Interacting Drug</b>	<b>Potential problem</b>	<b>Comment</b>
Omeprazole	Increases anticoagulant effect of warfarin	A small change in INR may be seen. Occasionally clinically significant interactions occur. Use Lansoprazole as an alternative.
Papaya	Increases anticoagulant effect of warfarin	Avoid use in patients taking warfarin. Monitor INR.
Paracetamol	Increases anticoagulant effect of warfarin when large doses are used over a prolonged time.	Intermittent use (<2.5g/week) unlikely to effect INR. A reduction in warfarin dose may be needed for regular paracetamol users.
Penicillins	Increases and decreases in the anticoagulant effect of warfarin have been seen.	Uncommon and unpredictable effect. Close monitoring of INR recommended.
Phenytoin	Can increase or reduce anticoagulant effect of warfarin	Monitor INR and adjust dose of warfarin accordingly.
Piroxicam	Increases anticoagulant effect of warfarin	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.
Rifampicin / Rifabutin	Markedly reduces anticoagulant effect of warfarin	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.
Simvastatin	Generally small, clinically irrelevant increase in anticoagulant effects	Monitor initially or after dose increases of Simvastatin.
St John's Wort	Moderate reduction in the anticoagulant effects of warfarin	CSM advises stopping St John's Wort and adjusting the dose of warfarin as necessary.
Sulindac	Increases anticoagulant effect of warfarin	Uncommon and unpredictable – monitor INR. Avoid NSAIDs where possible. Ibuprofen or Naproxen less likely to interact.
Tamoxifen	Markedly increases anticoagulant effect of warfarin	Monitor and reduce warfarin dose as necessary – may need to reduce dose by half.
Thyroid hormones	Increases anticoagulant effect of warfarin	Monitor and adjust warfarin dose as necessary. Warfarin dose may need to be changed as thyroxine doses are altered.
Vitamin K	Anticoagulant effects of warfarin are reduced or abolished	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.

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1. Stockley's Drug Interactions 6<sup>th</sup> Edn. (2002). Ed. Ivan H Stockley. Pharmaceutical Press, London.
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3. Ernst, E, Ewings P et al., Co-ingestion of herbal medicines and warfarin. British Journal of General Practice (2004; 50: 439-441).
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5. Interactions between complimentary medicines and conventional medicines. National Collaborative Medicines Management Services Team of East Birmingham PCT, October 2002.

## Appendix 8

### STH WARFARIN SLOW START REGIMEN

This warfarin induction regimen<sup>1</sup> should be used for both inpatient and outpatient initiation of warfarin for suitable patients (see indications and exclusions below).

For outpatient use, patients should be referred to RHH or NGH anticoagulant clinics using the Anticoagulation Referral Form, stating indication and marked 'Slow-start regimen'.

If started as an inpatient, follow regimen below. At discharge, refer patient to the RHH or NGH anticoagulant clinic using the Anticoagulation Referral Form, accompanied by a copy of the warfarin prescription chart(s).

All patients referred to the Anticoagulant clinic are seen within 7 days or earlier if clinically indicated.

#### Background

Patients not requiring rapid anticoagulation can be safely managed using a slow loading regimen which results in therapeutic anticoagulation within 3-4 weeks in the majority of patients. This appears to avoid over-anticoagulation and bleeding associated with rapid loading<sup>2</sup>.

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;
- 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.

