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NHS Sheffield Clinical Commissioning Group

ANTICOAGULATION MONITORING SERVICE

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

Version:	5
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Approved by:	Area Prescribing Group
Date approved:	21 October 2021
Review date:	September 2026
Target audience:	All clinical staff involved in the provision of anticoagulation service commissioned by NHS Sheffield CCG

Anticoagulation Standard Operating Procedure		
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1 Scope of this document

This document aims to provide guidance and standards for the monitoring of INR in primary care settings for patients prescribed vitamin K antagonist (VKA) anticoagulants (i.e. warfarin, acenocoumarol and phenindione). Warfarin is the commonly prescribed VKA anticoagulant, and it shares the same monitoring principles with the other VKAs. This document aims to address the monitoring requirements and standards for warfarin to support the locally commissioned anticoagulation service.

This document does not provide guidance and standards for the prescribing and ongoing monitoring of non-vitamin K oral anticoagulants (NOACs), otherwise known as direct oral anticoagulants (DOACs). In this document the term DOACs will be used to refer to these medications e.g. rivaroxaban, apixaban, dabigatran and edoxaban.

2 Introduction

2.1 VKA anticoagulants have a narrow therapeutic margin and are safe only if monitored closely. In primary care, warfarin is one of the drugs commonly associated with fatal medication errors.

2.2 Locally in Sheffield, warfarin is generally prescribed on a shared care basis, with treatment initiated in secondary care being continued by GP practices. Safe warfarin therapy involves good communication when transitioning across the primary and secondary care interface.

2.3 This document sets out standardised and clinically effective procedures for the care of patients whose warfarin is monitored in primary care.

2.4 These procedures should be adopted by those providers who have been commissioned by NHS Sheffield CCG to provide level 3, 4 or 5 anticoagulation services. See appendix 8 for further details of service level.

2.5 National guidance for anticoagulation management during the COVID pandemic was issued by NHS England and Improvement. Please consider this guidance when reviewing/initiating anticoagulation for patients.

2.6 Self-testing of INR guidance was also produced during the COVID-19 pandemic to support patients anticoagulated with warfarin in whom treatment with a DOAC may not have been suitable.

3 National Guidance and Additional Resources

Guidance in this document is produced taking into account:

I. Keeling et al. (2011) Guidelines on oral anticoagulation with Warfarin- Fourth edition. *British Journal of Haematology*, **154**, 311-324. http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2141.2011.08753.x/full

II. NHS Sheffield CCG. Locally commissioned service specification – anticoagulation monitoring.

III. The National Archives. National Patient Safety Agency – Patient Safety Alert on Actions that can make anticoagulant therapy safer, February 2007. (Archived 2018).

IV. STH Guideline for the Investigation and Treatment of Venous Thromboembolic Disease (Deep Vein Thrombosis and Pulmonary Embolism) September 2020.

V. STH Anticoagulation Clinic Clinical Guidelines, Version 5. June 2018.

VI. Roche Coaguchek® XS Systems Professional Training Manual for Self-Testing 2007-2016. [Accessed 27/05/21].

VII. Roche Coaguchek® XS User manual. Version 4 2015. [Personal communication August 2021].

4 Aim

To ensure the provision of warfarin monitoring service in primary care is safe and effective.

5 Objectives

The objectives are as follows:

- To provide standardised and clinically effective management to patients receiving warfarin therapy whilst minimising the associated risks.
- To identify patients receiving warfarin and offer transfer of care from hospital to primary care clinics for appropriate patients.
- To initiate warfarin therapy for suitable patients.
- To achieve optimum management of INR control.
- To educate patients in understanding their treatment, in terms of their condition requiring warfarin therapy, target range for INR, the effects of over- and under- coagulation, diet, lifestyle and drug interactions.
- To appropriately manage patients whose INR exceed their target range or who are under coagulated.
- To maintain a register of all patients receiving VKA anticoagulant therapy and have a treatment plan for each patient that is reviewed on a regular basis.
- To review the need for continuation of therapy at each visit.
- To identify and appropriately manage patients with specific needs i.e. poor compliance, unstable INR control or frequent non-attendees.
- To optimise care to patients receiving warfarin therapy in terms of accessibility, continuity and waiting times.
- To ensure complete and accurate documentation of the clinic process.

6 Responsibilities of NHS Sheffield CCG

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

- Ensuring anticoagulant guidelines are available for the management of under and over anticoagulation.

7 Responsibilities of warfarin monitoring service provider

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

- Ensuring that dose recommendations and recall are **guided** by Computerised Decision Support Software (CDSS).
- Ensuring patients receive education regarding warfarin therapy – see section 16.4 for further information.
- Ensuring recommendations are available for review by the patient's registered GP.
- Alerting GPs to patients with bleeding problems and INR > 8 or who are otherwise considered to be at risk of bleeding. Discuss possible admission to hospital with the patient's GP. If this is not possible, arrange for the patient to be assessed at the hospital.
- Hold an in-date stock of vitamin K (Konakion® MM Paediatric) for the management of over-anticoagulation (Appendix 6).
- Alerting the patient's registered GP when the anticoagulation service is provided at a different site to the GP practice. The protocol for communication between the anticoagulation service provider and the patient's registered GP should be followed (Appendix 2).
- Dosing decisions (the amount of drug (VKAs) the patient needs to take and frequency) **must** be made by registered **health-care professionals (HCPs e.g. registered nurses, GPs or pharmacists)** who have undergone an approved course for practitioners undertaking anticoagulant monitoring in primary care. See Training section 14.
- Non-registered staff e.g. healthcare support worker (HCSW) can undertake a finger prick blood test but are not deemed suitably qualified to make dosing decisions. The extended role of non-registered staff is under review and further information will be provided in due course.
- Ensuring that patients are not discriminated against on the grounds of gender, age, ethnicity, disability, religion, sexual orientation or any other non-medical characteristic.
- Ensuring that patients who do not speak, read or write English or who have communication difficulties (including without limitation hearing, oral or learning impairments) are provided with appropriate assistance. A responsible person or carer should be identified who can assist the patient with any dose alterations.

8 Responsibilities of the patient's GP

Overall responsibility for the care of the patients continues to reside with the registered GP, and includes:

- Being aware of appropriate advice and guidelines for anticoagulant care.
- Giving advice on dosage and duration of anticoagulation as guided by initiating clinician.
- Being aware of the potential effects of additional therapy given to a patient on warfarin and arranging earlier INR testing with the anticoagulation provider as required.
- Arranging admission to hospital if required.
- Issuing warfarin prescriptions.
- Advising the warfarin monitoring service provider when warfarin monitoring service is no longer required by the patient.
- Where the primary care anticoagulation service is provided at a different site to the patient's registered GP practice, the protocol for communication between anticoagulation service provider and the patient's registered GP should be followed (Appendix 2).

9 Patient selection/ inclusion for the service (see also section 20)

9.1 A formal referral to the primary care provider must be made from secondary care anticoagulation clinic using the agreed transfer process. If a patient is transferred from another service provider then this needs to be discussed with the primary care provider and an appropriate referral agreed.

9.2 The procedure for existing warfarin patients who are currently monitored in primary care who are admitted to and then discharged from STH is given in Appendix 3.

9.3 Patients should not be referred to the Sheffield anticoagulation primary care service from secondary care within six weeks of initiation of warfarin.

