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WARFARIN MANAGEMENT GUIDELINES

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Warfarin Management Guidelines

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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 When anticoagulants are prescribed on a shared care basis, safe anticoagulant therapy relies on clear communication between the two.

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

1.4 These guidelines should be used by those providers who have been commissioned by North Cumbria CCG to provide an enhanced anticoagulation service.

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

1.6 The direct oral anticoagulants (DOACs) on the market: currently dabigatran (Pradaxa®) which is a direct thrombin inhibitor and rivaroxaban (Xarelto®), apixaban (Eliquis®) and edoxaban (Lixiana®), which are direct factor X inhibitors, are not covered in this guidance.

1.7 This guidance seeks to advise on the safe prescribing of Warfarin where indicated, it does not seek to replace clinical guidance on choice and use of anticoagulants in clinical practice.

2 Aim

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

3 Objectives

To provide standardised recommendations for prescribers as follows:

3.1 In the clinically effective anticoagulation management of patients receiving warfarin therapy whilst minimising the risks associated with anticoagulation.

3.2 In optimum management of INR control.

3.3 In regard to the tools available 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.

3.4 In the appropriate management patients who are over or under anti-coagulated.

3.5 To identify and manage appropriately patients with specific needs i.e. patients with poor compliance, with time in therapeutic range (TTR) < 65% or frequent non-attendees.

4 Responsibilities of North Cumbria CCG

The role of North Cumbria CCG (or equivalent Place in North East and North Cumbria Integrated Care System) is to ensure that services provided in primary care are in accordance with the service level agreement for the enhanced service by:

- Updating and reviewing the Local Enhanced Service for Anticoagulation in Primary Care as necessary

- Signposting to appropriate training
- Monitor service via INR star analytics.

5 Responsibilities of GP Practice

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

- Ensure North Cumbria Warfarin Management Guidelines are distributed and available
- To develop Practice Standard Operating Procedures (SOP) or detailed policies, which are read and signed by all relevant staff and responsibilities of staff are clear and understood
- Ensuring appropriate training is undertaken by all staff involved in anticoagulation and evidence of this training is documented. All competencies must be satisfactory before undertaking the service
- Training on INR star (computer decision support software) is completed prior to implementation
- The appropriate equipment for testing INR and vitamin K is available at the anticoagulation clinic/ GP surgery
- Training on Near Patient Test meters (NPT) must be undertaken before testing can commence
- Ensuring cleaning, maintenance, internal and external quality control for the equipment used in anticoagulation is undertaken
- Ensure an experienced clinician is available at all times when anticoagulation services are offered to patients by the practice
- A systematic call and recall system should be in place, and the provider should implement appropriate strategies to ensure non-attendees are identified and monitored.
- Dosing decisions should be made by health-care professionals (e.g. GP's, registered Nurses or registered Pharmacists) who have undergone an approved course for practitioners undertaking anticoagulant monitoring in primary care and who are deemed competent under the NPSA competency framework
- Ensuring that all patients receive appropriate monitoring, either with primary care anticoagulation service or in secondary care
- Ensuring routine care of issuing warfarin prescriptions, arranging admission to hospital if required and to stop anticoagulant when specified duration is complete
- Make reasonable adjustments for people with additional needs and disabilities, in line with the Equality Act

6 Target population

6.1 Patients who are currently on warfarin therapy in primary care.

6.2 Complex high risk patients can be considered for monitoring in or advice and guidance from secondary care include:

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

Warfarin is contraindicated:

- In people with:
  - Haemorrhagic stroke.
  - Clinically significant bleeding.
  - Severe hepatic impairment.
- Within 72 hours of major surgery with risk of severe bleeding.
- Within 48 hours postpartum.
- In pregnant women — due to the risk of teratogenicity.
- In people taking drugs where interactions lead to a significantly increased risk of bleeding.

Warfarin should be used with caution in the following groups:

- Elderly people.
- People with increased risk of bleeding — warfarin should be used with extreme caution if the benefit of anticoagulation outweighs the risk. Risk factors for bleeding include:
  - History of gastrointestinal bleeding.
  - History of peptic ulceration.
  - Recent ischaemic stroke.
  - Uncontrolled hypertension.
  - Concurrent nonsteroidal anti-inflammatory (NSAID) use.
  - Recent surgery.
  - The postpartum period — should be delayed until risk of bleeding is low, usually 5–7 days after delivery.

- People with:
    - Thrombophilia — warfarin should be introduced slowly due to the risk of skin necrosis.
    - Thyroid disorders — the rate of warfarin metabolism depends on thyroid status. People with hyperthyroidism or hypothyroidism should be closely monitored.
    - Risk factors for over coagulation, such as severe hypertension, or severe renal or hepatic impairment — international normalized ratio (INR) should be monitored more frequently.
    - Mild to moderate hepatic or renal impairment.

The following factors may exaggerate the effect of warfarin and necessitate a dose reduction:

- Weight loss.
- Acute illness
- Smoking cessation.

The following factors may reduce the effect of warfarin and necessitate a dose increase:

- Weight gain.
- Diarrhoea.
- Vomiting.

- https://www.medicines.org.uk/emc/medicine/27651#gref
- https://cks.nice.org.uk/topics/anticoagulation-oral/management/warfarin/

7 Transfer between Care Settings process

7.1 Initiation takes place in a different care setting to maintenance dosing

At the first patient consultation, either primary or secondary care, appropriate anticoagulation documentation (see section 9.4) should be completed

If patients are initiated in secondary care (in patient or clinic) there must be transfer of first consultation documents. Risk Assessment (appendix 2) and counselling checklist (patient education) Appendix 3, and details of the documentation / dose and INR frequency(Appendix 4) needs to be received and completed for:

- Existing warfarin patients who are currently monitored by secondary care
- New warfarin patients initiated by secondary care
- Existing warfarin patients who are currently monitored in primary care who are admitted to and then discharged from secondary care

NOTE: Patients unable to be seen in primary care before their next hospital-booked clinic appointment will remain with their current arrangement until an appointment can be booked with the GP surgery.