#### **Aim:**

To initiate warfarin therapy with a target INR 2.5

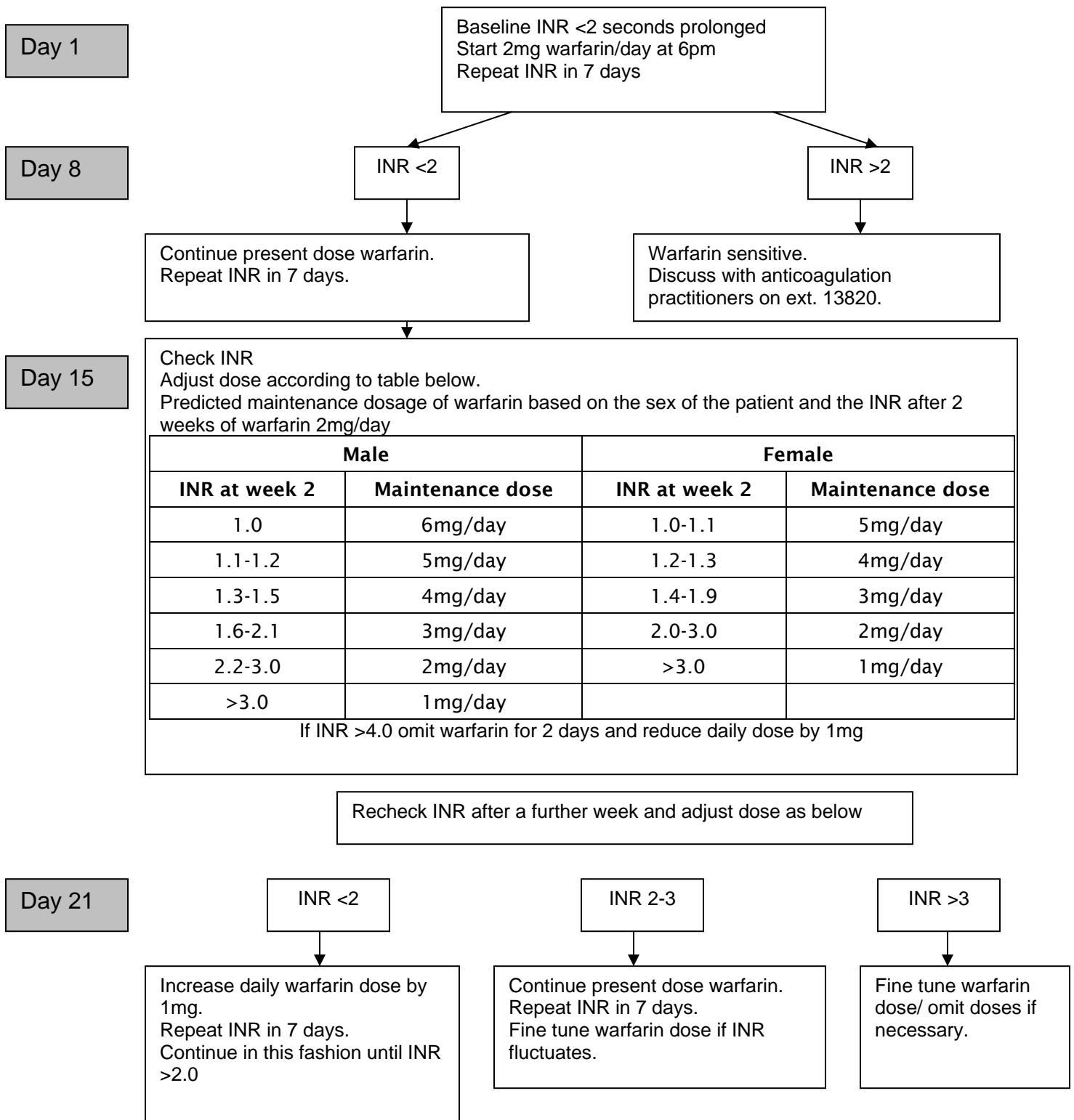
#### **Regimen:**

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. If in doubt, discuss with the patient's consultant. If baseline prothrombin time is >2 seconds prolonged, seek haematology advice.
3. Explain to the patient the indication for warfarin treatment and the risks and benefits of it.
4. Prescribe 2mg of warfarin daily at 6pm for 1 week. For inpatients prescribe on the warfarin prescription and monitoring chart. **Clearly mark the indication: Atrial Fibrillation Slow Start Regimen and cross through the dosing chart on the reverse of the warfarin chart.**
5. Repeat INR after a further 7 days of warfarin therapy.
6. Adjust dose as per nomogram **overleaf**.
7. At discharge refer to the anticoagulant clinic using the Anticoagulation Referral Form, accompanied by a copy of the warfarin prescription chart(s).
8. If unsure or concerned about the patient's anticoagulation, refer to the anticoagulation practitioners (RHH ext. 13820).