9.4 Patients should have stable INR control - demonstrated by the last three previous INR results in the therapeutic range (+ / - 0.5 of target INR). However, in agreement with secondary care, individual service providers may choose to accept patients that do not meet this criterion.

10 Patient exclusion criteria from the service

10.1 Patients with the following conditions / problems would not normally be managed in primary care. The acceptance of monitoring responsibilities of this group of patients should be at the discretion of the provider and clinicians due to the nature of INR management of this patient cohort. Similarly, if any of these conditions arise during monitoring, further consideration needs to be given as to the appropriateness of future monitoring in primary care. Some conditions must be referred back to secondary care e.g. pregnancy.

- A known hereditary or acquired bleeding disorder
- Alcoholics due to instability in anticoagulation management
- Severe malnourishment due to absorption difficulties
- Mentally ill with no carer support in the community
- Dementia with no carer support in the community
- Liver failure
- Severe renal impairment
- Documented evidence of CNS haemorrhage
- Severe heart failure
- Uncontrolled severe hypertension
- Gastric-intestinal bleeding in the last 6 months
- Pregnancy (urgent referral to appropriate haematologist consultant)
- Cancer patients undergoing cancer therapies or with metastatic malignancy are managed by the oncologist or haematologist.
- Children under 16 yrs. (to be managed by paediatrician and haematologist)
- Homozygous protein C deficiency (risk of skin necrosis)

10.2 Near patient testing (NPT) may not be suitable for patients who have significant anaemia or polycythaemia, due to unreliable results. Patients who have a packed cell volume (PCV)/ haematocrit in the range 25-55% can be tested; those with a PCV outside this range should not be tested, as the Coaguchek®/MicroINR® meter will register an error message.

11 Actions for those patients excluded from primary care management.

11.1 Patients who are not eligible for treatment under an approved primary care warfarin monitoring service will remain under their present secondary care monitoring service.

12 Actions for patients not wishing to transfer to primary care management.

12.1 All eligible patients will be encouraged to receive treatment under this standard operating procedure. This will be achieved through health education supported by written information and reinforced through follow-up telephone calls wherever feasible.

12.2 Patients will continue to have a choice on whether they attend secondary or primary care for monitoring, since they may have a valid reason for wishing to continue their monitoring with STHFT. However, the benefits to patients of a local primary care service should be promoted wherever possible.

13 Primary Care - Clinic organisation and set-up

13.1 All patients will be seen in person either in a clinic at a GP surgery, at a pharmacy or at home.

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

primary care provider. The provider will be responsible for appropriate liaison with the patient's registered GP and secondary care anticoagulation services when necessary.

13.3 Each provider will need to ensure that adequate cover by suitably trained HCPs is arranged to cover illness and holidays.

14 Training

14.1 Each service provider must ensure that **all** staff involved in providing **any** aspect of care under the scheme has the necessary training and skills to do so. A competency framework for registered healthcare professionals has been developed for use in primary care. See appendix 10.

14.2 Before a non-GP practitioner (e.g. practice nurse, practice or community pharmacist) can provide a warfarin monitoring service, they must demonstrate suitable qualification and competence and must have completed an approved course for practitioners undertaking INR monitoring in primary care. (See section 7 for non-registered staff e.g. HCSW)

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

14.4 The key competencies for registered healthcare professionals that must be demonstrated are as follows, also refer to appendix 10:

- Assessment of patient.
- Correct use and maintenance, including quality control, of NPT device.
- Able to access correct patient record and record relevant information in CDSS.
- Obtaining adequate blood samples.
- Determination of INR results.
- Interpretation and dose adjustment based on the INR result.
- Understanding the range of problems likely to be encountered in interpreting INR results.
- Giving dosage instructions, information and advice to patients.
- Recognition of instances where it is necessary to seek further advice.

14.5 All external and in-house training undertaken by the provider's staff should be recorded.

14.6 The following educational resources are recommended to update CPD where necessary:

www.bmjlearning.com
"Starting patients on anticoagulants: how to do it",
"Maintaining patients on anticoagulants: how to do it"
For GPs, practice nurses and other healthcare professionals.

http://www.mhra.gov.uk/ConferencesLearningCentre/LearningCentre/Medicineslearningmodules/Oralanticoagulants/index.htm
MHRA Oral anticoagulants learning module
For all clinical practitioners

www.cppe.ac.uk
"Anticoagulation: managing patients, prescribing and problems"
For pharmacists

15 Call and Recall Procedures

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

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

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

First clinic appointment with primary care provider

15.4 Following agreement, in writing, from the primary care provider to take responsibility for warfarin monitoring of an individual patient, an appointment in primary care should be made. This must be on or before their next booked anticoagulation clinic appointment.

15.5 Patients unable to be seen on or before their next hospital-booked clinic appointment will remain with their current arrangement until an appointment can be booked with the primary care provider.

15.6 At the first consultation, anticoagulation documentation as specified in the service specification should be completed OR a standard template completed.

16 Clinical Management

Individual management plan

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

Clinical procedures

16.2 The service provider must ensure that all clinical information is recorded in the patient's GP clinical system including appropriate READ or SNOMED codes which indicates that the patient is on warfarin and the indication for anticoagulation. Service providers who do not have access to the GP clinical records must ensure similar information is communicated to the GP in a timely manner, ideally within one working day.

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

Education of newly diagnosed patients

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

a. The name of the drug and current dose.
b. The reason they are taking the drug.
c. Therapeutic range/ target INR and monitoring needs/ frequency.
d. The anticipated length of treatment.
e. What to do if bleeding or unexplained bruising occurs.
f. What to do in the event of a missed dose.
g. Symptoms of underdose/overdose and action to take if these occur.
h. Drug/drug and drug/food interactions.
i. Clinic arrangements and how to obtain further medicine supplies.
j. What to do if dental treatment/surgery is required.
k. What to do if a surgical procedure is required/indicated.
l. Who to contact regarding any worries or concerns relating to their anticoagulation management.
m. The importance and role of the patient held record or printed sheet.

16.5 An information booklet should also be given to the patient (and/or their carer and support staff) to reinforce the verbal counselling. A comprehensive booklet 'Oral anticoagulant therapy patient information booklet' , produced by NPSA, is recommended. This is available on-line in a variety of different languages.

16.6 Patients should be encouraged to carry their patient held record with them at all times and to show it to their GP/health practitioner whenever they seek medical or dental treatment or purchase medicines from a pharmacy.

Supplies of the yellow oral anticoagulant information booklet and record booklet are available from Primary Care Support England Online Portal, which can be accessed on: http://pcse.england.nhs.uk/supplies/

17 Documentation - Patient Register and Patient Records

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

- Patient name
- Patient date of birth
- Registered GP practice
- Indication for treatment, including computerised linkage of medication to indication where available
- Length of treatment
- Target INR
- Named medical practitioner initiating treatment
- Discontinuation date, where applicable
- INR results, dosage instructions and review dates
- Whether the INR result is from NPT or central lab testing
- Missed days (i.e. a record of days when the patient has not taken their anticoagulant therapy in accordance with dosing instructions)
- Concurrent medication
- Medical conditions, hospital admissions likely to affect anticoagulation such as an increased risk of haemorrhage, where known (BSH Guidelines 2011)
- Bleeding episodes
- Any actions taken, as well as dosing and retest dates e.g. education, advice
- Occasions when the patient failed to attend an agreed clinic appointment
- Contact details for patient or for carers responsible for the administration of warfarin

17.2 The patient held record must be updated or a CDSS dosing sheet issued at each visit. If their usual booklet is not available, a temporary record booklet / sheet must be completed and given to the patient.

