Bedfordshire Community Health Services

NHS

SERVICE OPERATIONAL POLICY

BEDFORD WARFARIN SERVICE

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AUTHOR	Dupe Fagbenro –Lead Pharmacist BCHS Jaison Mathew – Lead Clinician Bedford Warfarin Service Michelle Warke – Senior Anticoagulation Nurse Helen Willis – Senior Anticoagulation Nurse
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SERVICE OPERATIONAL POLICY FOR BEDFORD WARFARIN SERVICE

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SERVICE OPERATIONAL POLICY FOR BEDFORD WARFARIN SERVICE

This procedure standardises the process for accepting and managing Warfarin anticoagulated patients in the Bedford Warfarin Service. The procedure is drawn from national and local guidelines e.g. NPSA Patient Safety Alert NPSA/2007/18: Actions That Can Make Anticoagulant Therapy Safer.

1.0 INTRODUCTION

1.1 Warfarin is a vitamin K antagonist oral anticoagulant indicated for the prophylaxis of systemic embolism in patients with rheumatic heart disease, atrial fibrillation and after insertion of prosthetic heart valves, as well as the treatment of venous thrombosis and pulmonary embolism; and transient attacks of cerebral ischaemia.

1.2 Warfarin has a narrow therapeutic index and so people receiving warfarin are at risk of under-coagulation, which can result in thrombosis, and over-coagulation, which can result in haemorrhage. Both of these can cause serious illness or death. It is therefore necessary to regularly monitor the international normalised ratio (INR) to allow adjustments to be made to the dose of Warfarin so as to minimise adverse events.

1.3 The monitoring of anticoagulation for patients taking oral anticoagulants has traditionally been performed in hospital anticoagulation clinics, however there are benefits to monitoring in primary care which include:

- Improved anticoagulation control
- Reduced number of INR tests required to maintain good control
- Improved patient safety
- Reduced potential for errors in dosing
- Improved patient convenience
- Improved efficiency in the use of doctor/nurse/staff time

1.4 The Bedford Warfarin Service manages stable or largely uncomplicated adult patients i.e. aged 18years and over.

2.0 SCOPE

2.1 This document provides guidance and standards for the monitoring of INR of patients registered with Bedford Warfarin Service who are prescribed the vitamin K antagonist (VKA) warfarin. It sets out the responsibilities of the Bedford Warfarin Service and the patient's registered GP.

2.2 This document does not provide guidance and standards for the monitoring of novel oral anticoagulants (NOACs) e.g. Rivaroxaban, Apixaban, and Dabigatran and other VKA oral anticoagulants e.g. Phenindione and Acenocoumarol.

3.0 AIM OF THE CLINIC

3.1. To provide a safe, cost effective, high quality and clinically effective warfarin monitoring service in primary care.

4.0 RESPONSIBILITIES OF THE PATIENT'S GP

4.1 Assessing and ensuring the suitability of the patient for treatment with Warfarin.

4.2 Identifying and referring suitable patients to the Warfarin Service using appropriate documentation.

4.3 Providing up to date information relevant to monitoring including concurrent medication, medical history, and details of carers responsible for administration.

4.4 Setting the target INR, duration and intensity of treatment.

4.5 Providing advice on management of anticoagulant therapy with Warfarin to the monitoring service staff as required.

4.6 Retaining overall responsibility for the care of their patients whilst under the care of Bedford Warfarin Service.

4.7 Being aware of appropriate advice and guidelines for anticoagulant care.

4.8 Being aware of the potential effects of concomitant medication on the anticoagulant effect on warfarin, and providing guidance on amending INR testing to accommodate these effects where appropriate.

4.9 Arranging admission to hospital if required.

4.10 Issuing warfarin prescriptions.

4.11 Informing the Warfarin Clinic when anticoagulation service is no longer required by patient.

5.0 RESPONSIBILITIES OF BEDFORD WARFARIN SERVICE

5.1 Reviewing referrals received from the GP and accepting the patient to the service caseload if the inclusion criteria for the monitoring service are met.

5.2 Informing the GP of acceptance or rejection, in writing/email, within 7 days of receiving a referral.

5.3 Arranging an appointment with the patient's accepted to the caseload within 3-7 days of receipt of a referral.

5.4 Maintaining an up to date register of patients to whom it provides a service.

5.5 Informing the GP of changes in patient's condition requiring attention; noncompliance with monitoring or medication and adverse incidents.

5.6 Monitoring INR of patient's and adjusting doses of warfarin, if indicated, to achieve the target INR set by the patient's GP.

5.7 Providing education on warfarin therapy to patient's in accordance with Appendix 6.

5.8 Ensuring that all staffs of the service are adequately trained and competent to carry out their duties.

5.9 Adhering to ELFT guidelines and policies

6.0 SERVICE ELIGIBILITY CRITERIA

6.1 Inclusion Criteria

- Prescribed Warfarin
- Registered with a GP in the Bedford locality
- Clinically stable i.e. last 4 consecutive INRs within target range.
- Housebound, whether stable or unstable, including post-operative patients who are temporarily immobile
- Patients currently in secondary care anticoagulant clinics who are stable and consent to being managed by the Bedford Warfarin
- Service.

6.2. Exclusion Criteria

Exclusion from the service will be considered if any of the following conditions apply. Acceptance in these instances will be at the discretion of the service clinicians, in liaison with the haematologists or Lead Clinician. Similarly, if any of these conditions arise after acceptance to the service, consideration will be given to the appropriateness of monitoring within the service.

- Not registered with a GP in the Bedford locality
- Under 18years of age
- Known hereditary or acquired thrombophilia
- Known hereditary or acquired bleeding disorder
- Liver failure
- Severe renal impairment
- Documented evidence of CNS haemorrhage in the last 6months
- Severe heart failure
- Uncontrolled severe hypertension
- History of gastro-intestinal bleeding in the last 6 months
- Pregnancy i.e. confirmed/ suspected/ planning
- (Urgent referral to appropriate Haematologist Consultant)
- Receiving chemotherapy for malignant tumours
- Homozygous protein C deficiency (risk of skin necrosis)
- Severe malnourishment due to absorption difficulties
- Mentally ill (including dementia) with no carer

- support in the community
- Alcoholics due to instability in anticoagulation management
- Intra Venous drug users
- Platelet count of <70
- Concomitant use of other oral anticoagulants

7.0 TRAINING

7.1. The following training should be completed by all clinicians working for the service:

- "Starting Patients on Anticoagulants: How to Do It" and "Maintaining patients on Anticoagulants: How to Do It": www.bmjlearning.com
- MHRA Oral anticoagulants learning module for all clinical practitioners: http://www.mhra.gov.uk/ConferencesLearningCentre/Learning Centre/Medicineslearningmodules/Oralanticoagulants/index.htm

- Coagucheck Training
- Clinical Decision Software System (INRStar) Training
- Use of Patient Group Directions
- Introduction to Anticoagulation: One Day Course from the University of Warwick

7.2. The key competencies that must be demonstrated by all staff who work in the clinic are as follows:

- Obtaining blood samples
- Appropriate use and maintenance of the coagulometer

8.0 REFERRALS

8.1 Referrals to the service will be taken from GPs or direct Hospital referral.

8.2 The referral form (Appendix 11) will be completed by the GP/Hospital and sent to the Warfarin Service via SystmOne (Electronic Patient Record) or by mail to bedford.warfarinclinic@nhs.net

8.3 Warfarin Service will inform the GP/Hospital via email/SystmOne of acceptance or rejection of the referral within 7 days of receiving the referral.

8.4. It is important to balance the need for accepting a referral with the need to ensure patient safety; as such referrals will be declined if adequate clinical and patient information is not received with the referral.

8.5. Adequate clinical information is defined as including all of the following: reason for anticoagulation, duration of anticoagulant therapy, target INR, referring clinician, and start date of anticoagulant therapy.

8.6. Adequate patient information must include: patient name, date of birth, NHS number and address.

8.7. The Warfarin Service is a monitoring service only and accepts no responsibility for the accuracy of treatment information provided to it. Patients will be treated strictly according to the information provided to the service and all referrers should be aware that this information is not routinely reviewed by medical staff within the service.

8.8. If a patient under the care of the service is deemed no longer suitable for monitoring in primary care, that patient will be referred to the Bedford Hospital Anticoagulant Clinic by the service using the “Unstable referral form for Bedford Hospital” (Appendix 11). The service will inform the GP and patient of the referral to Bedford Hospital. The patient will remain under the care of the service until they attend an appointment with Bedford Hospital Anticoagulant Clinic.

9.0 RECORD KEEPING

9.1. Up-to-date information on the patient including name, address, date of birth, NHS number, registered GP, name and contact details of carers, medical conditions, hospital admissions and concurrent medication must be kept.

9.2. The name of clinician who initiated warfarin (where available), Indication, duration of therapy (including discontinuation date) and target INR must be documented.

9.3. Every patient must have a written individual management plan which includes at a minimum the indication, duration and target INR for warfarin treatment.

9.4. Records of each appointment must include the current dose of warfarin, notes supporting dosing decision, INR results, counselling provided and the date of the next appointment. Any other actions taken during the appointment must also be recorded.

9.5. All details of adverse events and bleeding must be documented in the patient electronic records.

9.6. Missed appointments must be documented.

9.7. All patients must be issued an NPSA oral anticoagulant pack (including record book, information booklet and alert card). The record book will be updated by service staff at every appointment. All sections of the book must be completed.

9.8. A Training Log detailing training completed by staff and competency assessments completed must be kept.

9.9. A log of internal quality control tests must be kept

10.0 CALL AND RECALL PROCEDURE

10.1. Frequency of INR monitoring will be guided by Clinical Decision Software (CDSS); this is not a substitute for clinical judgement and CDSS recommendations may be overridden when it is appropriate to do so.

10.2. When determining the frequency of recall, clinicians must bear in mind that the full effect of a change in dose of warfarin on the INR may take 3 -7 days to become apparent.

10.3. If the patient's clinical condition is changing, or there have been alterations in other medication, then the INR may need to be checked more frequently.