7.2 Admission or discharge between care providers

When patients are transferred, it is important that the patient's handheld record of doses and INR result history is shared with the new care provider. If the patient hand held record is not available at the time of transfer, this information needs to be confirmed. History of doses and INR's are crucial and possible methods include:

- Access INRstar record
- Check ICE/INDIGO
- Check Summary Care Record (SCR)
- Check Great North Care record
- Contact GP surgery/ patient's relative/secondary care

8 Primary Care - Clinic Organisation

8.1 Each individual GP practice will organise their own clinics. If there are only a few patients at one practice, monitoring and dosing may be organised at another GP practice or within a Primary Care Network (PCN).

9 Clinical Management

Individual Management Plan

9.1 The patients registered GP in conjunction with the patient should prepare an individual management plan. The plan should outline, as a minimum, the diagnosis, planned duration of treatment and therapeutic range to be achieved. This should be reviewed annually including risk/ benefit of anticoagulation and time in therapeutic range.

9.2 All clinical information is recorded in the clinical system, including completion of the "significant problem" record with the indication for anticoagulation.

Initiating therapy

9.3 A GP may choose, or be asked, to initiate warfarin for suitable patients who require non-urgent anticoagulation e.g. in atrial fibrillation. Warfarin should be initiated according to the warfarin slow start guidelines (Appendix 6).

9.4 Risk assessment (appendix 2) and Counselling Checklist (appendix 3) are tools available to help when initiating new patients on warfarin.

Education of Newly Diagnosed Patients

9.4 The counselling checklist (Appendix 3) is a tool available for use in shared decision making and risk assessment prior to starting treatment and as a counselling tool for the safe use of Warfarin. The counselling should be comprehensive to ensure that patients are fully aware of their treatment.

9.5 Check the patient has received a yellow Anticoagulant pack. The yellow dose record book or INR Star printed record should be held by a patient as a record of their current dose, which may be requested when obtaining repeat prescriptions from the pharmacy. Patients should be encouraged to carry their yellow credit card style information card with them at all times and pro-actively show it when seeking medical or dental treatment, or buying medicines from a pharmacy.

9.6 Yellow books for Anticoagulant Information, record books and alert cards can be ordered from PCSE. Either via the online portal www.pcse.england.nhs.uk or via telephone 0333 014 2884 (free of charge)

9.7.1 Ten alternative language translated anticoagulant booklets are available to download from http://www.nrls.npsa.nhs.uk/resources/?EntryId45=61777

9.7.2 It is essential all warfarin patients keep their clinic appointments. Non-attendees should be identified immediately. The patient should be given and informed of new appointment within one week. If the patient fails to attend again, they 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.

10 Warfarin Supply

10.1 Different people require different doses of warfarin. Some pre-existing conditions or genetic dispositions may make patients more or less sensitive to warfarin. Drugs, herbal remedies and diet also have the potential to interact dangerously with anticoagulants (section 14).

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

10.3 Warfarin will be supplied from the patient's registered GP via a prescription. Wherever possible the patient should not be provided with more than two strengths of warfarin. Tablets should be routinely supplied in 1mg and 3mg strengths to ensure a consistent approach across primary and secondary care and minimize the risk of confusion. In exceptional circumstances e.g. high warfarin sensitivity or high dosage requirements, warfarin may be prescribed in 0.5mg or 5mg strengths. In these instances the prescription must indicate the strength prescribed in both numbers and words ("half mg" or "five mg") to ensure that the correct tablet is given. The patient should be supplied with the least number of different strengths of tablets possible.
All healthcare professionals should be aware that in March 2007 the National Patient Safety Agency (NPSA) issued alert 18: Actions that can make anticoagulant therapy safer. https://webarchive.nationalarchives.gov.uk/ukgwa/20171030131022/http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=59814&p=3
It is recommended that only 1mg strength warfarin tablets are used for the majority of patients. Where patients are on doses of greater than 5mg and can manage different strengths, it may be considered appropriate to use higher strength tablets. Use of 0.5mg dosing is not recommended to avoid confusion with the 5mg – take extra care when selecting

different strengths off a picking list. INR Star has the functionality to switch 0.5mg strength off, so that all doses are to the nearest mg.

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

Strength	Colour
0.5 mg	White
1 mg	Brown
3 mg	Blue
5 mg	Pink

10.5 Specific dosing instructions will not normally appear on the dispensing label (must include advice to follow written dose instructions). All dosing instructions will be given verbally and written in the patient's yellow warfarin booklet or on a computerised dosing sheet.

11 INR Testing

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

- Are they feeling generally well? i.e. do they have any illness that may affect the INR e.g. diarrhoea
- Have they been in hospital lately?
- Any pain in their face, arms or legs? Any loss of vision, speech or movement in arms or legs? Any numbness in some parts of the body?
- Has the patient experienced any signs of bleeding e.g. from nose, gums, bowels or bruising?
- Is the patient planning any dental or other surgery?
- Has the patient been taking their warfarin as directed by the warfarin clinic/GP or have they missed any doses?
- Has there been a change in the patient's other medications, herbal remedies or over the counter products since their last test?
- Any major changes in diet or alcohol consumption?

If the patient answers 'yes' to any of these questions, refer to the GP if necessary.

.2 Check patient contact details on a regular basis. Relevant information should be recorded in the patient record and CDSS.

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

Near Patient Testing and High INR Results

11.4 If the INR result is greater than 5.0, then repeat the patients INR using a new test strip using near patient testing device (NPT e.g. CoaguChek Pro II® or XS plus®)
When INR > 5.0 **ACTION MUST BEEN TAKEN IMMEDIATELY**.
Follow Guidelines of Treatment of Over-Anticoagulation as in Appendix 7 and 8.