17.3 The front of the patient held record must be completed i.e. indication, INR target range and duration of treatment, person with clinical responsibility, and emergency contact number. The anticoagulation service provider will contact the initiating hospital if any of these details are omitted.

18 Warfarin Supply, Testing and Dosing

18.1 Warfarin dosing is individual for each patient and the required doses show a wide variation. Some pre-existing conditions may make patients more or less sensitive to warfarin. Drugs, herbal remedies and diet also have the potential to interact dangerously with anticoagulants, and an indicative list of possible interactions is given at Appendix 4.

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

18.3 Warfarin will be supplied from the patient's registered GP via a prescription. Wherever possible the patient should not be provided with more than 2 strengths of warfarin. Tablets should be routinely supplied in **1mg and 3mg strengths** to ensure a consistent approach across primary and secondary care and minimize the risk of confusion. Note: STH only stock 1mg and 3mg strengths. 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 words and figures (e.g. '0.5mg / half mg' or '5mg / five mg') to ensure that the correct tablet is given.

18.4 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

18.5 Specific dosing instructions, the amount of drug (VKA) the patient needs to take, and frequency, will not normally appear on the dispensing label.
All dosing instructions will be given verbally as well as written in the patient held record or on a computerised dosing sheet.

INR testing

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

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

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

18.8 Those practices that are providing a level 3 anticoagulation service will receive their INR results from the laboratory via a pathology messaging system. Service providers must ensure a named person is responsible for promptly distributing the results and ensuring that a GP or a nurse is personally accountable for taking the necessary action.

18.9 Those providers undertaking a level 4 anticoagulation service will be using their own near patient testing equipment to obtain an INR result.

Near patient testing (NPT) and high INR results

18.10 If the INR result is greater than 5.0 then repeat the INR using a new finger prick test with the NPT device (e.g. Coaguchek®/ MicroINR®).

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

18.12 The devices will NOT record an INR of >8.0. If an INR result of above 8 is suspected, repeat the test. If the second result confirms the first, then send a venous sample to the central laboratory for testing.

18.13 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.

18.14 If a venous sample is sent for laboratory testing, full patient contact details, including alternative telephone numbers, must be on the form in case of urgent need for out of hours providers to contact the patient.

18.15 If an unexpected result occurs (higher or lower than expected from the patient's past history, e.g. >50% difference in the absence of any explanation for this), repeat the INR test.

18.16 If INR > 5.0, **ACTION MUST BEEN TAKEN IMMEDIATELY**.
Consider following guidelines for treatment of over-anticoagulation as in Appendix 6.

NPT and low INR results

18.17 If the INR is 1.7 or less action should be taken according to the appropriate INR target table in the 'Warfarin dose adjustment guidelines' Appendix 1 Section 2.

19 Dose Adjustment of Oral Anticoagulants

19.1 The warfarin dose should be adjusted by the registered healthcare professional, with reference to the patient's INR and any other changes that may be identified during the appointment (see 18.6 above).

19.2 Dosage of warfarin should be **guided** by using CDSS or by approved clinical guidelines (Appendix 1).

19.3 Dosing should not be increased by more than 10% of the total weekly dose.

Computerised decision support software (CDSS)

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

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

19.6 The trained / suitably qualified clinician can alter dosage and / or reset review dates if clinically appropriate.

Frequency of monitoring

19.7 The length of time between test dates varies, the maximum length of time being 12 weeks between tests (BSH Guidelines 2011). For those patients on warfarin long term for recurrent VTE or AF the maximum recommended interval is 12 weeks; for mechanical heart valves, the maximum recommended length of time between tests is 8 weeks. The length of time between tests will depend on the patient's stability and untoward occurrences likely to cause instability.

For INRstar the default maximum interval is set at 10 weeks. This requires adjustment to 12 weeks by the approved person responsible for INRstar.

Communicating dose changes

19.8 The provider must update the patient held record with dosage instructions. A printout of new doses from CDSS is acceptable to give to the patient, but these need to be kept to inform the patient handheld record, in accordance with the NPSA alert (2007).

19.9 Date of the next INR test should be recorded.

19.10 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.

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

19.12 Particular care should be taken when communicating dose changes to patients in social care settings (e.g. nursing or residential care homes). A suitably qualified member of staff should be informed of the warfarin dose and next review date over the phone. This information should be confirmed in writing e.g. by secure email or by post as appropriate. Providers are strongly recommended to develop a protocol for this.

19.13 Particular care should be taken when communicating dose changes to patients using monitored dosage systems (MDS e.g. NOMAD). Both the patient and the pharmacist filling the monitored dosage system should be informed of the warfarin dose and next review date over the phone. The information will be confirmed in writing to the patient and the pharmacist.

However, it is recommended that a risk assessment is done on patients prior to initiation of MDS and warfarin. Warfarin with its variable dosing and associated risks is not usually suitable for insertion into MDS. It may not be the most appropriate method of helping with medicine adherence and concordance.

NHS Sheffield CCG recommends the use of a standardised medicine assessment tool to assess the appropriateness of monitored dosage systems use.

20 Initiating Anticoagulant Therapy

20.1 A provider may choose, or be asked, to initiate warfarin for suitable patients who require non-urgent anticoagulation e.g. in atrial fibrillation. Warfarin should be initiated according to the STH warfarin slow start protocol (Appendix 5).

20.2 At the first appointment to initiate warfarin, the provider must ensure that the patient is given all the relevant information and education verbally and in writing – see paragraph 16.4 onwards. The provider should also complete the relevant sections of the patient held record and issue this to the patient.

20.3 This will be classed as a level 5 service and will be reimbursed accordingly. The patient will subsequently be managed on a level 3 or 4 service. See the service specification for further details.

21 Discontinuation

21.1 The maximum duration of overall treatment will be documented on the initial referral form and in the patient held record.

21.2 In respect of providers who are not the patient's registered GP practice (e.g. community pharmacies), towards the end of the maximum duration of treatment, a letter will be sent to the registered GP or to the responsible consultant asking for the date when warfarin therapy can be discontinued. Only when a reply has been received in writing will therapy be discontinued. If a reply is not received, then the provider should contact the registered GP to clarify the duration.

21.3 Warfarin will be discontinued completely on a defined date, unless otherwise specified by the registered GP or responsible consultant. The patient or carer will be informed in clinic, domiciliary visit or verbally by telephone and followed up by letter to confirm this.

21.4 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 regimen. A DOAC may be a suitable alternative for some patients, within its licensed indication. A national patient safety alert was released to identify DOACs prescribed inappropriately for mechanical valve replacement patients who should have continued their treatment with a VKA.

21.5 Patients with atrial fibrillation who are currently prescribed warfarin and are stable should have the option of switching to a DOAC at their next routine appointment as per the updated NICE Atrial Fibrillation guidance.

Those with poor control should be considered for a DOAC, within its licensed indication. Poor control is defined by NICE as:

- 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 last 6 months
- TTR less than 65%

For further information, refer to the Sheffield Anticoagulation for Stroke Prevention in Non-Valvular Atrial Fibrillation guidelines.