10.4. Any new medication has the potential to alter sensitivity to warfarin; therefore, consideration should be given to checking the INR within 1 week of starting new medication, including over the counter medication and herbal remedies.

10.5. More frequent routine monitoring (e.g. every 1-2 weeks) of the INR is recommended if the person:

- Has an increased risk of over coagulation (such as those with severe hypertension or conditions/lifestyles that affect their liver or renal function).
- Is at increased risk of bleeding e.g. people on high intensity anticoagulation (INR more than 4.0); age 65 years or over; highly variable INRs; history of gastrointestinal bleeding; anaemia; malignancy; trauma; morbidity changes (such as concurrent illness, or exacerbations of chronic conditions)
- May find adherence difficult

In the event that a patient fails to keep an appointment:

- Contact should be made with the patient after the clinic by telephone to arrange another appointment. Text messages and voice mail should be left when the patient cannot be reached immediately and the service should continue trying to reach the patient.
- If unable to make contact by telephone after the next day then the offer of another appointment should be made by letter.
- The timing of appointments will be by agreement with the patient, taking into account clinical criteria. For example, patients on weekly INRs should be seen in 3-5 days and patients on 6-10 weekly INRs in a week.
- If the replacement appointment is not kept, a third appointment should be offered within the following week.
- If two consecutive appointments are missed the GP should be contacted to review warfarin therapy as the risks of not monitoring INR may outweigh benefits of treatment. If the GP decides that continuation of therapy in the absence of monitoring is too risky they should ensure that no further prescriptions for warfarin are issued.
- If the service is unable to safely monitor INR due to non-attendance then this should be referred to the GP, and the patient notified in writing and discharged.

11.0 DISCONTINUATION OF THERAPY

11.1. Two weeks to the end of treatment, a letter will be sent to the patient's registered GP giving notice that Warfarin therapy will be discontinued on the set date and requesting that they inform the service if it was not to discontinue for any reason.

11.2. Consideration should 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, unable to follow the dosing regimen etc. The service will communicate with the GP to agree a course of action in these situations.

11.3. The patient and /or carer will be informed of discontinuation verbally in the clinic and the yellow record book will be annotated to confirm discontinuation.

12.0 INFECTION CONTROL

12.1. Staff must be aware of the risks on infection arising from contact with human blood and the potential for cross contamination between patients if appropriate procedures are not followed.

12.2. To reduce the risk of infection, staff must:

- Use disposable single use lancet device
- Comply with good practice as per mandatory training for all clinical staff
- Dispose of all waste products in accordance with Trust procedural
- guidelines for the handling, segregation and disposal of waste – RMPG13a
- Comply with Trust guidelines on Infection Control, ICPG1 Infection Prevention and Control Procedural Guidelines Section 9: Prevention and Management of Sharps Injuries/Contamination and Section 3: Infection Prevention and Control in Clinical Practice.
- Covid infection control policy, please copy link below for access: http://elftintranet/sites/common/Private/Contentobject_View.aspx?id=62477

13.0 QUALITY CONTROL

13.1. Internal Quality Control

- The CoaguChek XS Plus meter has a number of inbuilt quality control functions such as a check of the electronic components and functions every time the monitor is turned on, a check of test strip temp while a test is in progress and a check of the expiry date and lot information on the test strip
- In addition to inbuilt checks, internal quality control will be carried out by the team on all testing meters once a month as per Appendix 8

13.2. External Quality Control –NEQAS

- The service must subscribe to external quality control testing via the National External Quality Assessment Scheme (NEQAS).
- Renewal of subscription should be done every year when prompted by NEQAS
- Four sets of testing kits (each containing two samples) will be received from NEQAS ever year; approximately every 3 months
- The service must complete the quality control tests as per instructions accompanying the test kits and obtain the results of the tests via the NEQAS website
- If one, or both, of the results from the two samples sent are out with consensus, the service will contact NEQAS by phone on 0114 2673300 or by email at neqas@coageqa.org.uk to request further samples so that the tests can be repeated.
- If only one of the results is out with consensus, only one sample will be
- requested for retesting
- If, following the re test, the result falls within consensus, there is no need for further action. However, if the result is out with consensus again, NEQAS should be contacted for advice

14.0 INCIDENT REPORTING

14.1. All adverse incidents should be recorded on DATIX.

14.2. All serious incidents must be reported within 2 working days of the information becoming known to the practitioner to the commissioner via email to sui.bedfordshire1@nhs.net.

14.3. The patient's registered GP must be informed of all adverse incidents.

15.0 ANNUAL REVIEW

15.1. All patients on anticoagulation should have an annual review, to confirm that the risk/benefit ratio is maintained, i.e. the risk of treatment does not start to exceed the benefits, and that patients do not continue anticoagulation longer than recommended.

15.2. An assessment of appropriateness of ongoing therapy, such as advanced cognitive impairment/dementia or end stage illness, should be conducted during the review. Where significant changes in the patients' health are identified a task to the patient's regular GP should be sent asking them to confirm the requirement for ongoing anticoagulation, to include the current CHADSVASc and HASBLED scores.

15.3. At the review it should be confirmed that the degree of INR control is more than 65% time in therapeutic range and an assessment of issues such as patient adherence conducted.

15.4. The review should also serve as an opportunity for patient education/counselling and relevant counselling and patient information leaflets should be provided.

16.0 APPENDIX 1: CLINICAL INFORMATION: INDICATION, CAUTIONS, CONTRAINDICATIONS AND DRUG INTERACTIONS OF WARFARIN

Introduction

The GP or hospital consultant is responsible for initiation of anticoagulation. Lead Nurses for Bedford warfarin Service have also undergone training to initiate warfarin therapy via referral from GP for suitability. Appropriate clinical assessment must be made before initiating oral anticoagulants and treatment should be discussed with the patient to ensure they are aware of the risks, benefits and monitoring commitments required. Warfarin may take up to 5 days to achieve antithrombotic effects. If immediate anticoagulation is required, then Heparin should be used.

Cautions and Contraindication of Warfarin

It is important to consider cautions and contraindications to oral anticoagulant therapy before initiating and during therapy, these include:

Cautions

Conditions in which risk of bleeding is increased, e.g. history of gastro-intestinal bleeding, peptic ulcer, recent surgery, recent ischaemic stroke, postpartum (delay warfarin until risk of haemorrhage is low—usually 5–7 days after delivery), bacterial endocarditis (use only if warfarin otherwise indicated); uncontrolled hypertension; concomitant use of drugs that increase risk of bleeding, cranberry juice, hepatic and renal dysfunction.

Contraindications

These are haemorrhagic stroke, hypersensitivity to warfarin or to any of the excipients, clinically significant bleeding, use within 72 hours of major surgery with risk of severe bleeding, use within 48 hours postpartum, pregnancy (first and third trimesters), drugs where interactions that may lead to a significantly increased risk of bleeding.

Recommended intensity and duration of therapy

The decision regarding target INR and duration of therapy lie with the referring clinician, the values below are those recommended by BCSH.

BCSH guidelines state that:

“The target range is generally taken to be within 0.5 of the target, specifying tighter target ranges for fully anticoagulated patients e.g. 2.0–2.5 does not achieve tighter anticoagulation control but results in more blood tests and more INR results in ranges associated with increased risk of thrombosis and bleeding”

Target range values are therefore not included in the table below.

Indication for use of Warfarin and Target INR and Duration of treatment

<table>
<tr><th>Indication</th><th>Target INR</th><th>Duration</th><th>Comments</th></tr>
<tr><td>First episode VTE (DVT/PE)</td><td>2.5</td><td>6 weeks – 6 months</td><td rowspan="3">Duration of treatment for VTE will vary for each individual, depending on a variety of factors. Experts are not unanimous on the optimal duration of warfarin treatment, but usually it should be continued for at least:
6 weeks in people with distal DVT (calf vein thrombosis).
3 months in people with proximal DVT or PE where there are known temporary risk factors and there is considered to be a low risk of recurrence.
6 months in people with proximal DVT due to an unknown cause (idiopathic).
Long-term if there have been recurrent DVTs or PE.</td></tr>
<tr><td>Recurrent VTE whilst anticoagulated and within therapeutic range</td><td>3.5</td><td>Long term</td></tr>
<tr><td>VTE in cancer</td><td>2.5</td><td>Case based</td></tr>
<tr><td>Atrial Fibrillation</td><td>2.5</td><td>Long term</td><td></td></tr>
<tr><td>Atrial Fibrillation pre cardio-version</td><td>2.5</td><td></td><td>Patients undergoing elective cardioversion should be anticoagulated with warfarin for at least 3 weeks prior to and 4 weeks post cardioversion. To minimize cardioversion cancellations due to low INRs on the day of the procedure a target INR of 3.0 can be used prior to the procedure.</td></tr>
<tr><td>Mitral Stenosis or Mitral Regurgitation</td><td>2.5</td><td>Long term</td><td>Patients with mitral stenosis or regurgitation who have atrial fibrillation or a history of systemic embolism or left atrial thrombus or an enlarged left atrium</td></tr>
<tr><td>Mechanical Prosthetic</td><td>See table</td><td>Long Term</td><td>
<table>
<tr><th>Prosthesis thrombogenicity</th><th>Target INR- No patient risk factors</th><th>Target INR Patient related Factors</th></tr>
<tr><td>Low</td><td>2.5</td><td>3.0</td></tr>
<tr><td>Medium</td><td>3.0</td><td>3.5</td></tr>
<tr><td>High</td><td>3.5</td><td>3.5</td></tr>
</table>
Where an embolic event occurs during anticoagulation within target, elevation of the INR target or the addition of anti-platelet drugs should be considered</td></tr>
<tr><td>Bioprosthetic heart valve in mitral position</td><td>2.5</td><td>3 months</td><td></td></tr>
<tr><td>Bioprosthetic valve and left atrial thrombus at surgery</td><td>2.5</td><td>Till clot resolves</td><td></td></tr>
</table>

Post Myocardial Infarction	2.5	Long term	Where alternative strategies not indicated
Dilated Cardiomyopathy	2.5	Long term	
Antiphospholipid Syndrome	2.5.	Long term	
Peripheral Heart Disease	2.5	Long term	Patients with intermittent claudication should not routinely be treated with anticoagulants. Patients who suffer acute arterial embolism and proceed to embolectomy should be considered for long-term anticoagulation with warfarin

Drug Interactions

The table below provides a quick reference highlighting significant interactions between warfarin and commonly prescribed medicines, complementary therapies and food but does not provide an exhaustive list. Full details of interactions are available in the summary of product characteristics and the BNF.
Although not well documented in clinical trials, common experience in anticoagulant clinics suggests that INR can be altered by certain groups of drugs e.g. broad spectrum penicillins, analgesics, which may necessitate more frequent testing.