11.5 If the second result is within 0.5 of the original result then accept the result and proceed. If the second test is more than 0.5 different from the first then disregard the results. Send a venous sample to the central laboratory and perform Internal Quality Control on NPT device (see section 17.3).

11.6 For any INR result >6.4, please send a venous sample to central laboratory to confirm INR and dose recommendation given

11.7 The device will NOT record a specific measurement when an INR > 8.0. Send a venous sample to the central laboratory to obtain a specific INR measurement. Repeat NPT test if INR > 8.0 to confirm the first result and before administering vitamin K if indicated.

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

11.9 If a laboratory sample is required because of a high INR and there is no blood collection from the provider's base within 4 hours, the patient should attend the hospital for a blood test. Ensure patient's contact details are correct, so patient can be contacted urgently.

11.10 If an unexpected result occurs, repeat the INR test to double check.

11.11 If the patient has significant anaemia or polycythaemia, this may lead to unreliable results. Therefore, venous sampling should be used. All known polycythaemia patients must have full count sample taken to confirm PCV result before adjusted citrate tube should be used by INR (ADAS SOP IS-063 Patients with high PCV)

11.12 All patients who are known to have Antiphospholipid antibodies ie Lupus anticoagulant and/or anti-cardiolipin antibodies can be tested using the Coaguchek device, but should have a venous sample taken for laboratory confirmation (ADAS SOP IS-046 Patients with Antiphospholipid Antibodies)

12 Dose adjustment of oral anticoagulants

12.1 The anticoagulant dose should be adjusted by the practitioner, with reference to the patient's INR and any other changes that may be identified during the appointment (see 11.1 above for questions to be asked).

12.2 Dosage of oral anticoagulants should be **guided** by using Computerised Decision Support Software (CDSS) or by approved clinical guidelines (example is Appendix 1). CDSS is used in most practices eg INRstar and the clinician can accept or alter dosage and / or reset review dates if clinically appropriate. Please note that CDSS dosing is superior to manual dosing (BSH 2018)

12.3 Dose alterations should be done carefully in small increments, which will be depend on current weekly dose and level of INR. As a guide, doses should not be increased by an absolute maximum of 20% of the weekly dose.

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

Frequency of INR Monitoring

12.5 The length of time between INR test dates varies, the maximum recommended length of time allowed between INR tests is 12 weeks (BCSH Guidelines 1998). For those with mechanical heart valves, the maximum recommended length of time is 8 weeks. The length of time between INR tests will depend on the patient's INR measurement stability and untoward occurrences likely to cause instability.
https://cks.nice.org.uk/topics/anticoagulation-oral/management/warfarin/

Communicating Dose Changes

12.6 The provider will need to ensure the patient has written dose instructions. A printout of new doses from CDSS (INRstar) will be acceptable to give to the patient. Doses can be updated 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*).

12.7 Date of the next INR test and contact numbers for advice should be given to the patient.

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.

12.8 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 written instruction. Practices are strongly recommended to develop a protocol for this.

12.9 Particular care should be taken when communicating dose changes to patients in social care settings e.g. nursing or residential care homes. The person in charge should be informed of the warfarin dose and next review date over the phone. This information must be confirmed in writing eg send via secure nhs.net email to care home and pharmacy involved. Practices and care homes are strongly recommended to develop a protocol for this. CQC issued guidance in Oct 2020 https://www.cqc.org.uk/guidance-providers/adult-social-care/high-risk-medicines-anticoagulants

12.10 Inclusion of warfarin in Monitored Dosage System (MDS) is not recommended. NPSA recommends warfarin is administered from original packs dispensed for individual patients. MDS is not flexible enough to cope with the frequent dose changes.

13 Drug interactions

13.1 Many drugs, whether prescribed, over the counter, herbal or alternative remedies, can interact with warfarin. When prescribing, a non-interacting drug should be chosen when possible. For short courses of a new drug, warfarin dose adjustment is not essential. For a drug change lasting more than 7 days an INR test should be performed 3–7 days after starting the new medication so that the warfarin dose can be adjusted on the basis of the INR result.

13.2 . Up-to-date information on drug interactions with warfarin can be found in the British National Formulary or NICE CKS on warfarin

https://bnf.nice.org.uk/interaction/warfarin.html

https://cks.nice.org.uk/topics/anticoagulation-oral/management/warfarin/

13.3 There is now a dedicated website for HIV drug interactions or the primary care provider can be contacted for more information. Website: http://www.hiv-druginteractions.org/

13.4 There are also potential interactions with complementary medicines (Appendix 5.) or SPS (Specialist Pharmacy Service) CAMS (Complimentary and Alterative Medicines) information

https://www.sps.nhs.uk/articles/handling-questions-about-herbal-medicines-or-dietary-supplements-and-conventional-medicines/

14 Discontinuation

14.1 The maximum duration of overall treatment will be documented on the patient record and in patient's yellow warfarin booklet.

14.2 If a decision is taken to discontinue warfarin, it can be stopped on a defined date without any need to taper.

14.3 The patient or carer must be informed in clinic or domiciliary visit and followed up in writing to confirm this. It should be clearly documented on the patient's record.

14.4 Consideration may need to be given to the early discontinuation of therapy in situations where the risks outweigh the benefits of continued treatment, e.g. patients not attending regular monitoring, those unable to follow the dosing regime. DOACs are an alternative although they still need to be taken regularly.

14.5. If, after 6 months, the patients continues to have a low TTR value, the patient needs a review of their anticoagulant and the risk vs benefits and reason for low TTR values **NICE AF CG180 June 2018 Reassess anticoagulation for a person with poor anticoagulation control,** indicated by any of the following:

- 2 INR values higher than 5, or 1 INR value higher than 8 within the past 6 months.
- 2 INR values less than 1.5 within the past 6 months.
- Time in therapeutic range (TTR) is less than 65%.

15 Training

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

15.2 GPs who are providing an anticoagulation service should ensure that they stay up to date to maintain their competency.