#### **References**

1. Oates A. Jackson P.R. Austin C.A. Channer K.S. A new regimen for starting warfarin anticoagulation in out-patients. *British Journal of Clinical Pharmacology* 1998 46 157-61
2. Guidelines on oral anticoagulation (warfarin): third edition- 2005 update *British Committee for Standards in Haematology* [www.bcsghguidelines.com/pdf/OAC\\_guidelines\\_190705.pdf](http://www.bcsghguidelines.com/pdf/OAC_guidelines_190705.pdf)

## NOMOGRAM FOR WARFARIN SLOW START REGIMEN



By the time the patient has been taking warfarin for 6 weeks the INR should be in the therapeutic range. Fine tuning of the warfarin dose by using alternate day regimens (e.g. 2mg/3mg alternate days) can be used if INR fluctuating.

Discuss any queries with the anticoagulation practitioners (ext. 13820).

Any bleeding complications must be discussed with a haematology registrar (bleep via switchboard).

## **Appendix 9**

### **Training courses**

#### **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:

[http://www.anticoagulation.org.uk/training-info\\_3day.php](http://www.anticoagulation.org.uk/training-info_3day.php)

**Appendix 10**

**Near Miss, Incident and Serious Untoward Incident Reporting form**

(For use when reporting incidents relating to the anticoagulation service)

Date of Incident:

Practice details:

Name and number of contact person:

Details of the near miss, incident, or serious incident:

Action taken:

Outcome:

Will there be significant event analysis YES/NO

**Please fax this form to David Barker at the Risk Management Department on 0114 226 4051.**

**Please ensure that near misses and incidents are reported within 72 hours and serious untoward incidents are reported within 24 hours**

## **Appendix 11**

### **National External Quality Assessment Scheme (NEQAS)**

Sheffield PCT 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. This is available through NEQAS for blood coagulation via the laboratory at the Royal Hallamshire Hospital. Sheffield PCT funds the annual subscription fee in the LES.

#### **Registration**

To participate in the NEQAS scheme a registration form should be completed and returned to Sheffield PCT'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 Sheffield PCT. At present the Coaguchek XS machine is not part of the NEQAS scheme, but this is likely to change in the near future, and those practices using this version of the Coaguchek machine will be sent out a registration form in due course. If the practice has two machines based on different sites, then a registration form will need to be completed for both sites / machines.

#### **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. At the time of going to press, the total number of participants is just over 600.

#### **Performance analysis**

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

### **UK National External Quality Assessment Scheme for Blood Coagulation**

**Rutledge Mews**

**3 Southbourne Road**

**Sheffield**

**S10 2QN**

**Tel:0114 2673300**

## Appendix 12

### Guidelines for the management of over-anticoagulation

For those providers using near patient testing, instructions on appropriate further testing when high INR results are recorded is given at paragraph 17.10 onwards, page 10.

<b>Major Bleeding</b>	
All patients	Treat as a medical emergency and admit to hospital

<b>INR &gt; 8.0 with no bleeding manifestation</b>	
All patients	<p>If using near patient testing, send a venous sample to the central laboratory for testing to obtain INR estimation.</p> <p>Discuss with the on-call haematology doctor</p> <p>Omit warfarin;</p> <p>Give oral Vitamin K (Konakion MM Paediatric™ 2mg in 0.2ml); 1-2mg as advised by Haematologist;</p> <p>Repeat INR test following day.</p> <p><i>If this falls on a weekend or bank holiday it is the responsibility of the prescribing GP to ensure the test is done (either via the hospital or district nursing service) and the results acted upon.</i></p>

<b>INR 6.0 – 8.0 (with no bleeding or minor bleeding, e.g. epistaxis)</b>	
High risk patients	<p>Omit warfarin;</p> <p>Consider giving oral Vitamin K (Konakion MM Paediatric™ 2mg in 0.2ml); 1-2mg as advised by Haematologist</p> <p>Repeat INR test following day.</p> <p>Restart Warfarin as per guidelines in Appendix 5.</p>
Low risk patients	<p>Omit warfarin;</p> <p>Restart warfarin as per guidelines in Appendix 5.</p>
<p>1 High risk: age &gt; 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.</p>	

The primary care provider should complete the Patient Over-anticoagulation Report (Appendix 7) and send a copy to the patient's registered GP.