21.6 Early discontinuation of warfarin therapy should be discussed and communicated with secondary care clinician, where appropriate.

21.7 Discontinuation of warfarin may be necessary for some procedures. In certain cases, bridging anticoagulation may be needed. GPs should not be asked to prescribe or monitor bridging anticoagulation. Refer to the STH Bridging anticoagulation guidelines for more information.

22 Reporting near misses, incidents and serious untoward incidents

22.1 Whenever an incident or near miss occurs it must be reported to NHS Sheffield CCG Quality Manager for Primary Care. Email: SHECCG.SIManagement@nhs.net

22.2 Incidents should also be reported to the NHS England Patient Safety Events service.

22.3 Incidents should be reported as soon as possible after the event and at the latest within 48 hours of the incident being recognised.

23 Quality Assurance

General

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

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

Internal Quality Control (IQC) of NPT device

23.3 IQC are used to establish whether the particular technique is performing consistently over a period of time, to ensure day-to-day consistency. Many manufacturers of NPT devices and test strips for INR determination have control materials or electronic devices available for the purpose of IQC.

Those providers using CoaguChek® NPT device must perform IQC procedures; see below.

IQC for MicroINR® device is not required as this is completed each time an individual test strip is inserted into the device. Control solutions are available for use should providers policy require these.

IQC frequency of Professional CoaguChek® device

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

23.5 IQC results should be within range of INR units quoted by the manufacturer for one particular batch of test strips.

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

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

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

External Quality Assurance (EQA) of NPT

23.9 Those providers using NPT equipment are required to join an external quality assurance scheme (e.g. UK NEQAS).

Cleaning procedure

23.10 The NPT device should be cleaned and maintained as per the manufacturer's guidance.

24 Review of Care Pathway

24.1 It is strongly recommended that in each provider service, there is a nominated anticoagulation lead that understands the whole care pathway and reviews this periodically to identify potential problems. In particular, they should ensure that:

- There are robust clinical governance systems in place.
- There is a system for identifying all INR tests, which includes patients seen on home visits (this must not rely only on the phlebotomist).

- There is a failsafe system which ensures all results are received and appropriate action taken.
- The respective responsibilities of those in the pathway are clearly defined.
- Patients are aware of how they will be informed of their INR result, dosing instructions and recall date.
- Patients with specific needs are identified and appropriately managed, e.g. where the patient does not have a phone; there are communication problems; patients in social care settings; patients using MDS (e.g. NOMAD).

25 Audit

25.1 All providers will participate in an annual audit that will be based on the safety indicators identified by the National Patient Safety Agency (NPSA) and the criteria listed in the CCG Local Commissioned Service document. The audit results will inform local actions to improve the safe use of anticoagulants and will also be used as part of the quality assurance process of NHS Sheffield CCG.

Approved by APG: **21 October 2021**

Review date: September 2026

Appendix 1 - Warfarin prescribing guidelines

This section provides information summarised from Sheffield Teaching Hospital Anticoagulation Clinic: Clinical Guidelines v5 (June 2018). Its aim is to provide guidance for the prescribing of warfarin where no computer software is available or where advice is sought in conjunction with CDSS.

STH provides guidelines for inpatient warfarin treatment management. This can be accessed via the link below:

'STH Inpatient Warfarin Standards and Guidelines'

Available at:
http://nww.sth.nhs.uk/STHcontDocs/STH_CGP/Pharmacy/WarfarinGuidelines.docx

Section 1 – Warfarin indications, target INRs, and maximum recommended recall periods during maintenance therapy (not initiation)

Indication		Target INR	INR Range	Duration	Maximum recall interval (time between INR checks)
First episode VTE	PE or proximal DVT – provoked by surgery or other transient risk factors (eg COC pill, plaster cast)	2.5	2.0 – 3.0	3-6 months unless specified otherwise by Thrombosis Clinic or PE Clinic	12 weeks
	PE or proximal DVT – unprovoked	2.5		3-6 months, may be continued long term (balance of thrombotic vs bleeding risks)	
	Calf vein DVT	2.5		6 weeks - 3 months	
Recurrent VTE with INR in target range		3.5	3.0 – 4.0	Long term.	8 weeks
Antiphospholipid syndrome		2.5		Long term	12 weeks
Atrial fibrillation		2.5		Long term	12 weeks
Cardioversion		2.5	2.0 – 3.0	6 weeks prior to cardioversion. Long term after cardioversion (unless no recurrence of AF *and* low CHA_2DS_2VASc score, or patient insists)	Weekly for 6 weeks prior to cardioversion 12 weeks for all others
Mitral stenosis or regurgitation who have AF or a history of systemic embolism or left atrial thrombus or an enlarged left atrium		2.5	2.0 – 3.0	Long term	12 weeks
Acute arterial embolism followed by embolectomy		2.5	2.0 – 3.0	Long term	12 weeks
Dilated cardiomyopathy		2.5	2.0 – 3.0	Long term	12 weeks
Mechanical prosthetic valves – all patients will be discharged from the cardio-thoracic unit with a recommended target INR range					

Table 1: warfarin indications, target INRs and maximum recommended recall intervals

Section 2 - Warfarin Dose Adjustments

- All patients being transferred into the community for INR monitoring should have been on warfarin for > 6 weeks and fulfil the criteria for community anticoagulation (Section 9).

- Adjustment of the patient's anticoagulant dose will be performed by the appropriately trained pharmacist, nurse, or physician, in order to maintain the INR within the recommended range.

- These guidelines are for general guidance; consideration should be given to the patient's previous INR record, pattern of response, and the individual's specific details when making dose adjustments.

- Should the INR be outside the recommended range, the approved individual will first satisfy him/herself that there are **no obvious reasons** for this (e.g. drug interaction/ non-compliance/ change in diet or alcohol intake).

- It is recommended that appropriate CDSS e.g. INRstar N3 as approved by NHS Sheffield CCG be used for dosing.

- 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 treatment notes field.

- Appropriate circumstances in which it is appropriate to override the CDSS recommendations:
    - Where the practitioner has information about factors which may affect a patient's anticoagulation control (e.g. omitted doses of warfarin, medication changes, recent hospital admissions).
    - Where a practitioner takes into account the patient's previous response to dose changes.
    - Follow-up appointment intervals may be changed if necessary to account for holidays and other appropriate circumstances.
    - Where adjustment to total weekly dose may be necessary to avoid the use of 0.5mg doses (half tablets).

- INRstar will not make dose recommendations if the INR is less than 1.3 or greater than 5.0. In these circumstances dosing must be carried out manually using the guidance below.

Manual maintenance dosing adjustment

- If dosing is performed manually, and a dose adjustment is required, then the following general guidelines apply:

    - Adjustments to patient's weekly dose should be +/- 10%.
    - Boosting ("one off") doses should be approximately 50% greater than the patient's regular maintenance dose: therefore if daily dose 6mg, boosting

dose should be 9mg. **Again, consideration should be given to patient's previous pattern of response.**

- Manual dosing should be based on the following factors (if known):

    - Previous INR record
    - Previous pattern of response to dose adjustments
    - Patient-specific factors e.g. changes in clinical condition
    - Compliance issues
    - Drug interactions
    - Alcohol
    - Diet

- Dose change will take approximately 3 – 4 days to significantly alter INR reading if a boost dose has not been given.