15.3 Any staff who are involved in anticoagulation, are required to complete e-learning on anticoagulation. Evidence of undertaking the module and passing the assessment must be retained within the practice.

15.4 Various anticoagulation e-learning modules are available, for example:

- MHRA have produced an e-learning module for anticoagulation, which includes warfarin and the DOACs (New Oral Anticoagulants). https://www.gov.uk/government/publications/e-learning-modules-medicines-and-medical-devices/e-learning-modules-medicines-and-medical-devices

Please sign up for MHRA Learning Management System: Clientele – from drop down menu choose MHRA Click Learner Log In and then Register Here.
Once registration is completed, search for the Oral Anticoagulants module.
Complete e-learning module and pass the associated assessment.

- e-LFH https://portal.e-lfh.org.uk/Component/Details/506729

- BMJ e-learning modules - no longer freely available to NHS staff, but can be accessed via Athens

  Starting patients on oral anticoagulants in primary care: how to do it

  https://new-learning.bmj.com/course/10052760

  Maintaining patients on oral anticoagulants: how to do it

  https://new-learning.bmj.com/course/5004429

- PrescQIPP

https://www.prescqipp.info/learning/prescqipp-e-learning/course-overview/#acc30
e-learning based on NICE CG 180: Treatment of Atrial Fibrillation so not specifically warfarin orientated, but gives e learning on condition and anticoagulants, including warfarin

- Bluestream

Other sources of further anticoagulation training:

- **Birmingham University** National Centre for Anticoagulation Training provide courses.

http://www.birmingham.ac.uk/research/activity/mds/projects/HaPS/PCCS/anticoagulation/index.aspx

- **CPPE workbook** - https://www.cppe.ac.uk

This is a challenging e-learning package designed for pharmacists but has lots of good information on anticoagulants. "Anticoagulation: managing patients, prescribing and problems" for pharmacists

16 Reporting near misses, incidents and serious untoward incidents

16.1 It is important that providers will report all significant and serious untoward incidents which relate to anticoagulation to North Cumbria CCG via SIRMS (https://sirms.necsu.nhs.uk).

16.2 The purpose of sharing these is to allow the practice to review them, and see if there is any learning opportunities from the case. Once you have done that, we would be grateful for feedback on what was found, as this may have learning opportunities for other practices

16.3 GP surgery should have a system and protocol in place to review incidents, including ensuring the6learning and reflection from incidents is shared within the practice and with affected patients (where applicable) as part of the resolution process.

- CQC state that within a 'good' practice all staff should be open and transparent and fully committed to reporting incidents and near misses.
  The Duty of Candour sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.
- CQC recommend reflecting on incidents using Significant Event Analysis: https://www.cqc.org.uk/content/nigels-surgery-3-significant-event-analysis-sea
- Explanation of what is expected in the Duty of Candour Regulation http://www.cqc.org.uk/guidance-providers/gps/nigels-surgery-32-duty-candour-general-practice-regulation-20
- National Reporting and Learning System reporting for serious incidents: https://www.cqc.org.uk/content/nigels-surgery-24-reporting-patient-safety-incidents-national-reporting-and-learning-system

16.4 Key areas of risk are:

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

17 Quality Assurance

17.1 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.

17.2 The GP surgery must complete all relevant documentation pertinent to providing the service and record any action taken which is outside the service protocol.

Internal Quality Control (IQC) of Near Patient Testing (NPT)

17.3 Those GP surgeries using near patient testing must perform internal quality control procedures as per the manufacturer's instructions (contact manufacturer if needed).

Frequency of IQC tests

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

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

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

17.7 All IQC results, together with the batch/lot number of test strips employed at each clinic/surgery should be recorded to create an audit trail. This may be electronic.

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

17.9 Those GP surgeries using near patient testing equipment will be required to join an External Quality Assurance Scheme (e.g., UK NEQAS or WEQAS). Further information is given at Appendix 9.

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

18 Audit

18.1 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 North Cumbria CCG Local Enhanced Service document. The audit results will inform what local actions are needed to improve the safe use of anticoagulants, and will also be used as part of the performance management process of North Cumbria CCG.
See appendix 10 for template for practice anticoagulation audit

19 References

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19.29 ADAS (Anticoagulation Dosing Advisory Service) at Blackpool Hospital Trusts – thank you for their expert opinion and access to the SOP's relating to anticoagulation services

Appendix 1 - Warfarin prescribing guidelines

1 General Guidance

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

2 Background

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

Table 1: Indication and target INR's

	Target (±0.5)
Treatment of venous thrombosis [DVT]	**2.5**
Treatment of pulmonary embolism [PE]	**2.5**
Atrial fibrillation	**2.5**
Valvular heart disease	**2.5**
Tissue heart valves	**2.5**
Transient ischaemic attacks	**2.5**
Myocardial infarction: prevention of venous thromboembolism	**2.5**
Recurrent deep vein thrombosis and pulmonary embolism	**3.5**
Intravascular stent	**2.5**
Mechanical prosthetic valves – all patients will be discharged from the cardiothoracic unit with a recommended target INR range(see BSCH guidelines) The recommended target INR depends on the type and location of the valve. A target INR of 3 is usually recommended for mechanical aortic valves, and 3.5 for mechanical mitral valves. https://cks.nice.org.uk/anticoagulation-oral#!scenariorecommendation:32	

3 Dosage Regimens

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

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

4 Duration of therapy

4.1 After a single episode of venous thromboembolism, 3 or 6 months of warfarin therapy is necessary depending on the thrombus position. The duration of therapy needed after a second episode of DVT or PE is uncertain but long-term anticoagulation is normally advocated.

4.2 For patients with atrial fibrillation and heart valves, the duration is as long as the condition is present. In most cases this is long-term. Often it is a change in a patient's condition (e.g. becomes confuses) that requires the cessation of therapy.