Interacting Drug	**Potential Effect**	**Comment**
Allopurinol	Increases anticoagulant effect of warfarin	Uncommon but unpredictable interaction – monitor INR more closely when allopurinol started.
Amiodarone	Increases anticoagulant effect of warfarin	The onset of this interaction may be slow and may persist after amiodarone has been withdrawn.
		Starting amiodarone - patients have been stabilised on a maintenance dose • Check INR within 3 to 7 days of starting amiodarone • Reduce warfarin dose by approximately one-third (33%) • Check INR weekly and adjust warfarin dose further if necessary. Continue to check INR weekly for at least 4 to 6 weeks and until INR is stable.
		Starting amiodarone – patients

		who are unstable, or have not yet stabilised on a maintenance dose • Check INR twice weekly (i.e. every 3 – 4 days) for two weeks and adjust dose as necessary • Continue to check INR weekly for at least 4 to 6 weeks and until INR is stable Patients stopping amiodarone • Check INR weekly until stable. The dose of warfarin will need gradually increasing.
Amitriptyline	Unpredictable increase or reduction in anticoagulant effect	Monitor INR closely. INR may be difficult to control in patients taking tricyclic antidepressants.
Analgesics: Aspirin	Increases anticoagulant effect of warfarin	Avoid aspirin as an analgesic – use paracetamol as a safer alternative. (refer to antiplatelet- aspirin below for low dose aspirin 75mg daily)
Analgesics: 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 and Naproxen are less likely to interact with warfarin.
Analgesics: Co-proxamol	Increases anticoagulant effect of warfarin	Uncommon and unpredictable. Use Paracetamol as a safer alternative.
Analgesics: Paracetamol	Increases anticoagulant effect of warfarin when large doses are used over a prolonged time.	Intermittent use (<2.5g/week) unlikely to affect INR. A reduction in warfarin dose may be needed for regular paracetamol users
Antibacterials (macrolide): erythromycin, clarithromycin	Increases anticoagulant effect of warfarin	Marked increase in INR has been reported. The elderly are at greater risk of serious interaction. If a macrolide is required, Azithromycin is a safer alternative. Monitor closely.
Antibacterial: cefaclor	Increases anticoagulant effect of warfarin	Cefuroxime, cefalexin or cefradine are safer alternatives

Antibacterial: 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.
Antibacterial: Penicillins	Although not well documented in clinical trials, common experience in anticoagulant clinics suggests that INR can be altered	Recommend to check INR 3–7 days after starting the new medication and adjust warfarin dose accordingly
Antibacterial: 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.
Antibacterial: Quinolones e.g. Ciprofloxacin	May increase the anticoagulant effect of warfarin	Rare and unpredictable interaction. Monitor INR. Use alternative antibiotic if possible.
Antidepressants: SSRIs e.g. fluoxetine, sertraline, citalopram, paroxetine	Possibly increases anticoagulant effect of coumarins	Mixed reports about effects on warfarin.SSRIs have been associated with gastrointestinal bleeding: risk may be increased in patients on warfarin.
Antiepileptics: 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.
Antiepileptics: Carbamazepine	Reduces anticoagulant effect of warfarin	Dose of warfarin may need to be increased (up to double dose). Oxcarbamazepine does not appear to interact.
Antiepileptics: Phenytoin	Can increase or reduce anticoagulant effect of warfarin	Monitor INR and adjust dose of warfarin accordingly
Antifungals: Fluconazole, itraconazole, ketoconazole	Increases anticoagulant effect of warfarin	Increase in anticoagulant effect is greater with larger doses and in the elderly. Monitor and reduce warfarin dose accordingly. Advise patients to report any unexplained bruising or bleeding.
Antifungal: Miconazole (oral gel and possibly vaginal and topical preparations)	Increases anticoagulant effect of Warfarin	Avoid - potentially serious interaction. Use nystatin instead.

Antifungal: Griseofulvin	Reduces anticoagulant effect of warfarin	Unpredictable (effects some but not all patients) – monitor INR.
Antiplatelet: aspirin	May increase bleeding risk	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.
Antiplatelets: Clopidogrel, prasugrel, dipyridamole, ticagrelor	Mild bleeding can occur even though INRs remain stable and within range.	Increased risk of bleeding due to antiplatelet effect. Avoid concomitant use.
Antiretrovirals: Ritonavir, efavirenz etc.		Variable effects on INR. Monitor response and adjust warfarin dose accordingly.
Corticosteroids	Variable response	Significantly increased INR with high dose/pulsed steroids. Effects of low - moderate doses are less certain.
Cytotoxics	Increases anticoagulant effect of warfarin reported with some cytotoxics	Refer patients on concurrent cytotoxic agents to secondary care for management of anticoagulation
Disulfiram	Increases anticoagulant effect of warfarin	Review concurrent use of warfarin in patients requiring Disulfiram.
Flutamide	Increases anticoagulant effect of warfarin	Monitor and reduce warfarin dose as necessary
Influenza vaccine	Usually safe and uneventful, but small numbers of bleeding episodes reported.	Evidence shows that influenza vaccination in those taking warfarin is normally safe and uneventful. Advise patient to report any unexplained bleeding.
Lipid-regulating drugs: Fibrate	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).
Lipid-regulating drugs: Simvastatin	Generally small, clinically irrelevant increase in anticoagulant effects	Monitor initially or after dose increases of simvastatin
Oestrogens	May enhance or reduce anticoagulant effect of coumarins	Generally avoided in thromboembolic disorders
Orlistat	Increases anticoagulant effect of warfarin	Decreases fat absorption and therefore may decrease absorption of vitamin K from diet.

Progestogens	May enhance or reduce anticoagulant effect of coumarins	Monitor and adjust dose as necessary
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.
Ulcer-healing drugs: Cimetidine	Increases anticoagulant effect of warfarin	Unpredictable but common interaction. Use ranitidine instead.
Ulcer-healing drugs: Proton pump inhibitors (Esomeprazole and omeprazole)	Increases anticoagulant effect of warfarin	A small change in INR may be seen. Occasionally clinically significant interactions occur. Use lansoprazole as an alternative.
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
COMPLEMENTARY THERAPIES		
Antidepressants: 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.
Boldo	May increase anticoagulant effect of warfarin	Modest rise in INR seen in a patient taking Boldo and Fenugreek.
Coenzymne Q10	Reduces anticoagulant effect	Monitor INR. Avoid use of products containing coenzyme Q10.
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.
Dong quai (Angelica sinensis)	Reports of marked increase in anticoagulant effect of warfarin	Advise patients not to use Dong quai whilst taking warfarin. Increased bleeding time & bruising.
Feverfew	Altered bleeding time reported	Advise patients not to use Feverfew whilst taking warfarin. Monitor INR.
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.

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.
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.
Papaya	Increases anticoagulant effect of warfarin	Avoid use in patients taking warfarin. Monitor INR
FOOD INTERACTIONS		
Alcohol	Increases anticoagulant effect of warfarin	Fluctuations in prothrombin time in heavy drinkers or patients with liver disease.
Cranberry Juice	Increases anticoagulant effect of warfarin	If a patient wishes to consume cranberry juice, they should be advised to drink the same amount each day and use the same brand all the time (as the cranberry content of different drinks varies).
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.

17.0 APPENDIX 2- MANAGEMENT OF SUB-THERAPEUTIC ANTICOAGULATION

In the first month after acute VTE:

- There is an estimated a risk of recurrence of 40% in the first month after VTE if patients are not anticoagulated. If an INR falls below 1.7 within the first month of an acute VTE, a clinical decision will need to be made on whether to initiate bridging therapy with Low Molecular Weight Heparin (LMWH). The patient's GP should be contacted to review anticoagulation and make the decision on whether to initiate LMWH. The GP may seek advice from the haematologist or the Lead Clinician with regards to initiating LMWH.
- In making the decision to refer the patient to the GP for consideration of bridging therapy with LMWH, consideration should be given to the patient's previous INR record and pattern of response. The clinician should satisfy him/herself that there are no obvious reasons for the sub therapeutic INR (e.g. drug interaction/ non-compliance/ change in diet or alcohol intake).
- There is no definitive guidance on under-anticoagulation, but BCSH 4th edition guidelines recommend that bridging therapy be considered if the INR becomes significantly sub-therapeutic within the first month of an acute VTE. Whilst there is no consensus on the value that constitutes significantly sub therapeutic INR opinions range from <1·5 to <1·7.
- The service will continue to provide monitoring of INR for the patient whilst on LMWH. LMWH treatment should continue until the INR is back within therapeutic range on 2 consecutive days.

Other instances of sub therapeutic anticoagulation:

- There is a lack of national guidelines on managing sub therapeutic INR, except for in the first four weeks of a VTE.
- It is not uncommon for INRs to fall below the target value in patients taking long term warfarin.
- In a patient with a single INR value below therapeutic value, the clinician should explore possible causes for the low INR such as noncompliance, interacting medicines (prescribed, bought over the counter or herbal) and lifestyle or dietary changes.
- The decision on whether to adjust dose and/or address the causes will be made on a case by case basis and INR retested within the next 3-5 days.
- When serial INRs (on more than 2 occasions) are below therapeutic range and there is no improvement in control following interventions, the patient should be referred back to their GP for management.