Boost doses

- Boost doses may be considered to correct sub-therapeutic INRs in high risk patients i.e.
    - Mechanical heart valves with additional risk factors (valve replacement within last 3 months, previous valve related thrombosis, stroke, atrial fibrillation).
    - VTE in the previous 4 weeks
    - AF with previous stroke
    - Recurrent VTE whilst anti-coagulated

- A boost dose consists of one or two doses that are higher than the maintenance dose. A boost dose should be approximately 50% greater than the patient's regular dose.

- If a 'non high-risk' patient is known to have missed doses of VKA, it is reasonable consider administering a boost dose of VKA, and continue on same maintenance dose.

- If the INR is low due to an irreversible reason (e.g. a change to the patient's usual medication) a boost dose may be given and the regular dose also increased.

- Patients who struggle to follow instructions should not usually be given boost doses (unless their medication is administered by a carer). If such 'high-risk' patients have poor anticoagulation control, they should be discussed with the patient's clinician.

Warfarin dose adjustment guidelines (STH Anticoagulation Clinic, Clinical Guidelines v5, 2018).

Target INR 2.5 (range 2.0 – 3.0)

The following guidance applies to results obtained from venous samples and CoaguChek®/MicroINR® meters. As the latter will not report INRs greater than 8, the management of these patients is slightly different.

INR	Dose adjustment	Next Appointment	
1.7 or less	Increase dose. Boost doses may be considered in high risk patients (see above) *If VTE within previous 4 weeks, consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range. If advice is required on starting LMWH contact the on-call Haematology registrar at STH.* *If mechanical heart valve, can* ***consider*** *LMWH if patient considered at high risk of thrombosis (valve replacement within last 3 months, previous valve related thrombosis, stroke, atrial fibrillation). Contact the cardiothoracic surgical team for advice.*	1 week (3-5 days if on LMWH)	**If any active bleeding, regardless of INR, see guidance below**
1.8 – 2.2	Increase dose if consistently low	If dose changed: 2 weeks If dose not changed: standard retest interval (see below)	
2.2 – 2.8	In range – no change required	Standard retest intervals – see below	
2.9 - 3.3	Decrease dose if consistently high	If dose changed: 2 weeks If dose not changed: standard retest interval	
3.4 – 4.2	Decrease dose.	2 weeks	
4.3 – 4.5	Omit dose for 1 day, decrease dose.	Maximum 1 week	
4.6 – 7.0	Omit doses for 2 days, decrease dose	Maximum 1 week	
7.1 – 8.0	Ask patient about signs of bleeding Stop warfarin, restart at reduced dose when INR <5.0 Consider Vitamin K as advised by haematologist (see appendix 6)	3 - 5 days	
8.1 or greater, or unreadable on Coaguchek®/MicroINR® meter: see vitamin K guideline (Appendix 6)			

Target INR 3.5 (range 3.0 – 4.0)

The following guidance applies to results obtained from venous samples and CoaguChek®/MicroINR® meters. As the latter will not report INRs greater than 8, the management of these patients is slightly different.

INR	Dose adjustment	Next Appointment	
1.7 or less	Increase dose. Boost doses may be considered in high risk patients (see above) *If VTE within previous 4 weeks, consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range. If advice is required on starting LMWH contact the on-call Haematology registrar at STH.* *If mechanical heart valve, can* ***consider*** *LMWH if patient considered at high risk of thrombosis (valve replacement within last 3 months, previous valve related thrombosis, stroke, atrial fibrillation). Contact the cardiothoracic surgical team for advice.*	1 week (3-5 days if on LMWH)	**If any active bleeding, regardless of INR, see guidance below**
1.8- 2.7	Increase dose. Boost doses may be considered in high risk patients (see above)	1 week	
2.8- 3.2	Increase dose if consistently low	If dose changed: 2 weeks If dose not changed: standard retest interval	
3.3 – 3.8	In range – no change required	Standard recall intervals	
3.9 - 4.2	Decrease dose if consistently high	If dose changed: 2 weeks If dose not changed: standard retest interval	
4.3 – 5.0	Reduce dose	1 week	
5.1 – 7.0	Omit for 1-2 days and reduce dose	Maximum one week	
7.1-8.0	Omit for 1-2 days and reduce dose	3-5 days	
8.1 or greater, or unreadable on CoaguChek®/MicroINR® meter: see vitamin K guideline (Appendix 6)			

Target INR 3.0 (range 2.5 – 3.5)

The following guidance applies to results obtained from venous samples and CoaguChek®/MicroINR® meters. As the latter will not report INRs greater than 8, the management of these patients is slightly different.

INR	Dose adjustment	Next Appointment	
1.7 or less	Increase dose. Boost doses may be considered in high risk patients (see above) *If VTE within previous 4 weeks, consider starting low molecular weight heparin (LMWH) until INR is within therapeutic range. If advice is required on starting LMWH contact the on-call Haematology registrar at STH.* *If mechanical heart valve, can* ***consider*** *LMWH if patient considered at high risk of thrombosis (valve replacement within last 3 months, previous valve related thrombosis, stroke, atrial fibrillation). Contact the cardiothoracic surgical team for advice.*	1 week (3-5 days if on LMWH)	**If any active bleeding, regardless of INR, see guidance below**
1.8- 2.2	Increase dose. Boost doses may be considered in high risk patients (see above)	1 week	
2.3- 2.7	Increase dose if consistently low	If dose changed: 2 weeks If dose not changed: standard retest interval	
2.8 – 3.3	In range – no change required	Standard recall intervals	
3.4 – 3.7	Decrease dose if consistently high	If dose changed: 2 weeks If dose not changed: standard retest interval	
3.8 – 4.2	Reduce dose	1 week	
4.3 – 4.5	Omit for 1 day and reduce dose	Maximum 1 week	
4.6 – 7.0	Omit for 2 days and reduce dose	Maximum 1 week	
7.1 – 8.0	Ask patient about signs of bleeding Stop warfarin, restart at reduced dose when INR less than 5.0	3 – 5 days	
8.1 or greater, or unreadable on CoaguChek®/MicroINR® meter: see vitamin K guideline (Appendix 6)			

Evidence of bleeding will require a change in this schedule, and referral to the responsible physician, at any INR. Consideration should be given to correction of the INR in 'high risk' patients whose risk of bleeding is higher.

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.

Section 3 - Standard retest intervals

When 2 consecutive doses have remained unchanged, the recall interval may be increased as follows:

Previous test interval	Next test interval
1 week	2 weeks
2 weeks	3 weeks
3 weeks	4 weeks
4 weeks	6 weeks
6 weeks	8 weeks
8 weeks*	10 weeks
10 weeks	12 weeks

*The maximum test interval for patients with mechanical heart valves is 8 weeks.
The maximum test interval for patients with AF is 12 weeks.
The maximum test interval for patients on warfarin long term for recurrent VTE is 12 weeks.

Appendix 2:

Protocol for the communication between the primary care anti-coagulation service provider and the patients registered GP

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

Responsibility of anticoagulation service provider
The responsibilities of the anticoagulation service provider are to ensure the service is in line with the Sheffield SOP, which states:

1. The service provider must ensure completeness and accurate documentation of the clinic process
2. Ensure recommendations are available for review by the patients registered GP
3. Alert GPs to patients with potential problems e.g. bleeding
4. Ensure appropriate liaison with the patients registered GP and secondary care anticoagulation services when necessary

Process to be followed by anticoagulation service provider
At the end of every clinic, a summary sheet printed by INRstar, should be sent to the patient's GP practice. A summary sheet is to be sent for all the patients who have attended clinic that day. This gives the practice all the information they will need.