## **Vitamin K Protocol**

Konakion MM Paediatric™ (phytomenadione 10mg/ml) 0.2ml ampoules should be used to manage high INRs in the community as per the protocol below. 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 (0.1ml = 1mg, 0.2ml = 2mg);
- Hold dispenser in patient's mouth (at the back of the tongue) and press plunger;
- Offer patient a glass of water as the solution has a very bitter taste.

### **How to obtain Konakion MM Paediatric™**

All 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 13**

**Patient Over-Anticoagulation Report**

Dear Dr. \_\_\_\_\_

Date: \_\_\_\_\_

Your patient \_\_\_\_\_

Patient Name

Patient Number

Has been seen at the anticoagulation clinic today for their warfarin therapy.

His/Her INR reading today was \_\_\_\_\_

This reading is possibly due to: \_\_\_\_\_

Previous two INR readings, dates and doses were:

Date:                      INR:                      Dose:

Date:                      INR:                      Dose:

The following action has been taken with this patient (please tick as appropriate)

- ( ) Patient sent to the anticoagulation department at \_\_\_\_\_ hospital.
- ( ) Patient has been admitted to \_\_\_\_\_ by the hospital anticoagulation team
- ( ) Vitamin K given by \_\_\_\_\_
- ( ) Sent home with the following instructions:

Additional Relevant Information

**Signed:** \_\_\_\_\_ **Name:** \_\_\_\_\_

**GP Practice / Pharmacy:** \_\_\_\_\_

## Audit Proforma for Providers of Anticoagulation Management Services in Primary Care

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

Location of anticoagulation management clinic:  
 .....

Name of others involved in anticoagulation management clinic:  
 .....

GPs:	Practice Nurses:	Other (state designation):

### TRAINING

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

	GPs:	Practice Nurses:	Other:
<b>Clinical</b>			
Sheffield Hallam Course			
Birmingham University 3-day Course			
Birmingham University Updates			
BMJ Learning Modules			
CPPE Workbook			
<b>Non-Clinical</b>			
INRStar Training			
Coaguchek Training			

Please give details of any prior knowledge and experience:  
 .....  
 .....  
 .....

Please indicate guidelines used in your anticoagulation management clinic:  
 (Tick all relevant boxes)

- British Committee for Standards in Haematology guidelines on oral anticoagulation
- NHS Sheffield Standard Operating Procedure
- Other (please state)

.....  
 .....

**REGISTER**

Do you have a register of warfarin patients?  Yes  No

If yes, how many patients are on the register? .....

Who manages your patient's anticoagulation?

	No Patients	%
In-house clinic		
Hospital		
Unknown		

What strengths of warfarin are your patients prescribed?

	No Patients	%
0.5mg		
1mg		
3mg		
5mg		

**SAFETY INDICATORS**

Do you provide a level 5 anticoagulation service?  Yes  No  
 (e.g. initiate warfarin for AF patients in primary care) (Complete A+B) (Complete B only)

**A. For patients starting oral anticoagulation treatment in the last 12 months:**

	No Patients
How many patients have been started on oral anticoagulants in primary care in the last 12 months?	
How many of these patients followed a slow start protocol?	
How many of these patients had a major bleed in the first month of anticoagulant therapy?	
How many of these patients had a major bleed with INR above therapeutic range?	
How many patients were referred to your anticoagulation management clinic with incomplete information (e.g. diagnosis, target INR, stop date, dosage on discharge)?	
How many patients were not issued with patient-held information and written dosage instructions at the start of therapy?	