18.0 APPENDIX 3- MANAGEMENT OF OVER ANTICOAGULATION

There is an almost exponential increase in the risk of bleeding with increasing INR, e.g. patients with INR higher than 8 are at a significantly high risk of bleeding, but the exact risk in the individual patients is more difficult to define. Patient characteristics that increase the risk of bleeding include, older age, uncontrolled hypertension, diabetes, renal or liver failure, previous gastrointestinal or cerebral bleed and use of anti-platelet medication.

The aim of management in over anticoagulation is to restore the INR to the target range as quickly as possible, without leading to sub therapeutic anticoagulation, which may be associated with a risk of thrombosis.

The use of vitamin K results in more rapid reduction in INR than discontinuation of the warfarin alone. In the non-bleeding patient, oral administration of vitamin K is preferred over the intravenous route as equal correction is achieved at 24 hours. It is recommended that all patients with INR ≥8, showing no signs of bleeding, should receive 1–5 mg of oral vitamin K. At these doses overcorrection is infrequent and resistance to re-anticoagulation does not occur. It is reasonable to consider giving oral vitamin K to patients with an INR of 5.0-8.0, if they are judged to be at high risk of bleeding, but it is not necessary to offer this routinely to all patients.

All patients showing signs of bleeding should be referred to secondary care for management. A DATIX report should be completed for all incidents of over anticoagulation and the patient's GP must be informed.

The following table summarises management of over anticoagulation in patients on warfarin treatment.

INR ≥ 8.0 with no signs of bleeding	
All Patients	• Repeat test to confirm INR result, results within 0.5 of each other are considered accurate, if results are variable contact Lead Clinician or patient's GP for advice. • Withhold warfarin until INR < 5 • Give oral vitamin K (Konakion® MM Paediatric 2mg in 0.2ml); 2mg (as per Vitamin K PGD) • Repeat INR test 24 hours later. If this falls on a weekend or bank holiday it is the responsibility of the prescribing GP to ensure the test is done and the results acted upon. Inform GP of need for further testing • If INR ≥ 8 after 24 hours repeat administration of oral vitamin K • If INR ≥8 after two days of successive oral vitamin K administration, refer to the

	registered GP/specialist for advice • Investigate cause of elevated INR • Reduce the maintenance dose of warfarin when it is restarted
INR >5.0 but less than 8.0 (with no bleeding)	
High Risk Patients	• Withhold warfarin for 1-2 doses • Reduce maintenance dose. In general, when adjusting the dose, a 15% change in dose is expected to result in a change in the INR of 1, and a 10% dose adjustment is expected to result in a 0.7–0.8 change in the INR. • Investigate cause of elevated warfarin • Consider giving oral vitamin K ((Konakion® MM Paediatric 2mg in 0.2ml); 2mg (as per Vitamin K PGD). Seek advice from specialist/ patient's registered GP for this. • Repeat INR in 24 hours if vitamin K is administered
Low risk Patients	Withhold warfarin for 1-2 doses Reduce maintenance dose Investigate cause of elevated INR
Signs of bleeding at any INR	
All Patients	• Refer to GP/specialist for advice and follow up • All patients showing signs of major bleeding should be referred to A&E.

19.0 APPENDIX 4- WARFARIN DOSE ADJUSTMENT

The maintenance dose of warfarin depends on the international normalized ratio (INR) during monitoring. The average daily maintenance dose of warfarin is usually around 5 mg daily, however there is wide variation and the daily dose may be between 1–15 mg.

Consideration should be given to the patient's previous INR record, pattern of response, and the individual's specific details when making dose adjustments. Dose adjustment should be guided by CDSS. However, the patient's clinical condition may warrant overriding CDSS. Circumstances in which it is acceptable to override CDSS dose include:

- Where the practitioner has information about factors which may affect a patient's anticoagulation control (e.g. omitted doses of warfarin, medication changes, and recent hospital admissions).
- Where a practitioner takes into account the patient's previous response to dose changes.

- Where adjustment to total weekly dose may be necessary to avoid the use of 0.5mg doses (half tablets)

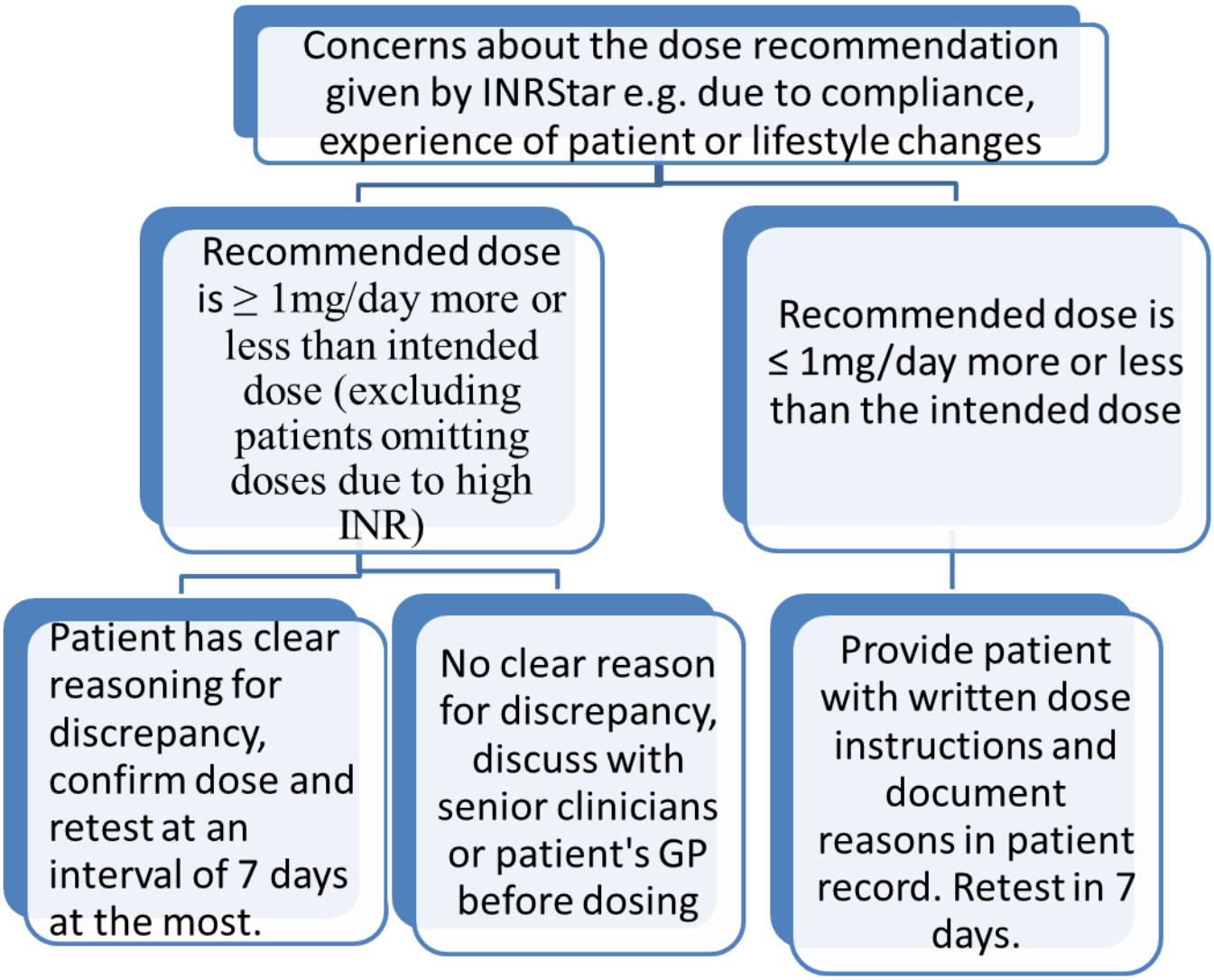
Follow-up appointment intervals may be changed if necessary to account for holidays and other appropriate circumstances.

Overriding CDSS recommendations introduces the possibility of error, and should therefore be kept to a minimum. If CDSS recommendations are overridden, the reason should be documented in the patient records.

The following principles of dose adjustment should be adhered to:

- Dosing should not be increased by more than 5-20% weekly dose.
- Use the least number of tablets each day.
- Warfarin should be taken at a fixed time each day, usually in the evening.
- Keep the INR within 0.5 INR units of the target INR.
- Use constant daily dosing and not alternate day dosing to aid compliance
- Use mg and not number of tablets.
- Always check compliance and influencing factors before deciding to adjust dose

REQUIREMENT TO DEVIATE FROM INRSTAR DOSING OR RECALL RECOMMENDATION



20. APPENDIX 5- ANTICOAGULATION IN DENTAL SURGERY

Guidelines for the management of patients on oral anticoagulants requiring dental surgery D. J. Perry, T. J. C. Noakes & P. S. Helliwell British Dental Journal 203, 389 - 393 (2007) - Summary of key recommendations

- The risk of significant bleeding in patients on oral anticoagulants and with a stable INR in the therapeutic range 2-4 (i.e. <4) is very small and the risk of thrombosis may be increased in patients in whom oral anticoagulants are temporarily discontinued. Oral anticoagulants should not be discontinued in the majority of patients requiring out-patient dental surgery including dental extraction.
- For patients stably anticoagulated on warfarin (INR 2-4) and who are prescribed a single dose of antibiotics as prophylaxis against endocarditis, there is no necessity to alter their anticoagulant regimen.
- The risk of bleeding in patients on oral anticoagulants undergoing dental surgery may be minimised by the use of oxidised cellulose (Surgicel) or collagen sponges and sutures and 5% tranexamic acid mouthwashes used four times a day for two days.
- For patients who are stably anticoagulated on warfarin, a check INR is recommended 72 hours prior to dental surgery.
- Patients taking warfarin should not be prescribed non-selective NSAIDs and COX-2 inhibitors as analgesia following dental surgery.