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

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

Responsibility of patients' GP practice
In order to ensure safety and efficacy of anticoagulation therapy, GP practices need to ensure timely record keeping. A GP or designated person from the practice must go through the summary sheets and record the information on the patient's clinical records as soon as is practicable. The GP must record on the patients' medical record the responsible provider of anticoagulation.

Joint responsibilities for the patient
The communication channel between service provider and patients GP must be a two way process and the GP must be prepared to communicate freely with the service provider any relevant information about the patient, e.g. any medication changes etc.

Secondary care must also be made aware of the service provider of anticoagulation services for each GP practice. This must be confirmed in writing to the patient's consultant haematologist. This is then logged onto the hospital computer system, and when any warfarin patients are admitted to hospital, the service provider can be contacted, with discharge dates and follow up appointments can be made.

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

This agreement is between *(insert anticoagulation service provider)* and *(insert medical centre name and lead partner name)*. The agreement covers the period *(insert dates from and to)*. From here in the two parties to this agreement agree to follow the agreed NHS Sheffield CCG protocol regarding the communication of the agreed anticoagulation service provider and the patients registered GP.
Only one of these signed forms is required to cover one GP practice patient set, **NOT** one per patient.

Signature Sheet

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

Signature on behalf of anticoagulation service provider:

Signature	Name	Provider name and address	Date

Signature on behalf of patients registered GP Practice:

Signature	Name	Practice Name and address	Date

When signed please return to Contracts Manager, Sheffield CCG, 722 Prince of Wales Road, Darnall, Sheffield S9 4EU.

Appendix 3

Current procedures relating to admission and discharge from STH for existing primary care warfarin patients

Section 1: STH Procedure for Discharging Patients on Oral Anticoagulants following admission

- The STH Anticoagulation Clinic has guidance relating to the discharge of new and pre-existing patients on oral anticoagulants.

- This can be accessed using the following link:

http://nww.sth.nhs.uk/STHcontDocs/STH_CGP/Haematology/QuickGuideToDischargePILOT.docx

Section 2: STH Procedure for discharging patients on Peri-procedural Anticoagulation Bridging

- The STH Anticoagulation Clinic has guidance relating to the discharge of pre-existing patients on oral anticoagulants.

- This can be accessed using the following links:

http://nww.sth.nhs.uk/STHcontDocs/STH_CGP/Haematology/QuickGuideToDischargeOnBridgingPILOT.doc

The 'Bridging anticoagulation: the peri-procedural management of patients on oral anticoagulants' is available here:

http://nww.sth.nhs.uk/STHcontDocs/STH_CGP/Haematology/BridgingAnticoagulationGuideline_Dalteparin.doc

Please note: Sheffield GPs should not be asked to prescribe or monitor bridging anticoagulation

Section 3: Anticoagulation Service Transfer of Care Form following admission

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Anticoagulation Referral **Form B**
STH Referral to Primary Care Provider
for Resumption of Anticoagulation Management

For patients usually monitored in primary care, taking Warfarin, Acenocoumarol (Sinthrome), Phenindione: (vitamin K antagonists VKAs).

Name:
Date of Birth:
Hospital No: *Patient Details*
NHS No: *or Sticker*
Consultant:

Refer to STHFT Anticoagulation clinic for monitoring if discharged to an Intermediate care bed or if being managed as per peri-procedural (Bridging) Anticoagulation guideline.

Instructions for use:

1) Discharging medical team to complete this form and 'scan to email' or use Encryption (see Axe the Fax guidance on Sharepoint) http://sharepoint.sth.nhs.uk/Projects/AxeTheFax/SitePages/Home.aspx . Include also a copy of the discharge summary (medication list) and VKA dosing chart.
2) Ensure patient is notified of VKA dose to be taken (generally for 1 week after discharge and until next INR appointment)
3) Give a copy of this document and discharge summary to the patient before discharge, or post it to them if they have already left.

Referring ward /OPD clinic…….. Site: NGH / RHH / WPH / JW

Telephone Number……..

VKA Warfarin ☐ Sinthrome ☐ Phenindione ☐

Target INR 2.5 (2.0-3.0) ☐ 3.0 (2.5-3.5) ☐ 3.5 (3.0-4.0) ☐
Other…….

Duration Long term ☐ 3 Months ☐ 6 Months ☐
Other…….

Medication administration

Who administers the patient's medication? Patient ☐ Relative ☐ Friend ☐ Homecare provider ☐

If not the patient, please give details: Name……
Tel.No…….

Is their usual medication in a monitored dosing system e.g. NOMAD? YES NO

Discharge destination: Is the patient being discharged to their home address? YES NO

If another address, please specify……..

……Tel No…….

To Primary Care Provider……

We are discharging this patient on ……(date) and we request that you resume the monitoring of their anticoagulation therapy.

Signature……Print Name……

Designation……Date……Time…….

Appendix 4

Warfarin Drug Interactions

This guide is intended as a quick reference to highlight significant interactions between warfarin and commonly prescribed medicines, food/ drink or complementary medicines. It is not intended to be exhaustive or give detailed information. Prescribers should refer to the SPC or the current BNF for further information or contact NHS Sheffield CCG Medicines Optimisation Team for advice.

NB: 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 problem	Comment
Alcohol	Increase/decrease anticoagulant effect of warfarin	Acute intake of a large amount of alcohol may inhibit the metabolism of warfarin and increase INR. Conversely chronic heavy alcohol intake may induce metabolism of warfarin. Avoid consumption of alcohol where possible otherwise do not to exceed the recommended intake. Currently 14 units a week for both men and women.
Allopurinol	Possibly increases anticoagulant effect of warfarin	Uncommon but unpredictable interaction – monitor INR more closely when allopurinol started.
Amiodarone	Increases anticoagulant effect of warfarin	The interacting effect occurs within days of starting amiodarone and may be maximal after 2-7 weeks. Amiodarone has a long half- life, and there is a potential for drug interactions to occur for several weeks (or even months) after treatment with it has been stopped.
		Note that amiodarone induced hyperthyroidism will increase a patient's warfarin requirements. ***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