How many patients were discharged from hospital without an appointment for their next INR check or an appointment to discuss their anticoagulation?	
---	--

**B. For patients established on oral anticoagulation treatment:**

	No Patients
Percentage of patients who are within their INR target more than 50% of the time:	%
In the last 12 months, how many INR tests were taken?	
How many of these INR tests were between 5.0 and 8.0?	
How many of these results were above 8.0?	
How many patients were admitted to hospital with INR above 5.0?	
How many patients were lost to follow-up?	
In how many patients is the diagnosis unknown?	
In how many patients is the target INR unknown?	
In how many patients is the stop date unknown?	
How many patients have gone past their stop date?	
How many patients have an inappropriate target INR for their diagnosis?	
How many patients do not have written patient information?	
How many patients are given written dosage instructions at each clinic visit?	
How many patients do not have appropriate clinical information on their records (e.g. diagnosis, target INR, last dosing record)?	

**FOLLOW-UP**

What systems do you have in place to ensure that patients are not lost to follow-up?  
*(Tick all relevant boxes)*

- Patients re-booked into follow-up appointment at end of current appointment
- DNAs followed up by telephone
- DNAs followed up by letter
- Overdue patients on INRStar checked at end of clinic
- Other (please state)

.....  
 .....

**PATIENT INFORMATION**

What verbal and written patient information relating to anticoagulation do you provide?  
*(Tick all relevant boxes)*

- Patient information leaflet 'Living with Anticoagulants'
- Yellow anticoagulation book
- Verbal explanation at first appointment which is followed up at each INR clinic visit
- Other (please state)

.....  
 .....

**CARE HOMES**

How many anticoagulated patients reside in care homes?.....

What systems do you use to communicate changes to patients in care homes?  
*(Tick all relevant boxes)*

- Telephone nurse in charge with dose and review date
- Fax written instructions for dose and review date
- Post written instructions for dose and review date
- Other (please state)

.....  
 .....

**MONITORED DOSE SYSTEMS**

How many anticoagulated patients use Monitored Dose Systems? .....  
 (e.g. NOMAD)

What systems do you use to communicate changes to patients using monitored Dose Systems?  
*(Tick all relevant boxes)*

- Telephone pharmacist with dose and review date
- Fax written instructions for dose and review date to pharmacy
- Post written instructions for dose and review date to pharmacy
- Other (please state)

.....  
 .....

**THANK YOU FOR YOUR TIME**

**Please return your completed form to:**

Rachel Smith  
 Clinical Audit & Effectiveness Officer  
 NHS Sheffield  
 722 Prince of Wales Road  
 Sheffield  
 S9 4EU

By .....

## Appendix 15

### Useful Contacts

#### STHFT anti-coagulation clinics

Hallamshire	Switchboard	271 1900
Northern General	Switchboard	243 4343
Rhona Maclean	Haematology Consultant (based at RHH)	Ext. 12484
Linda Carver	Clinical Nurse Specialist	271 3820
Stuart Rollings	Clinical Nurse Specialist	271 3820
Lesley Lyons	Nurse Practitioner	271 3820

#### Patient yellow booklets *These are free to practices*

Family Health Services	General Office	271 1002
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#### NHS Sheffield

Dr Richard Oliver	GP, Joint PEC Chair <a href="mailto:richard.oliver@gp-c88039.nhs.uk">richard.oliver@gp-c88039.nhs.uk</a>
Peter Magirr	Head of Medicines Management <a href="mailto:peter.magirr@sheffieldpct.nhs.uk">peter.magirr@sheffieldpct.nhs.uk</a>
Laura Godden	Clinical Practice Pharmacist <a href="mailto:laura.godden@sheffieldpct.nhs.uk">laura.godden@sheffieldpct.nhs.uk</a>
Sam Lindop	Senior Finance Manager (GP contracts) Tel: 3051283 <a href="mailto:sam.lindop@sheffieldpct.nhs.uk">sam.lindop@sheffieldpct.nhs.uk</a>