21.0 APPENDIX 6- PATIENT EDUCATION

At the first appointment following transfer from secondary/primary care, education should be provided according to the counselling checklist below. The counselling should be comprehensive to ensure that patients are fully aware of their treatment and should include:

1. **The indication for warfarin**
2. **Current dose**

3. **How to take warfarin** – at the same time each day

4. **What to do in the event of a missed dose**
    - They should not miss doses, or take additional doses, without advice from a healthcare professional.
    - They must inform anticoagulant healthcare staff if they think they have taken too much warfarin or have missed any doses.
    - If a dose is accidentally missed, they should continue with the regimen as prescribed, and never take a double dose (unless specifically advised).

5. **Side effects of warfarin**
   Warfarin has a number of adverse effects, the most common of which is bleeding; they should seek immediate medical advice if:
    - Spontaneous bleeding occurs whilst on warfarin, and the bleeding does not stop or recurs. This includes bruising, bleeding gums, nosebleeds, prolonged bleeding from cuts, blood in the urine or stools, coughing up blood, a subconjunctival haemorrhage, and vaginal bleeding in a postmenopausal woman.
    - They get sudden severe back pain (which may indicate spontaneous retroperitoneal bleeding).
    - They experience difficulty breathing, increased breathing rate, or chest pain (symptoms of pulmonary embolism).
    - If they require surgery they may have to stop warfarin treatment temporarily. Most people do not have to stop warfarin if they are having dental treatment.

6. **Importance and frequency of monitoring and the target INR**

7. **The anticipated duration of treatment**

8. **Drug/drug, alcohol and drug/food interactions**
    - They should inform the clinic staff if any medicine is started or, stopped, or the dose of any medicine they usually take is changed. Medicines include not only prescribed drugs, but also products that may be bought without prescription, such as aspirin and medicines containing aspirin, vitamins, food supplements, and herbal or homeopathic remedies.
    - Seek medical advice before undertaking any major changes in diet, especially if their diet is rich in vitamin K (such as broccoli, kale, or spinach) — this can potentially affect control of anticoagulation.

- Limit the amount of alcohol to a maximum of one or two drinks a day, and never binge drink.
- Expect to bruise more easily.
- Take extra care when brushing teeth or shaving, and consider using a soft toothbrush and an electric razor

9. **Clinic arrangements and how to obtain further medicine supplies**

10. **What to do if dental treatment/surgery is required –** see Appendix 5.

11. **What to do if a surgical procedure is required/indicated.**

12. **Who to contact regarding any worries or concerns relating to their anticoagulation management**

13. **The importance and role of the 'yellow anticoagulant record booklet. Advise to:**
    - Always carry their anticoagulant alert card with them at all times
    - Show card to the pharmacist before purchasing over the counter medication and alternative remedies
    - Always bring the anticoagulant treatment booklet when they come to the warfarin clinic to have their INR checked

14. **Women who are of a childbearing age** should be advised:
    - To take precautions to prevent becoming pregnant while taking warfarin because it is a known teratogen.
    - If pregnancy occurs or is planned — the need to stop taking warfarin and to start using low molecular weight heparin
    -

15. **How anticoagulants may affect activities such as sports and travel**

Bedfordshire Community Health Services

NHS

Local Procedure for Self – Testing of Oral Anticoagulation with Warfarin

VERSION NUMBER:	1
AUTHOR:	Kikelomo Pinheiro Helen Willis Michelle Warke
CONSULTATION GROUPS:	Anticoagulant Nurses
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APPROVAL BY :	Medicine Committee

EXECUTIVE SUMMARY
This document provides guidance to Anticoagulation Nurses overseeing the self – testing of coagulation by adult patients under Bedfordshire Community Health Services care. It does not cover self-management of anticoagulation or in-patient services.
The Trust monitors the implementation of and compliance with this clinical guideline in the following ways;
Audit

LOCAL PROCEDURE FOR SELF – TESTING OF ORAL ANTICOAGULATION WITH WARFARIN

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- **APPENDIX 2 -TRAINING RECORD FORM**

LOCAL PROCEDURE FOR PATIENT SELF – TESTING OF ORAL ANTICOAGULATION WITH WARFARIN

1.0 INTRODUCTION

1.1 Point of care coagulometers are designed to monitor the clotting tendency of blood in people on long term vitamin K antagonist therapy in the form of International Normalised Ratio (INR).

1.2 Several Coagulometers have been shown to give reliable and accurate results. NICE recommends the use of Coagucheck XS/INRange system for self-monitoring of coagulation in patients with atrial fibrillation and heart valve disease.

1.3 Self-testing refers to the patient doing the INR test themselves and then contacting their healthcare professional with the reading for advice on any change of the dose of the anticoagulant that may be needed. Self- managing refers to the patient doing the test and self-adjusting the dosage of the anticoagulant according to an agreed protocol.

1.4 The use of coagulometers may reduce the frequency of visits to the clinics for patients and enable them to be monitored more regularly, which may lead to improved health outcomes and avoidance of adverse effects.

2.0 SCOPE

2.1 This guidance aims to support anticoagulant nurses overseeing the self - testing of adult patients with atrial fibrillation, heart valve disease and venous thromboembolism on long term warfarin therapy

2.2 It does not cover self -testing in In-patient units

2.3 It should be read in conjunction with local procedures for warfarin as well as the Trust policies for safe and secure handling of medicines and waste disposal

3.0 CRITERIA FOR SELF- TESTING

NICE CG144 discourages the routine offering of self-management or testing of INR to patients who have had DVT or PE and are having treatment with a vitamin K antagonist. All decisions on self –testing for this group of patients must be ratified by the Lead Doctor for the service.

The GP must be informed that the patient desires to self-test and consent for self-testing obtained from the GP.

Patients or carers (where the patient is unable) who are motivated can be considered to conduct self- testing. They must however:

3.1 Be capable of giving, and provide informed consent, prior to commencement of self-testing, in the form of a completed self –testing agreement form.

3.2 Have an indication that warrants warfarin use for at least 12 months

3.3 Be physically (manual dexterity and sufficient eye sight for normal daily tasks) and cognitively (mental capacity) competent to self-test. Prior to commencement competence to perform an INR test must be assessed and signed off by the anticoagulant nurse.

3.4 Have and be trained in the effective use of the CoaguChek XS/INRange portable INR monitoring device.

3.5 Have maintained good INR control in the last 3-6 months.

3.6 Understand rationale for warfarin therapy and monitoring requirement.

3.7 Be willing to undergo and successfully complete training.

3.8 Be assigned a named anticoagulant nurse who will oversee self-testing.

4.0 TRAINING FOR THE USE OF THE METER

Patient training should include the following:

1. **Theoretical aspects of anticoagulation management** –outline of mechanism of action of warfarin, reason for warfarin therapy, importance of monitoring, how to monitor and the frequency of coagulation monitoring, problems with monitoring, warfarin interactions, target INR for their condition and the importance of maintaining the INR within 0·5 of the target, recognizing complications and actions to take in the event of complications.

2. **Equipment required for self- testing and how to obtain them:** Coaguchek XS meter/INRange meter, Coaguchek XS Test strips/INRange test strips and corresponding calibration chip, lancets, sharps container, hand washing facility

3. **At least one practical session which should include:**

    - operating the coagulation monitor
    - practising a coagulation test
    - performing fingerprick sampling procedure
    - identifying possible sources of error
    - recording test results
    - how to store test strips
    - disposal of strips and sharps
    - Limitations of the coagulometers

4. **External quality control –** patient should be informed to bring coagulometers to the clinic for external quality control checks every six months. This will be conducted by testing a fingerprick sample on the patient's own device and a device used in the anticoagulant clinic. The clinic device should itself be assessed externally through an EQA programme. Results should be within 0·5 INR of each other

5. **Advice, support and clinical responsibility**: The INR test is performed at a specified weekday and time agreed with the clinician responsible, to enable easy access for advice if necessary. (All telephone contacts should be recorded in the patient notes.)

6. **The training record form (Appendix 2)** should be completed and signed by both patient/carer and trainer. One copy should be scanned to the patient electronic records and the other given to the patient.

7. **Competency Assessment**

5.0 COMMUNICATION AND DOCUMENTATION

5.1 INR results will be documented in the Yellow Book and communicated by email to the anticoagulant clinic from the patient. In the event that there are challenges with the IT systems, results will be communicated via the telephone. Where telephone is used a follow up email should be sent when IT issues are resolved. E –mail/ telephone conversation must include:

- At least 2 patient identifiers, this can be any of the following: Name, date of birth, address and NHS number. – we don't use hospital numbers generally
- Date of INR test and INR result.
- Any changes to current medications/omitted/missed doses.
- Any side effects experienced e.g. bruising/bleeding.
- Any changes to lifestyle/diet/alcohol consumption.
- Any recent illness
- Any upcoming procedures

5.2 Dosing advice will be communicated by email or telephone, in the event of challenges with the IT system, from the anticoagulant clinic to the patient as follows:

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- INR test results and anticoagulant dosing instructions must be clearly stated
- Dosing advice will be returned with at least 2 patient identifiers as stated above
- Date of next INR test must be included

6.0 APPENDICES

APPENDIX 1: Self –testing Agreement Form

Self-testing Agreement Form

Name:
Agreed Email Address:
Telephone:
Personal Address:

……..is the anticoagulant nurse responsible for ensuring the above named patient is a suitable candidate for self-testing of warfarin therapy in accordance with the Local Procedure for Patient Self – Testing of Oral Anticoagulation with Warfarin

1. Follow up review will be every ……months. The above patient will be responsible for arranging the appointments with the anticoagulant clinic.

2. INR results and dates as well as any problems will be documented accurately in the anticoagulant record book provided and communicated by email or telephone to the anticoagulant clinic in the agreed format.

3. Previous dosing instructions remain valid until new dosing instructions are received. Please allow 24 hours for new dosing instructions to arrive (emails will not be looked at on weekends or bank holiday.)

4. External quality control will be performed at least 6 monthly. The patient's machine will be brought to the clinic for this purpose. The named anticoagulant nurse is responsible for making the arrangements.