5 Frequency of INR Monitoring

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

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

One INR high	Recall in 7 to 14 days (stop treatment for 1 to 3 days) (maximum 1 week in prosthetic valve patients)
One INR low:	Recall in 7 to 14 days
One INR therapeutic:	Recall in 1 to 2 weeks
Two INRs therapeutic	Recall in 2 to 3 weeks
Three INRs therapeutic	Recall in 3 to 4 weeks
Four INRs therapeutic	Recall in 4 to 5 weeks
Five INRs therapeutic	Recall in 6 to 8 weeks (maximum of 8 weeks for prosthetic valve patients)
More than 5 INRs therapeutic	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)

6 Factors affecting Warfarin Dosing

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

6.2 The following conditions cause warfarin sensitivity [i.e., need for reduced dose]:

i. Liver dysfunction
ii. Heart failure
iii. Hyperthyroidism
iv. Acute pyrexial episode

6.3 Some conditions cause warfarin requirements to be increased [i.e. need for greater than normal dose]:

i. Hypothyroidism

ii. Vitamin K containing remedies, e.g. some herbal remedies and enteral feeds

7 Warfarin Dose Adjustments

7.1 It is recommended that computer dosing decision software be used for dosing. If dosing is performed manually, and a dose adjustment is required, this should not normally be changed by more than 10% a week.

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

8 Suggested Dose Adjustments Regimens

8.1 Sub-therapeutic INR

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

	INR	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.

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

	INR	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†	1 week

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

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

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

8.2 Over-anticoagulated

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

		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. Restart when INR <5.0 at reduced dose. Consider Vitamin K (see appendix 7&8)	Next day

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

	INR	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 (see appendix 8&9)	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 and that the results are acted on.

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

Appendix 2 – Risk Assessment Tool

The decision to anticoagulated is a clinical decision depending on diagnosis and risk of an event. NICE guidance NG196 has provide risk assessment tools to include CHAD2VASC2 and ORBIT (or HASBLED until ORBIT becomes available on EMIS) for non-valvular atrial fibrillation https://www.nice.org.uk/guidance/ng196/chapter/Recommendations#assessment-of-stroke-and-bleeding-risks

The warfarin risk assessment tool should be used annually to decide if patient's circumstances have changed and if warfarin is an appropriate choice of treatment

Risk Assessment Tool for warfarin

If a patient is to be started on warfarin, this risk assessment tool helps identify any risk factors to be considered before prescribing warfarin. These following points are for guidance only and ticking "yes" in any section is not necessarily an absolute contraindication to warfarin, but should help you balance the risks. The decision to use warfarin or a direct oral anticoagulant or to continue anticoagulation is the responsibility of the prescriber.

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

Appendix 3 – Warfarin Counselling Checklist

Patient name:
Patient NHS Number:
Date of Birth:

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

Counselled by: (Signature): ……..……..……..…..
Print name and Designation……..……..…… ……..……..……..……..…
Date……..……

Warfarin Counselling Advice

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

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

4. Indication for therapy – explain why the patient is taking warfarin. Common examples (list not exhaustive) and patient explanations include: • DVT/PE – "to prevent the clot getting bigger or returning • AF- "when the heart is not beating regularly the blood will not flow smoothly. Therefore there is a risk of getting a clot which may travel through the body and cause damage e.g. a stroke" • Pre & post DC cardioversion for AF • Heart valves – "there is a risk of getting clots around the valve, which may float through the body and cause damage; also to prevent valve damage" • Some cancer patients who are receiving thalidomide in combination with chemotherapy and dexamethasone – "to reduce the risk of getting a clot which is sometimes associated with this group of patients

5. Expected duration of therapy (if known) – if unsure, check with Doctor. Do not assume or guess. • DVT/PE- may be a short course (3 – 6 months) or life long if recurrent • AF/heart valves – treatment will be lifelong • DC cardioversion – e.g. at least 4 weeks before and 4 weeks after, the latter depending on success of DC cardioversion (may be longer in practice – 8 weeks) • Cancer patient receiving thalidomide in combination with chemotherapy and dexamethasone – until end of treatment

6. Tablet identification • Explain colour of the different tablet strengths and that they will always be the same colour for each strength even if the supplier is different. • White 500 micrograms/Brown 1mg tablets/Blue 3mg tablets/Pink 5mg tablets. It is unusual for patient to get all 4 strengths.

7. Dose • Varied dosing according to blood result/INR • Warfarin should be taken at same time of day, every day (which is often around teatime / (6-7pm). If patient decides to take it in the morning, tell patient to inform hospital staff if (s)he is ever admitted to reduce the risk of getting a double dose (since many hospitals prescribe in-patient warfarin at 6pm) • How to use the different tablets strengths to make up the dose intended • If a dose is missed, OK to take on the same day within 6 hours of when dose was due. NEVER double up on a dose but carry on as normal on next day if dose is missed. Make a note of the date the dose was missed in the yellow book and let anticoagulant clinic/doctor know. If unsure then it is better to miss the dose rather than risk taking a double dose

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

9. Monitoring • INR is monitored regularly initially (daily/every few days) and gradually less often once dose and INR settles (monthly or up to 12 weekly) • Outpatient monitoring clinics / GP practice (and importance of attendance)/ District Nurse

10 Side effects of warfarin and poor control of anticoagulation (and what to do if experienced) • Recurrence of thomboembolism: contact GP if original symptoms recur • Signs/symptoms of excess dosing: severe bleeding or multiple bruising with or without high INR is the most common side effect: contact doctor immediately if unusual or severe • Contact GP if these occur: bloody stools or urine, nose bleeds (if lasting for >5mins or if pt does not usually suffer from nose bleeds), bloodshot eye, coughing or vomiting blood, excessive vaginal bleeding, cuts that take longer that 5 mins to stop bleeding • Bleeding from gums (use a soft toothbrush) • Any other side-effects: discuss with GP

11. Potential for drug interactions: may be affected by many medicines, therefore: • Patient should always let doctor/dentist/pharmacist know that (s)he is on warfarin • Not to take aspirin unless prescribed by doctor.