#### British Committee for Standards in Haematology

*Guidelines on oral anticoagulation (Warfarin): third edition - 2005 update at:*  
[www.bcshguidelines.com/pdf/OAC\\_guidelines\\_190705.pdf](http://www.bcshguidelines.com/pdf/OAC_guidelines_190705.pdf)

#### Roche

##### Orderline 0808 100 76 66

Charles Adebayo, Roche Representative

Mobile: 07738 574199 Email: [charles.adebayo@roche.com](mailto:charles.adebayo@roche.com)

#### National External Quality Assessment Scheme (NEQAS)

UK National External Quality Assessment Scheme for Blood Coagulation

Rutledge Mews, 3 Southbourne Road, Sheffield S10 2QN

Tel: 267 3300 Email: [neqas@coageqa.org](mailto:neqas@coageqa.org)

## Full equalities impact assessment

Directorate: Standards & Engagement

Service: Medicines Management Team

Piece of work being assessed: Anticoagulation Monitoring Service: Standard Operating Procedure for the provision of a Level 3, 4 and 5 Anticoagulation Service

Name of lead person: Laura Godden

Other partners/stakeholders involved:

Date of assessment: July 2008

<b>Single Equality Scheme strand</b>	<b>Baseline data and research –</b> What is available? What does it show? Are there any gaps? Use both quantitative and qualitative research and user data Include consultation with users if available	<b>Is there likely to be a differential impact?</b> If 'yes', is that impact direct or indirect discrimination?
<b>Gender</b>	Incidence of atrial fibrillation is higher in men than women <sup>1</sup> . No information available on the incidence of thromboembolism, PE, valvular heart disease in different genders.	No
<b>Race</b>	No information available regarding the proportion of different races who are anticoagulated or the incidence of indications for anticoagulation. Sheffield City Council figures for 2005 show that the population of Sheffield is 86% white British. Of the remaining 14%, 3% are Pakinstani, 2% are Eastern European (mainly Polish and Slovak). Other minority populations include Caribbean, Indian, Bangadeshi, Somali, Yemeni and Chinese.	Unknown
<b>Disability</b>	No information available	Unknown
<b>Sexual orientation</b>	No information available	No

<b>Age</b>	Incidence of atrial fibrillation and deep vein thrombosis/pulmonary embolism requiring anticoagulation increases with increasing age although age is not an independent risk factor <sup>1,2,3</sup> . Children under 16 years should be managed by a paediatrician and a haematologist.	No
<b>Religion/belief</b>	No information available	No

### References

1. Ruigomez, A. et al. Incidence of chronic atrial fibrillation in general practice and its treatment pattern. *Journal of Clinical Epidemiology*. 2002. 55: 358-363
2. Feied, C.F. and Handler, J.A. Pulmonary Embolism. [www.emedicine.com](http://www.emedicine.com) June 7<sup>th</sup> 2006
3. Bandolier 110. Independent evidence based health care. 2003. Vol 10, Issue 4. [www.ebandolier.com](http://www.ebandolier.com)

## Equalities Impact Assessment Action Plan

Strand	Issue	Action required	How will you measure the impact/outcome?	Timescale	Lead
Gender	The initial assessment of the SOP does not indicate any likelihood of a differential impact.	No action required	N/A	N/A	N/A
Race	Potential discrimination through possible language barrier.	Obtain evidence	Audit	12months	Laura Godden
Disability	Potential discrimination against patients with communication problems, learning difficulties and housebound patients and others that cannot access provider.	Obtain evidence	Audit	12months	Laura Godden
Sexual orientation	The initial assessment of the SOP does not indicate any likelihood of a differential impact.	No action required	N/A	N/A	N/A
Age	The initial assessment of the SOP does not indicate any likelihood of a differential impact. Children under 16 year are excluded from the SOP for safety	No action required	N/A	N/A	N/A
Religion/belief	The initial assessment of the SOP does not indicate any likelihood of a differential impact.	No action required	N/A	N/A	N/A