5. Needles are disposed of safely in a sharps container and other contaminated material wrapped up carefully and placed in the in the usual waste bin. Arrangements should be made with the clinic for the disposal of sharps boxes.

6. Mr/Mrs…….is responsible for ordering supplies of equipment directly from manufacturer. The anticoagulant clinic is responsible for providing a supply of test strips. Lancets and sharps boxes can be obtained on prescription from the GP.

7. Test strips are refrigerated at a temperature between +2 and +8 degrees centigrade (normal refrigerator temperature)

8. …….. is informed if patient is intending to move away or stops self-testing so that arrangements can be made for alternative management.

9. …….. will undergo an annual clinical review to assess capability to self- test.

Signature of clinician responsible: ……Date…….

Signature of patient ……Date……

Appendix 2: Training Record Form

Patient Training Record

Patient Name: **Signature:** **Date:**

Trainer Name: **Signature:** **Date:**

Please check off boxes to confirm the following information has been given, and sign to confirm this:

CRITERIA	√
Meter Set Up	
Batteries	
Display Check	
Date Format	
Date Setting	
Time Format	
Time Setting	
Set Test Measurement	
Beep Tone	
Therapeutic Range	
Coaguchek XS Test Strips	
Storage Conditions	
Handling Test Strips	
Calibrating code chip	
Changing code chip	
Internal quality control	
Expiry date check	
Sample testing area	
Obtaining a Fingerprick Sample	
Hand washing	
Sampling sites	
Time limits	
Sampling problems	
Recording Results	
Anticoagulation Record	
Memory	
Retrieving saved results	
Maintenance and Troubleshooting	
Cleaning meter	
Common error codes	
Technical support information	

CRITERIA	√
Performing a Test	
Switching on meter	
Checking screen	
Insertion of test strips	
Confirm code lot number	
Strip warming	
Using Lancet	
Device components	
Removal of protective sheath	
Insertion of lancet	
Depth setting	
Ejecting lancet	
Equipment	
How to obtain	
External quality control	
Waste disposal	
Communication and documentation	
Email procedure	
Recording in Yellow book	
Dosing advice	
Theory of anticoagulation	
Mechanism of action of warfarin	
Interactions – medicines, food ,alcohol	
Relevance of monitoring	
Frequency of monitoring	
INR target	
Complications and treatment – under and overcoagulation	
Contact details of named nurse and clinic	

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END

22.0 APPENDIX 7- CLINIC PROCEDURE

- Prepare the Coaguchek device, and complete any quality control procedures that are required, and record these appropriately.

- Advise the patient of the process and use the checklist below to capture information relevant to anticoagulant therapy:

Since the last INR test, has the patient:

- Had a stay in Hospital?
- Had any kind of trauma /injury?
- Had any unexpected bruising or bleeding? For example:

- Prolonged bleeding from cuts
- Bleeding that does not stop by itself
- Nose bleeds
- Bleeding gums
- Red or dark brown urine
- Red or black stools
- For women, increased bleeding during periods (or any other vaginal bleeding)

- Missed or changed anticoagulant tablet?
- Changed or started any prescription or other over the counter medicine, including any vitamins or herbal remedies?
- Made any major dietary / alcohol changes? For example:

- Crash diets
- Binge Eating
- Marked changes in alcohol consumption

- Planning a holiday in the next 2 months?
- Had any surgery/dental/Cardioversion appointment booked in the next 2 months?

- Follow the testing procedure as per Appendix 8
- Enter the results into INRStar
- Follow the suggestions given by INRStar for dosing and recall interval, unless there is a requirement to deviate from the recommendation for clinical reasons. Should deviation from the recommended dose be required, please follow Appendix 4
- Complete the patient's yellow book, and confirm the instructions for the dose and testing interval with the patient.
- Record the INR, warfarin dosage, and the recall date in both INRStar and System1.

23.0 APPENDIX 8- COAGUCHECK PLUS METER PROCEDURES

The CoaguChek XS system measures the International Normalised Ratio (INR) using capillary blood.

Before using the meter for the first time (i.e. after the batteries have been inserted), the date and time must be set correctly. Each time the batteries are replaced the date and time should also be checked and adjusted if necessary. The memory facility should not be used when a single device is being used across multiple patients.

Care of CoaguChek XSPlus Meter

- Pointed and sharp objects can damage the touch screen and are not recommended.
- The Optical Plate must be kept clean and dry. Periodically clean the optical plate using the following procedure:
    - Carefully remove the measurement chamber cover.
    - Clean the optical plate with a slightly damp, lint free swab using soap and water.
- Do not use paper towels or any abrasive materials that could damage the surface of the optical plate.
- Following cleaning, allow to dry for at least 10 minutes before replacing the measurement chamber cover.

Operating Conditions

To ensure that your CoaguChek XS System functions properly, please observe the following guidelines:

- Only use the meter at a room temperature between 15°C and 32°C.
- Only use the meter at a relative humidity between 10% and 85%.
- When testing, place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
- If the meter is to remain unused for a longer period of time, keep it in the carry-case supplied

Internal Quality Control Check

To perform a liquid quality control test using controls, the following equipment is required:

- CoaguChek XS Plus meter
- The test strip code chip supplied with the test strip container you are using. (A code chip is provided with every test strip container.)
- Test strips that came with that code chip.
- Bottles of CoaguChek XSPlus PT Controls, diluent droppers, and the quality control code chip provided.

Directions for running the quality control test are available in the Youtube video on https://www.youtube.com/watch?v=vitrlygQBmY.

Directions are also provided below:

1. Prepare for a liquid quality control test in the same way you would prepare to perform a test with a capillary blood sample. The only difference is the use of control solution instead of blood
2. Open the plastic cap and rubber bung on the QC vial.
3. Ensure no liquid is in the end of pipette and cut end off carefully
4. Empty all contents into glass vial, ensuring not to touch the powder
5. Replace the black cap and swirl on desktop (do not shake), until all the powder has dissolved. The Solution is now stable for 30 minutes: Note the time the solution is made up and ensure completion of the QC procedure within 30minutes of that time.
6. Select `Control Test` from the main menu on the CoaguChek XS Plus meter screen.
7. Insert test strip when prompted and test strip code chip (if prompted)
8. Check the lot number on the side of QC bottle then select from list or select 'New'.
9. If 'New' option selected, insert code chip when prompted.
10. Once the 180 second countdown starts, apply the solution to the test strip using the pipette.
11. The sample will be analysed and the result and acceptable range will be displayed on the screen.
12. If the result is **not within an acceptable range do not use meter.**

Procedure for INR measurement

1. Switch on the CoaguChek XS Plus meter
2. Select `Patient Test` from the main menu
3. If prompted enter the Patient ID via touch screen, then touch the tick button.
4. Remove the test strip from the container and hold it in front of the meter so the lettering `CoaguChek XS PT` is facing forward. Close the container as soon as the test strip has been removed.

5. Insert test strip when prompted as far in as it goes. A beep tone indicates that the meter has detected the test strip.

6. If prompted insert code chip

7. The meter will find the code chip information and warms the strip A further, longer beep tone will sound followed by a 180-second countdown to indicate that the meter is ready for the test solution.

8. Put gloves on and ask patient to warm up their hands by rubbing them together or placing them under their thigh, when sitting.

9. Prick the patient's finger using a sterile lancet and discard the lancet into the sharps bin.

10. Massage the side of the finger and palm to draw out more blood. Do not squeeze or press the finger.

11. Within 15 seconds of lancing the finger, apply a hanging drop of blood directly onto the sample application area of test strip (semi-circular area).

12. A further longer beep indicates that the meter recognised the sample, and then the results will be shown.

13. Place a cotton wool on the finger to cover the bleed and ask the patient to apply pressure to stop bleeding. Offer a plaster if required.

14. Record the INR result on the patient's clinical record and Yellow Book.

15. Review the warfarin dose if indicated.
16. If INR >8 follow procedure for managing excessive anticoagulation.

Further details on use of care and use of Coaguchek XPlus meter are available in the manufacturer's manual below

CaoagChek XPlus
User Manual

24.0 APPENDIX 9-TRAVEL

Patients should be encouraged to discuss travel plans with clinic staff so that appropriate advice with regards to compliance, monitoring and general travel advice can be given.

Clinic staff can support patients whilst on holiday with information on dosing and monitoring but only where the service had been informed in advance and arrangements for monitoring agreed with the patient.

It is the patient's responsibility to arrange an INR test and to provide the results to the service whilst on holiday. The service bears no responsibility for the validity of the INR result provided by the patient whilst on holiday. These responsibilities must be conveyed to the patient before they travel and written consent to manage warfarin therapy in this way obtained for each episode of travel. Anticoagulant Europe provides information on INR testing abroad which can be accessed at:

http://www.anticoagulationeurope.org/advice/inr-abroad

All communication with and from patients during travel period should be in writing and must be documented in the patient's electronic records.

Patients who are out of the country for more than 3 months at a time are no longer entitled to treatment under the NHS. Advice on dosing and monitoring should therefore not be provided in these instances.

Consideration should be given to carrying out INR testing earlier than scheduled to remove the need for providing monitoring whilst the patient is away.

The risk for developing travel related VTE should be assessed for any patient who is considering travel by air as stated below. Journey's greater than 3 hours in duration carry the highest risk of travel related thrombosis.

For continuous journeys lasting more than 3 hours, classify the risk of travel-related deep vein thrombosis (DVT) as:

Low risk if the person has:

- No history of DVT or pulmonary embolism (PE), *and*
- Not undergone surgery in the previous 4 weeks, *and*
- No other risk factors to indicate moderate or high risk.

Intermediate risk if the person:

- Has a previous history of DVT or PE. However, people with a recent DVT or PE who are on anticoagulant treatment are considered to be at low risk.
- Has undergone surgery under general anaesthesia lasting more than 30 minutes in the previous 2 months but not in the last 4 weeks.
- Is pregnant or postpartum.
- Has clinically evident cardiac disease (such as recent myocardial infarction or uncontrolled heart failure) or other major acute illness (such as pneumonia).
- Is taking combined oral contraceptives or hormone replacement therapy.
- Is obese (body mass index greater than 30 kg/m^2).
- Has varicose veins with phlebitis.