Interacting Drug	Potential problem	Comment
		Patients stopping amiodarone Check INR weekly until stable. The dose of warfarin will need gradually increasing.
Amitriptyline (Tricyclic Antidepressant)	Unpredictable increase or decrease in anticoagulant effect	May increase variability in INR, and a possible interaction should be considered if INR is difficult to stabilise.
Analgesics: Aspirin	Increased risk of bleeding	Avoid aspirin as an analgesic – use paracetamol as a safer alternative. (refer to antiplatelets- aspirin below for low dose aspirin 75mg daily)
Analgesics: Non-Steroidal Anti-inflammatory Drugs (NSAIDs)	NSAIDs irritate stomach lining and reduce platelet aggregation, increased risk of bleeding.	Avoid where possible. If concomitant use cannot be avoided, monitor INR and adverse events. Ibuprofen or naproxen are less likely to interact with warfarin.
Analgesics: Co-proxamol **Note: co-proxamol is unlicensed and not recommended in primary care**	Isolated case reports of increased anticoagulant effect of warfarin	Uncommon and unpredictable. Use paracetamol as a safer alternative.
Analgesics: Paracetamol	Possibly increases anticoagulant effect of warfarin when large doses are used over a prolonged time.	Taking more than small, occasional doses of paracetamol or taking it for longer periods may increase INR. This is more likely to occur if paracetamol is taken in doses greater than 2g (4 tablets) daily for more than a few days. (NHS choices)
Analgesic: Tramadol	Reports of increased INR with major bleeding and ecchymoses in some patients.	Manufacturer advises caution should be exercised during concomitant treatment.
Antibacterials: Amoxicillin Ampicillin	Alters anticoagulant effect of warfarin.	Manufacturer advises monitor INR and adjust dose.
Antibacterial: cefaclor	Increases anticoagulant effect of warfarin	Cefuroxime, cefalexin or cefradine are safer alternatives.
Antibacterial: Co-trimoxazole	Increases anticoagulant effect of warfarin.	Manufacturer advises monitor INR.
Antibacterials Macrolide eg 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: Metronidazole	Increases anticoagulant effect of warfarin	If concurrent use cannot be avoided, reduce the warfarin dose by one-third and monitor closely. Topical preparation unlikely to cause interaction as absorption is low.

Interacting Drug	Potential problem	Comment
Antibacterial: Penicillins	Although not well documented in clinical trials, common experience in anticoagulant clinics suggests that INR can be altered	Recommend checking INR 3–7 days after starting penicillin and adjust warfarin dose accordingly.
Antibacterial: Quinolones e.g. Ciprofloxacin	May increase the anticoagulant effect of warfarin	Rare and unpredictable interaction. Monitor INR. Use alternative antibiotic if possible.
Antibacterial: Rifampicin / Rifabutin	Markedly reduces anticoagulant effect of warfarin within 5-7 days.	Seek advice from anticoagulant clinic as warfarin dose may need to be double or trebled and reduced on stopping Rifampicin or Rifabutin. Monitor INR closely.
Antibacterial: Tetracycline eg Demeclocycline Lymecycline Oxytetracycline	Increases anticoagulant effect of warfarin.	Manufacturer advises monitor INR.
Antidepressants: SSRIs e.g. fluoxetine, sertraline, citalopram, paroxetine	Possibly increases anticoagulant effect of warfarin	Mixed reports about the effects on warfarin. SSRIs have been associated with gastrointestinal bleeding: risk may be increased in patients on warfarin.
Antidepressants: St John's Wort (*Hypericum perforatum*)	Moderate reduction in the anticoagulant effects of warfarin	St John's Wort must not be used whilst taking warfarin due to a proven risk of decreased plasma concentrations and reduced clinical effects of 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 2-4 days, reaching a maximum after about 3 weeks and may still be evident up to 6 weeks after stopping the barbiturate. Care must be taken not to withdraw the barbiturate without also reducing the anticoagulant dose; otherwise over-anticoagulation will occur.
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 decrease anticoagulant effect of warfarin	Monitor INR and adjust dose of warfarin accordingly. Warfarin can also increase phenytoin levels by an unknown mechanism. Monitor patient for signs of toxicity.
Antifungals: Fluconazole, itraconazole, ketoconazole	Increases anticoagulant effect of warfarin	Increase in anticoagulant effect is greater with larger doses and in the elderly (includes single dose of fluconazole). Monitor the INR closely and reduce warfarin dose accordingly.

Interacting Drug	Potential problem	Comment
Antifungal: Miconazole (oral gel and possibly vaginal and topical preparations)	Increases anticoagulant effect of warfarin	Avoid - potentially serious interaction. Use nystatin instead. Should concurrent use be necessary, INR should be closely monitored and suitable dose reductions made.
Antifungal: Griseofulvin	Reduces anticoagulant effect of warfarin	Unpredictable (effects some but not all patients) – monitor INR and adjust doses of warfarin accordingly.
Antiplatelets: Aspirin Clopidogrel Prasugrel Dipyridamole Ticagrelor	May increase risk of bleeding even if INRs remain stable and within range	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. Avoid concomitant use unless advised by a specialist.
Antiretrovirals: Ritonavir, efavirenz etc.	Variable effects on INR.	Monitor response and adjust warfarin dose accordingly.
Azathioprine	Reduces anticoagulant effect of warfarin	Warfarin dose may need to be increased when azathioprine started or dose change and reduced if azathioprine is stopped. Monitor INR weekly until stabilised.
Boldo	May increase anticoagulant effect of warfarin	Modest rise in INR seen in a patient taking Boldo and Fenugreek. Advise patient to avoid combination.
Coenzyme Q10	Reduces anticoagulant effect	Advise patient to avoid combination with warfarin.
Colestyramine	Reduced absorption of warfarin, administration time of colestyramine important.	Reduced absorption of warfarin (and other drugs) – which may be limited by taking warfarin more than one hour before or more than 4 to 6 hours after colestyramine.
Corticosteroids (systemic)	Variable response	Significantly increased INR with high dose/pulsed steroids. Effects of low - moderate doses are less certain.
Cranberry Juice	Increases anticoagulant effect of warfarin	Advise patients not to drink cranberry juice. If a patient wishes to consume cranberry juice, they should be advised to drink only moderate amounts and use the same brand all the time (as the cranberry content of different brands varies). Increased INR monitoring may be required if patients consume cranberry whilst on warfarin. If patients already consume cranberry and then start warfarin then they should be consistent in the amount and brand of cranberry taken.
Cytotoxics	Increases anticoagulant effect of warfarin reported with some cytotoxics	Refer patients on concurrent cytotoxic agents to secondary care for management of anticoagulation.

Interacting Drug	Potential problem	Comment
Danshen	Increases anticoagulant effect of warfarin	Advise patients not to use Danshen whilst taking warfarin.
Devil's Claw	Increases anticoagulant effect of warfarin	Purpura has been reported in patients taking warfarin and devil's claw concurrently, suggesting over-anticoagulation. Devil's claw should be avoided or used cautiously in patients taking warfarin. Warfarin dose adjustments may be necessary.
Disulfiram	Increases anticoagulant effect of warfarin	If concurrent use is assessed as appropriate, the effects of warfarin should be monitored, and suitable dose adjustments made when adding or withdrawing disulfiram.
Dong quai (*Angelica sinensis)*	Reports of marked increase in anticoagulant effect of warfarin	Advise patients to avoid combination of Dong quai whilst taking warfarin. Dong quai is thought to inhibit platelet activation and aggregation
Dronedarone	Possibly enhanced anticoagulant effect	Conflicting evidence, until more is known increase the frequency of INR monitoring after dronedarone is first started and adjust the dose of warfarin accordingly.
Feverfew	Increase risk of bleeding with warfarin	Advise patients not to use Feverfew whilst taking warfarin, but if used monitor INR closely.
Flutamide	Case reports of Increased anticoagulant effect of warfarin	Monitor and adjust warfarin dose as necessary. Refer to secondary care for further advice on management of 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	Case reports of increased risk of bleeding	Advise patients not to use Gingo Biloba whilst taking warfarin as increased bleeding risk.
Ginseng	Decrease anticoagulant effect of warfarin.	Ginseng can decrease the effectiveness of warfarin. To avoid this potential interaction, advise patients not to take ginseng with warfarin.
Glucosamine / Chondroitin	Taking glucosamine alone or in combination with chondroitin might increase the anticoagulant effects of warfarin and increase the risk of bruising and bleeding.	Patients taking warfarin should be advised to avoid using glucosamine/chondroitin. If the patient wishes to take the combination then they should take it consistently. Increased INR monitoring is required when starting/stopping treatment with glucosamine/ chondroitin.
Grapefruit juice	May increase anticoagulant effect of warfarin	May cause a modest rise in INR. If the patient wishes to take grapefruit with warfarin then they should take it consistently.