Care with OTC painkillers (e.g., Ibuprofen/aspirin preparations). Paracetamol is preferred • Caution with antibiotics and always check with pharmacist/anticoagulant clinic before taking herbal remedies • Inform GP/anticoagulant clinic of any drugs stopped started or if doses are changed

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

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

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

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

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

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

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

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

20. Further advice/ information GP surgery or patient information leaflets

Appendix 4 - Transfer of Care Anticoagulation Referral Form

ANTICOAGULATION TRANSFER OF CARE FORM

GP : GP email Referring Specialist Contact details:	Name: DoB : (Affix Patient Label Here) Hosp N°: NHS N°:

Name of current anticoagulant: warfarin ☐ other ☐ please specify……..……..……

Date anticoagulation started:

Indication and duration of anticoagulant:

☐	Tick as appropriate	Target	Duration	☐	Tick as appropriate	Target	Duration
	Calf DVT	2.5	12 weeks		AF	2.5	Long term
	Proximal DVT	2.5	26 weeks		TIA	2.5	Long term
	Recurrent DVT	2.5	long term		CVA	2.5	Long term
	Recurrent DVT whilst On warfarin	3.5	long term		Cardiomyopathy/ Mural thrombus	2.5	Long term
	PE	2.5	26 weeks		Mitral/aortic valve disease	2.5	Long term
	Recurrent PE	2.5	long term		Tissue prosthetic heart valve	2.5	12 weeks
	Recurrent PE whilst On warfarin	3.5	long term		Mechanical Prosthetic heart valve		
	Prophylactic	2.5	long term		Other- please specify		
Please specify if post – op				**Yes/ No**			

Please list the previous 3 INR results (or more if possible) and dose of warfarin

Date	INR	Warfarin dose

Current dose of warfarin……..……..……..…

Any factors which could have affected INR eg Significant medical or surgical problems

Other Medication started or stopped which could affect warfarin (see BNF for list of interactions):

Is the patient on any anti-platelet or anticoagulant drugs? ☐ Yes Specify……..……..……... ☐No

If yes, are these to continue? ☐ Yes ☐ Stop when INR is in target range ☐ No

	Date	Signature
Risk Assessment complete		
Counselling checklist complete		
Transfer of care form complete		
Next INR appointment made		
Yellow book issued		
Transfer of care form and checklist sent between settings		

https://bnf.nice.org.uk/treatment-summary/oral-anticoagulants.html

Appendix 5 - Warfarin Drug Interactions

This guide is intended as a quick reference to highlight significant interactions between warfarin and commonly prescribed 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.

Interacting Drug	Potential problem	Comment
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.
Cranberry Juice	Increases anticoagulant effect of warfarin	Avoid use in patients taking warfarin.
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 increases 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 Gingko 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.
Glucosamine	Reports of increases in INRs	Patients on warfarin are recommended not to take glucosamine.
Interacting Drug	**Potential problem**	**Comment**
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.

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.
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.

References:

- Stockley's Drug Interactions 10th Edn. (2013). Ed. Karen Baxter. Pharmaceutical Press, London.
- Pharmaceutical Society of Great Britain. Pharmaceutical Press, London.
- Ernst, E, Ewings P et al., Co-ingestion of herbal medicines and warfarin. British Journal of General Practice 2004; 50:
- 439-441
- Interactions between complimentary medicines and conventional medicines. National Collaborative Medicines
- Management Services Team of East Birmingham PCT, October 2002.

Appendix 6 - Warfarin Slow Start Regimen

This warfarin induction regimen[1] should be used for both primary and secondary care initiation of warfarin for suitable patients (see indications and exclusions below).

Background

Patients not requiring rapid anticoagulation can be safely managed using a slow loading regimen which results in therapeutic anticoagulation within 3 to 4 weeks in the majority of patients[1] [2]. This appears to avoid over-anticoagulation and bleeding associated with rapid loading. There is no need to cover with heparin as no procoagulant state occurs when slow loading the patient.

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

Indications: For use in patients for whom immediate anticoagulation is **not** required. These include:

- chronic or paroxysmal atrial fibrillation;
- selected patients with left ventricular thrombus;
- selected patients with mitral stenosis;
- stroke outpatients in sustained AF who have waited 14 days following the acute event with a CT head scan that has excluded haemorrhage;
- selected patients with pulmonary hypertension.

Exclusion Criteria: Patients requiring immediate anticoagulation. These include:

- deep vein thrombosis and / or pulmonary embolus;
- mechanical prosthetic cardiac valve insertion;
- arterial embolus;
- selected patients with atrial fibrillation, left ventricular thrombus, mitral stenosis; pulmonary hypertension associated with venous thromboembolic disease.

Regimen:

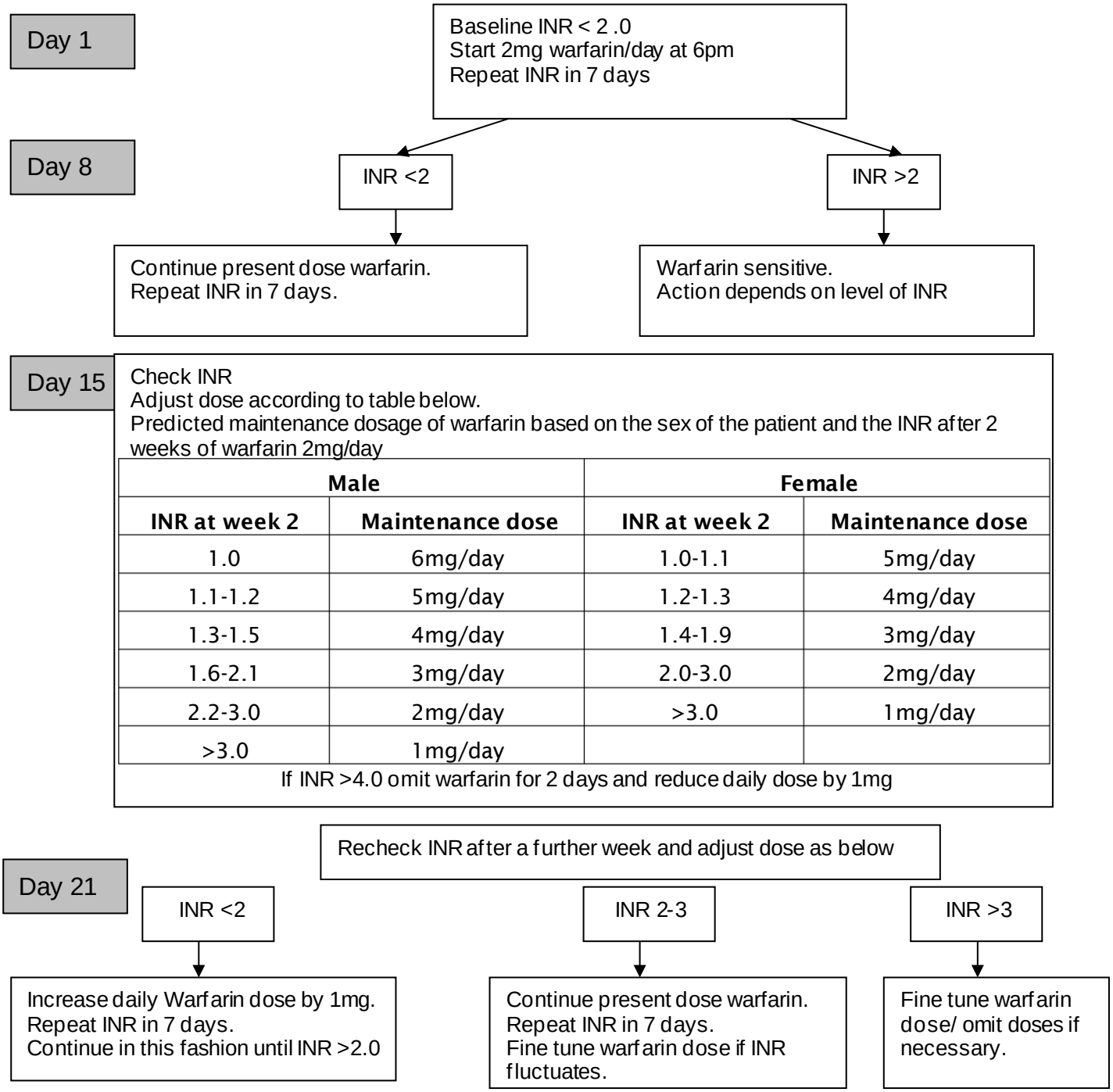
1. Ensure the patient has no contraindications to warfarin and confirm with a senior member of the medical team that the slow start regimen is appropriate. Generally if a patient is taking aspirin, this should be continued until the INR is therapeutic then STOPPED.
2. Ensure baseline bloods (FBC, U&E,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

References

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): fourth edition- 2011 *British Committee for Standards in Haematology* http://www.bcshguidelines.com/documents/warfarin_4th_ed.pdf

NOMOGRAM FOR WARFARIN SLOW START REGIMEN



Male		Female	
INR at week 2	**Maintenance dose**	**INR at week 2**	**Maintenance dose**
1.0	6mg/day	1.0-1.1	5mg/day
1.1-1.2	5mg/day	1.2-1.3	4mg/day
1.3-1.5	4mg/day	1.4-1.9	3mg/day
1.6-2.1	3mg/day	2.0-3.0	2mg/day
2.2-3.0	2mg/day	>3.0	1mg/day
>3.0	1mg/day		

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. Tait, R.C. & Sefcick, A. (1998) A warfarin induction regimen for out-patient anticoagulation in patients with atrial fibrillation. *British Journal of Haematology*, **101**, 450–454
3. Janes, S., Challis, R. & Fisher, F. (2004) Safe introduction of warfarin for thrombotic prophylaxis in atrial fibrillation requiring only a weekly INR. *Clinical and laboratory haematology*, **26**, 43–47

Appendix 7 - Guidelines for the Management of Over-anticoagulation

Major Bleeding	
All patients	Treat as a medical emergency and admit to hospital
INR> 8.0 with minor bleeding	
	If using near patient testing, send a venous sample to the central laboratory for testing to obtain INR estimation. Omit warfarin give phytomenadione by slow intravenous injection. Repeat INR test following day. *If this falls on a weekend or bank holiday it is the responsibility of the prescribing GP to ensure the test is done and the results acted upon.* Restart Warfarin when INR <5.0 Reduce maintenance dose and investigate cause of high INR
INR > 8.0 with no bleeding manifestation	
All patients	If using near patient testing, send a venous sample to the central laboratory for testing to obtain INR estimation. Omit warfarin Give oral Vitamin K 1 to 5mg (Konakion MM Paediatric™ 2mg in 0.2ml) Repeat INR test following day. *If this falls on a weekend or bank holiday it is the responsibility of the prescribing GP to ensure the test is done and the results acted upon.* Restart Warfarin when INR <5.0 Reduce maintenance dose and investigate cause of high INR
INR 5.0 – 7.9 (with no bleeding or minor bleeding, e.g. epistaxis)	
High risk patients	Stop warfarin and withhold for 1-2 days Consider oral Vitamin K 1mg (Konakion MM Paediatric™ 2mg in 0.2ml) Repeat INR test following day. Restart Warfarin when INR <5.0 Reduce maintenance dose and investigate cause of high INR
Low risk patients	Omit warfarin Restart warfarin when INR <5.0 Reduce maintenance dose and investigate cause of high INR
1 High risk: age > 75 years; diabetes; renal failure; stroke; previous gastro-intestinal haemorrhage. The GP will use his or her own judgement in managing the risk for an older person living alone.	