- Has a family history of venous thromboembolism in a first degree relative.
- Has polycythaemia.
- Has a lower-limb fracture in plaster.

(The presence of multiple risk factors will further increase the risk of an individual developing travel-related DVT.)

High risk if the person:

- Has undergone major surgery in the previous 4 weeks.
- Has known thrombophilia.
- Has cancer — untreated or currently on treatment.

The absolute risk of an individual developing a travel-related DVT remains low even if they are classed as being at relative moderate or high risk. It is likely that recent major surgery (within 1 month), active malignancy, previous unprovoked VTE, previous travel-related VTE with no associated temporary risk factor or presence of more than one risk factor identifies those travellers at highest thrombosis risk.

For people considered to be low risk, offer general travel advice as follows:

- Avoid periods of prolonged immobility by:
  - Sitting comfortably in the seat and reclining as much as possible.
  - Wearing loose-fitting clothing.
  - Storing hand luggage in the overhead lockers to keep the floor in front of the seat free from obstruction.
  - While seated, bending and straightening legs, feet, and toes every 30 minutes during the flight.
  - Pressing the balls of the feet down hard against the floor or footrest to increase the blood flow in the legs and reduce clotting.
  - Doing upper body and breathing exercises to further improve circulation.
  - Taking occasional short walks around the cabin whilst the aircraft is cruising at altitude.
  - Taking advantage of refuelling stopovers where it may be possible to get off the plane and walk about.
  - Avoiding alcohol, which in excess leads to dehydration and inertia
  - Avoiding taking sleeping pills, which also cause inertia.

- Maintain a normal fluid intake and avoid excessive alcohol which can lead to dehydration and inertia.
- Seek urgent medical advice (for example from a local doctor or the nearest Accident and Emergency department) if they develop the following after the trip:
  - Swollen, painful legs, especially where one is more affected than the other, *and/or*
  - Breathing difficulties (suggesting pulmonary embolism).
- Obtain adequate medical insurance before they travel.
  - They should declare *all* their medical problems (this will probably result in premium loading or cover excluding existing illnesses).

For people at intermediate and high risk:

- Provide advice on general measures to reduce the risk of travel-related DVT as above.
- Refer to the GP to discuss the use of graduated compression stockings and assessment of suitability to travel.

25.0 APPENDIX 10-TRAINING COMPETENCES AND LOG

TRAINING LOG

	Name of staff	Date Completed	Comments
BMJ Online – maintaining warfarin therapy			
MHRA Anticoagulation Online			
Warwick University- Introduction to Anticoagulation			
Warwick University – Update Course			
Training Sessions with Lead GP			
INRSTAR Training			
Coagucheck Training			
Others			

COMPETENCY ASSESSMENTS

Anticoagulant Management Clinical Competencies for Annual Update

Name of Delegate	
Designation	
Date of Assessment	

An observational assessment must be performed to assess candidate competence (please tick as appropriate.

Performance Number	Criteria	Pass	Fail	N/A	Comments
Standard 1: The referral contains:					
PCS 1	**Patient name and contact details**	☐	☐	☐	
PCS 2	**Date of birth and gender**	☐	☐	☐	
PCS 3	**NHS number**	☐	☐	☐	
PCS 4	**Signature of referring person and contact details**	☐	☐	☐	
Standard 2: There is a clear understanding and confidence in using the IT system for patient management and evidence that patient information can be assessed and updated					
PCS 5	**Accesses patient management plan**	☐	☐	☐	
PCS 6	**Can access and update the following: medication**	☐	☐	☐	
	diet	☐	☐	☐	
	physical/mental health	☐	☐	☐	
	Current warfarin therapy and duration of treatment	☐	☐	☐	
	Recent admissions to hospital/A&E	☐	☐	☐	
PCS 7	**Can demonstrate safe use of IT systems used in anticoagulant management**	☐	☐	☐	
Standard 3: There are correct safety checks in place prior to Near Patient Testing Procedures					
PCS 8	**The patient's identity is correctly confirmed:**	☐	☐	☐	
	Full name	☐	☐	☐	
	Date of birth	☐	☐	☐	
	First line of address	☐	☐	☐	
PCS 9	**The patient's Yellow Book confirms identity**	☐	☐	☐	
PCS10	**The patient's Yellow Book is correctly completed**	☐	☐	☐	
PCS11	**Is aware of GP practice should patient forget Yellow Book or have out of date**	☐	☐	☐	

	information				
PCS 12	**Is aware of how to access additional Yellow Books**	☐	☐	☐	
PCS 13	**Verbal consent is obtained prior to the procedure**	☐	☐	☐	
PCS 14	**Consent to carer/ other HCP presence is obtained**	☐	☐	☐	
PCS 15	**Patient's history/side effects reviewed:**	☐	☐	☐	
	verbally	☐	☐	☐	
	electronically	☐	☐	☐	
PCS 16	**If confused carer is used to confirm patient's identity**	☐	☐	☐	
Standard 4: The correct procedure is followed in Near Patient Testing					
PCS 17	**Code number matches test strip**	☐	☐	☐	
PCS 18	**Meter switched on correctly**	☐	☐	☐	
PCS 19	**Battery level, date and time checked**	☐	☐	☐	
PCS 20	**Patient ID entered (if applicable)**	☐	☐	☐	
PCS 21	**Test strip correctly inserted**	☐	☐	☐	
PCS 22	**Waits for hourglass and "bleep"**	☐	☐	☐	
PCS 23	**Correctly interprets blood icon and 120 second countdown**	☐	☐	☐	
PCS 24	**Patient's finger correctly pricked**	☐	☐	☐	
PCS 25	**Blood correctly applied to semi-circular transparent application area within 15 seconds**	☐	☐	☐	
PCS 26	**Blood touched against the side of the sample application area**	☐	☐	☐	
PCS 27	**Correctly interprets INR results**	☐	☐	☐	
PCS 28	**Can identify < > and actions to take if noted**	☐	☐	☐	
PCS 29	**Analyser is correctly cleaned and stored**	☐	☐	☐	
PCS 30	**Patient's results correctly entered into IT system and Yellow Book**	☐	☐	☐	
PCS 31	**Patient follow –up appointment made**	☐	☐	☐	
Standard 5: There are robust quality control systems in place					
PCS 32	**There is evidence of quality control checks**	☐	☐	☐	
PCS 33	**Control aliquots are stored**	☐	☐	☐	

	correctly				
PCS 34	**Test strips are stored correctly**	□	□	□	
Standard 6: Practitioners have an understanding of error symbols on the analyser					
PCS 35	**Correctly identifies 5 error messages**	□	□	□	

Knowledge Assessment

Name of Delegate	
Designation	
Date of Assessment	

The candidate will demonstrate an understanding of the importance of the following points (tick as appropriate)

Criteria	Pass	Fail	N/A	Comments
Actions to take if referral form incomplete				
Actions to take if referral incorrect on patient details				
Actions to take if unable to access patient management plan or patient information				
Actions to take if patient has experienced changes to medication, diet, lifestyle, physical health, hospital/A&E admission				
Actions to take if Yellow Book lost				
Actions to take if patient does not give consent				
Actions to take if patient identity cannot be safely confirmed				
Able to manage a minimum of 5 error messages on the analyser				
Understands the term “antagonise”				
Can state two medicines that antagonise warfarin				
State two side effects of warfarin and actions if noted				
Understands the term “potentiate”				
Can state two medicines that potentiate the effects of warfarin				
Can state two medicines that are contra indicated with warfarin				
Advice to be given to patient on warfarin about to undergo surgery or visiting a dentist				

Competency Passed	□	**Competency failed**	□

Name of Assessor	
Designation	
Signature	

Date	

Questions for use by the Assessor

Name of Delegate	
Designation	
Date of Assessment	

The following questions should be used to ascertain the candidate understands the statements in the above knowledge assessment

Q. What would you do if the information on the referral form did not match that on your records? The Yellow Book or what the patient says?

A.

Q. What would you do if you are unable to access the patient's IT records due to a problem with the IT system?

A.

Q. How would you record your data?

A.

Q. What actions would you take if you were informed that there had been a change in:
a. the patient's medication
b. diet
c. physical health
d. admission to hospital/A&E

A.

Q. What would you do if a patient lost their Yellow Book ?

A.

Q. What would you do if a patient refused to give consent to blood testing?

A.

Q. What actions would you take if you were unable to safely identify a patient?

A.

Q. What are the side effects of warfarin therapy?

A.

Q. What advice would you give a patient on warfarin undergoing surgery or attending a dental appointment?

A.

FURTHER ASSESSMENT MATERIALS FOR NEW NURSES IN ADDITION TO ANNUAL UPDATE ASSESMENTS

1. How does warfarin work?
2. What is the INR?
3. Choose 3 different medications and discuss how they affect Warfarin.
4. Discuss reasons for high INRs.

Case Studies:

How will you manage these patients?

1. 71 year old lady with AF. Was well controlled on 5 mg daily for 1 year. Today's INR 1.6.
2. 66 year old gentleman with Aortic Valve Replacement. Has been getting SOB over the last few weeks, GP started Furosemide 3 days ago. Today's INR 6.6, has had a nosebleed in the morning lasting 15 minutes.
3. 71 year old patient, INR today 2.6 on 3 mg Warfarin daily. She tells you that the GP has started Clarithromycin for a chest infection yesterday. She seems generally well in herself.
4. Call from a patient with recurrent PE, last seen in Clinic 3 weeks ago. Asks for advice: Dentist is going to extract a tooth in 4 days. Has been well controlled few months on 4 mg daily.