References

1. Guidelines on oral anticoagulation (warfarin): fourth edition- 2011 *British Committee for Standards in Haematology* http://www.bcshguidelines.com/documents/warfarin_4th_ed.pdf
2. http://www.sign.ac.uk/guidelines/fulltext/36/section13.html
3. https://bnf.nice.org.uk/treatment-summary/oral-anticoagulants.html
4. https://cks.nice.org.uk/topics/anticoagulation-oral/management/warfarin/

Vitamin K Administration

Konakion MM Paediatric™ (phytomenadione 2mg in 0.2ml) 0.2ml ampoules should be used to manage high INRs in the community. Although this product is licensed for several routes of administration this protocol refers to oral use, which is off licence. Clinicians should use this framework and professional judgement on the best route of administration for the patient's situation based upon individual circumstances.

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

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

How to obtain Konakion MM Paediatric®

All practices providing an anticoagulation enhanced service must have this product readily available when the service is operating.

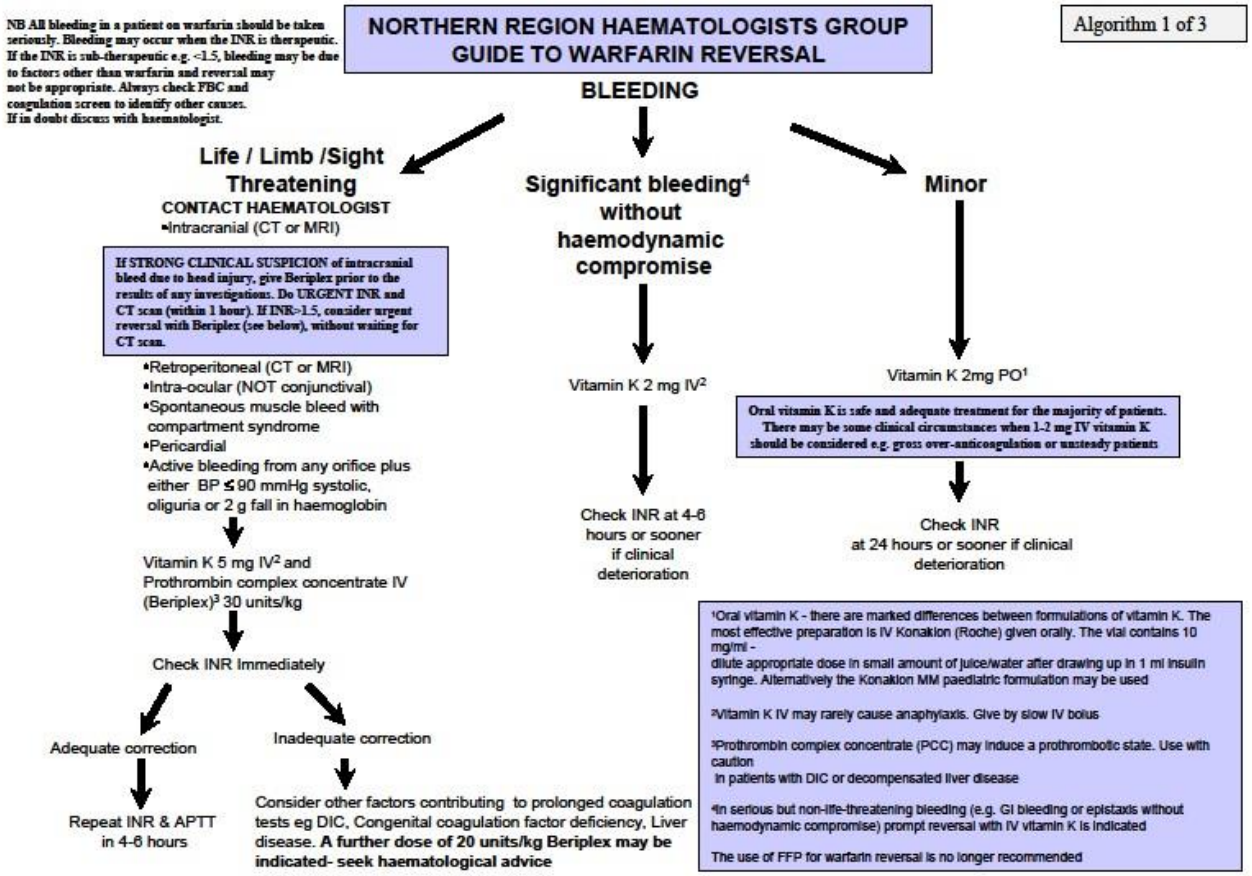
Your local community pharmacist can supply this on receipt of a signed order.

Clinical governance

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 8 - Northern Region of Haematologist Group Guide to Warfarin Reversal



Appendix 9 - National External Quality Assessment Scheme (NEQAS)

All providers are required to join an external quality assurance scheme, to identify the degree of agreement between one centre's results and those obtained by others.

Registration

To participate in the NEQAS scheme a registration form should be completed.

Surveys

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

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

Results

Results and associated data from participants will be treated with strict confidentiality. Each registered participant will be given a unique participation number, which should be quoted in all correspondence.

Performance analysis

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

Contact Details

UK National External Quality Assessment Scheme for Blood Coagulation
3rd Floor, Pegasus House
463A Glossop Road
Sheffield
S10 2QD

Tel: 0114 267 3300
Email: neqas@coageqa.org
URL: http://www.ukneqasbc.org

Appendix 10 - Example of Training Log for Annual Audit

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

……

Location of anticoagulation management clinic:

……

Please list the name of all staffs involved in anticoagulation management clinic and record the type and dates of training and education relevant to the anticoagulation management service received by practitioners and staff:

Name	Designation	Details of Training undertaken – please specify details					
		CDSS	Date	NPT device	Date	e-learning	Date
example	*Pharmacist*	*INRstar*	*20.11.2019*	*Coagucheck Pro II*		*MHRA module*	