Choose one answer for each of the following questions

1. How does warfarin work to inhibit clot formation
   a. It actually "thins" the blood
   b. It antagonises vitamin K which is needed to form clots
   c. It antagonises vitamin E which is needed to form clots
   d. It works with vitamin K to inhibit clot formation

2. Which of the following is not an appropriate indication for warfarin therapy
   a. Atrial fibrillation
   b. Mitral Valve Replacement
   c. Hypercholesterolemia
   d. DVT or PE

3. Which of the following are common goal INR ranges?
   a. 2-3
   b. 2.5-3.5
   c. 4-5
   d. Both a. and b. are correct

4. Which of the following routes of administration is predictably effective, safer, and more convenient thus the preferred way to administer vitamin K?
   a- Oral
   b- Intramuscular
   c- Intravenous

d- Subcutaneous

5. If co administered with warfarin, which of the following medications can cause dangerous rises in the INR?
   a- Bactrim (Trimethoprim / Sulfamethoxazole)
   b- Tricor (fenofibrate)
   c- Cordarone (amiodarone)
   d- All of the above

6. If co administered with warfarin, which of the following can cause the INR to decrease?
   a- Zocor (Simvastatin)
   b- St Johns Wort
   c- Tegretol (carbamazepine)
   d- B. And C. Are both correct

7. If a patient misses a dose of warfarin, what should he or she be instructed to do?
   a- Notify the healthcare provider
   b- Take an extra dose the next day
   c- Skip the missed dose and continue with the current dosing regime
   d- Both a. And C. Are correct

8. Once a patients warfarin therapy is stopped, how long will the anticoagulation effect last?
   a. End immediately
   b. Gone the next day
   c. About 2-5 days
   d. Last 1-2 weeks

9. True or false. All patients taking warfarin should avoid green vegetables
   a. True
   b. False

10. True or false. All patients undergoing dental surgery must stop warfarin before the procedure.
    a. True
    b. False

11. True or false. It is OK for patients to cut warfarin tablets in half?
    a. True
    b. False

USE OF COAGUCHECK

Date	Correct use of coagucheck	Comments / Areas of learning
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	

Date	Competent in use of Coagucheck	Supervisor signature	Trainee Signature
	Yes / No		

Comments –

Case ID	Target INR	Previous dose	New INR	New Dose	Rationale

Date	Competent in dosing patients using INR star	Supervisor signature	Trainee Signature
	Yes / No		

26.0 APPENDIX 11- REFERRAL FORMS

BEDFORDSHIRE WARFARIN SERVICE - REFERRAL FORM

WHEN FULLY COMPLETED PLEASE EMAIL TO bedford.warfarinclinic@nhs.net

All fields must be completed or the referral will be returned

PATIENT DETAILS

NHS NUMBER		NAME		
DATE OF BIRTH		AGE		GENDER F M
CONTACT TELEPHONE NUMBER FOR SUPPORT: 01234 317182	**This information will be in the yellow book** Diagnosis: Target INR Range 2.5 or other: …… Start Date of Treatment: Intended Duration: 13 wks 26 wks Indefinitely Is patient taking any other coagulation? Yes No	NEXT OF KIN NAME: ADDRESS: TELEPHONE NUMBER:		

PATIENT ADDRESS (Incl. Postcode)						
TELEPHONE No		MOBILE No.				
VISIT CRITERIA (PLEASE TICK)		Patients visit GP surgery	SPEAKS ENGLISH?	Y N	INTERPRETER REQUIRED?	Y N
		GP's visit patient at home	FIRST LANGUAGE			
REFERRING GP NAME AND FULL ADDRESS			GP TELEPHONE No			
			REFERRING GP's SIGNATURE			
We welcome any printouts with any relevant information.						
PMH:						

Current Problems:	
Current Medication:	
ADDITIONAL INFORMATION (including risks)	ACCESS INSTRUCTIONS i.e. Keysafe

BCCG – Bedford Locality – ANTICOAGULANT
UNSTABLE REFERRAL FORM
Until the patient is reviewed by the Clinic,
Anticoagulant Control is the responsibility of the referring clinician

Patient Name: Address: Hospital No: Date of Birth: Tel no: GP: GP address: GP tel no:	Next of Kin: ..... Name: Address: Tel. No: Has anticoag appointment been made with the clinic (ext.2207) Yes ☐ No ☐ If yes, when for .....

Diagnosis: .....

Target INR Range: .....

Intended Duration: ☐ 13 wks ☐ 26 wks ☐ Indefinitely .....

Is the patient taking any other anticoagulation? ☐ Yes ☐.....

Include a print out of the INR & dosing history from your software system ☐

PMH: .....

Current Problems : .....

Current Medication: .....
.....

Signature of Referring Doctor: Date: Time:

When completed, please send the referral form to Haematology Dept, South Wing, Bedford Hospital bhn-tr.anticoagulation@nhs.net

FOR NON REGISTERED patients within the service please send a copy to Haematology AND to the registered GP.

27.0 APPENDIX 12- AUDIT REPORTS REQUIRED BY CCG

The criteria for reports required are based on the National Patient Safety Agency's Safety Alert Notice (NPSA/2007/18).

The annual audit is in two parts – an audit of the total Practice register, and a documentation audit of 25 randomly selected notes. The results should be recorded on the Clinical Audit Data Collection Form then discussed at the Service's clinical meeting. The Clinical Audit Summary Report and the Significant Event Summary Report forms should also be completed.

Part 1: Overview information

Practice Name		
Audit Period (state exact start date and end date)		
Name of Clinician responsible for Audit	Name: Job Title:	
Total number of patients treated under Anticoagulation service in Audit year		
Total number of Patients on Warfarin (at the end of the audit period)		
	Registered patients	Non-registered patients
Total number of patients on service register currently on Warfarin		N/A
Total number of patients not suitable/ declined service (i.e. not stable)		

Declaration of Training and Development on Anticoagulation Therapy

Audit Criteria 1. All staff caring for patients on anticoagulation therapy must have the necessary work competencies as stated in the contract. Any gaps must be addressed through this training to ensure that all staff may safely undertake their duties.		
Name of Healthcare Professional	Training & Development undertaken in last year	Training & Development identified in current PDP
Audit Criteria 2. Internal and external quality assurance check of point of care testing kit.		
Number of internal calibration checks		

Number of external calibration check	
Date of most recent external calibration check	

Part 2: Service Register Audit Form – Anticoagulation Services

Total numbers of patients receiving anticoagulation services		
Number of these patients registered with practice?		
Number of Non-Registered patients?		
Service Register The service is required to keep a register of all patients treated under this Service to include the information listed below for each patient (this should also be included in the patients record). Compliance should be audited annually for all patients on the register.		
Service Register Criteria Recorded	Numbers met criteria	% meeting criteria
Patient name		
Patient address		
Date of birth		
NHS number		
Patient's registered practice		
Date of referral		
Date of next appointment		

Part 3: NPSA Audit Criteria for all patients ESTABLISHED on oral anticoagulant therapy

The table below asks questions based on the **INRstar Reports** generated by your Practice. Please complete under the correct heading with the figures shown on your INR report.

Total number of INR tests carried out over the audit period		
Variance Report (this report calculates the % of tests in each INR category)	Number of tests	Percentage of tests
Patients within INR 0.5		
Patients within INR 0.75		
Patients with INRs >5.0		
Patients with INRs >8.0		
Patients with INRs > 1.0 unit below target		
Patients with INRs in range		
Point Prevalence Report (for selected audit period). This report calculates the number and % of INR test falling within and above the target range for the selected period.	Number of patients	Percentage of patients
Low		
In-range		

High		
Time in Range report (for all active patients) This report calculates the % of time-in-range for all active patients.	Number of patients	Percentage of patients
Less than 30%		
31-50%		
51-70%		
More than 70%		

Part 4: Annual Documentation Audit – Anticoagulation Services

a. This should include non- registered patients.

The **service** is required to audit a **minimum of 25 sets** of notes
The read code 66QB is used for Annual Warfarin Assessment

Audit Period (state exact start date and end date)						
Name of Clinician responsible for Audit						
Sample size – registered patients	Sample size – non registered	Number of notes audited		% of patients notes audited		
Audit Criteria All patient records must document the following		Numbers met criteria		% met criteria		
Indication for treatment						
Length of treatment						
Target INR						
INR therapeutic range						
Dosing information						
Current INR						
Current dosage						
Details of all prescribed and over the counter medication recorded						
Details of all medical conditions						
Record of any adverse incidents/complications per patient						
Patient has copy of the NPSA's Information Booklet						
Ongoing advice to patients re medication						
Ongoing advice to patients re diet						
Individual management plan						
Annual review						
Significant event reporting		Y	N	N/R	Y	N	N/R

Date of missed appointments	Y	N	N/R	Y	N	N/R

Any Additional information:

_____
_____
_____
_____
_____
_____
_____

Anticoagulation Service Clinical Audit Summary Report

Practice Name:		
Clinical Audit Report Date:		
Date collated audit results discussed within ELFT		
Practice summary of Audit Results:		
What changes will be implemented to address any areas where the audit did not meet the required standards?	Who will be responsible?	When will the action be completed?
In light of the audit results and any views the provider has regarding this service, what changes would you like the BCCG to consider in its annual review of this service?		

Anticoagulation Service Significant Event Summary Report

This report should include all significant complications, complaints or events that have occurred within the Practice in the last year in relation to the Anticoagulation. This should include:

- failures in equipment and communication
- incorrect interpretation and/or dosage errors
- record keeping errors
- bleed or thrombosis
- drug reaction or interaction
- death of a patient on warfarin, whatever the cause.

Any emergency admissions or death of any patient who is receiving this service where this may be due to the anticoagulation therapy the Practice must report in line with the BCCG Serious Adverse Incident Policy.

<table>
<tr><td colspan="4">Practice Name:</td></tr>
<tr><td colspan="4">Total number of events relating this service in last year:</td></tr>
<tr><td>Number of complications:</td><td>Number of complaints:</td><td>Number of other SEAs (excl major):</td><td>Number of major SEAs:</td></tr>
<tr><td colspan="4">Please give details of all significant events for shared learning purposes:</td></tr>
</table>

28.0 APPENDIX 13- REFERENCES

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END