Interacting Drug	Potential problem	Comment
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 but small numbers of bleeding episodes have been reported. Therefore advise the patient to report any unexplained bleeding.
Lipid-regulating drugs: Fibrate eg Fenofibrate Bezafibrate MR	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 Atorvastatin Pravastatin Rosuvastatin Fluvastatin	Possible increased anticoagulant effect dependant on statin taken.	Studies with atorvastatin, pravastatin, and simvastatin suggest that they do not usually alter the effects of warfarin, although isolated cases of bleeding have been seen when these statins were given with warfarin. Fluvastatin can increase warfarin plasma levels. Rosuvastatin can increase the anticoagulant effects of warfarin but does not alter warfarin pharmacokinetics. Monitor initially or after dose increases of any statin.
Mercaptopurine	Reduces anticoagulant effect of warfarin	Decreased efficacy of warfarin. Significant changes in the dose of warfarin may be required when mercaptopurine stops/starts. Monitor INR weekly until re-stabilised.
Multivitamins and other vitamin supplements containing vitamin K	Anticoagulant effects of warfarin are reduced or abolished	Vitamin K may be present in multivitamins, enteral feeds, health foods, food supplements, some green vegetables, green tea, which antagonises effects of warfarin. Dose adjustment may be required, and patients should be encouraged to take the vitamin supplement consistently. If patients are “warfarin resistant” consider this interaction.
Oestrogens	May enhance anticoagulant effect of warfarin	Usually contraindicated in those with thromboembolic disorders but if oestrogens must be used, be alert for any changes in the anticoagulant response.
Orlistat	Modest increase in anticoagulant effect of warfarin	Orlistat may reduce the absorption of fat soluble vitamins including vitamin K and a change to a lower fat diet associated with the use of orlistat may also contribute to changes in the balance between vitamin K and warfarin. Patients should be closely monitored for changes in INR.
Papaya	Increases anticoagulant effect of warfarin	Concomitant use might potentiate the effects of warfarin increasing INR, advise patients to avoid the combination.
PDE P5 Inhibitors Sildenafil, tadalafil	Possible increased bleeding risk at high doses	Increased risk of nose bleeds in patients taking high doses for pulmonary hypertension. This might be greater in patients taking warfarin.

Interacting Drug	Potential problem	Comment
		Otherwise, no interaction noted when used as recommended doses for erectile dysfunction.
Progestogens	May enhance or reduce anticoagulant effect of warfarin	Monitor and adjust dose as necessary
Quinine- including Tonic Water	Increases anticoagulant effect of warfarin	Effect unlikely with quinine at usual doses. Elevated INR has been observed when tonic water consumed in significant quantities (>1 litre/day)
Tamoxifen	Markedly increases anticoagulant effect of warfarin	Monitor and reduce warfarin dose as necessary – may need to reduce dose by one half to two-thirds.
Thyroid hormones and treatments e.g. levothyroxine, carbimazole	May enhance or reduce anticoagulant effect of warfarin	Monitor and adjust warfarin dose as necessary. Warfarin dose may need to be changed as thyroxine doses are altered.
Tranexamic Acid	Antagonistic effect	The concurrent use of oral anticoagulants and tranexamic acid would be expected to antagonise the effects of both drugs.
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 where possible. Monitor the INR if stopping or starting omeprazole or esomeprazole

References:

1. NICE British National Formulary https://bnf.nice.org.uk Updated: 29 April 2021. [Accessed 26/05/21].

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3. Sheffield Teaching Hospital, 2018. Anticoagulation Clinic: Clinical Guidelines v5.

4. NHS Choices: Can I take Paracetamol if I'm on warfarin. April 2014. Available at:http://www.nhs.uk/chq/Pages/858.aspx?CategoryID=73&SubCategoryID=103> [Accessed 27/2/17].

5. Medicines Complete, Stockley's drug interactions, 2017. Royal Pharmaceutical Society. Available at : https://www.medicinescomplete.com/about/publications.htm?pub=stockley> [Accessed on 27/2/17]

6. Rx List- The Internet Drug list. Drug interactions with phenytoin oral and warfarin oral. 2017. Available at: http://www.rxlist.com/drug-interactions/phenytoin-oral-and-warfarin-oral-interaction.htm> [Accessed 03/03/17].

7. Natural medicines comprehensive database, 2017. Available at: http://naturaldatabase.therapeuticresearch.com/home.aspx?li=0&st=0&cs=&&AspxAutoDetectCookieSupport=1> [Accessed on 6/03/17]

Appendix 5

STHFT WARFARIN SLOW START REGIMEN

This warfarin induction regimen[1] should be used for both inpatient and outpatient initiation of warfarin for suitable patients (see indications and exclusions below).
For outpatient use, patients should be referred to RHH or NGH anticoagulant clinics using the Anticoagulation Referral Form, stating indication and marked 'Slow-start regimen'.
If started as an inpatient, follow regimen below. At discharge, refer patient to the RHH or NGH anticoagulant clinic using the Anticoagulation Referral Form, accompanied by a copy of the warfarin prescription chart(s).
All patients referred to the Anticoagulant clinic are seen within 7 days or earlier if clinically indicated.

Background
Patients not requiring rapid anticoagulation can be safely managed using a slow loading regimen which results in therapeutic anticoagulation within 3-4 weeks in the majority of patients. This appears to avoid over-anticoagulation and bleeding associated with rapid loading[2]. This regimen is suitable for use in both the secondary and primary care setting and allows for induction of anticoagulation therapy requiring only weekly monitoring.

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

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

Exclusion Criteria:
Patients requiring immediate anticoagulation.
These include

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

Aim:
To initiate warfarin therapy with a target INR 2.5

Regimen:

1 Ensure the patient has no contraindications to warfarin and confirm with a senior member of the medical team that the slow start regimen is appropriate. Generally if a patient is taking aspirin, this should be continued until the INR is therapeutic then STOPPED.
2 Ensure baseline bloods (FBC, U&E, LFT, coagulation screen) are satisfactory. If in doubt, discuss with the patient's consultant. If baseline prothrombin time is >2 seconds prolonged, seek haematology advice.
3 Explain to the patient the indication for warfarin treatment and the risks and benefits of it.
4 Prescribe 2mg of warfarin daily at 6pm for 1 week. For inpatients prescribe on the warfarin prescription and monitoring chart. **Clearly mark the indication: Atrial Fibrillation Slow Start Regimen and cross through the dosing chart on the reverse of the warfarin chart.**
5 Repeat INR after a further 7 days of warfarin therapy.
6 Adjust dose as per nomogram **overleaf**.
7 At discharge refer to the anticoagulant clinic using the Anticoagulation Referral Form, accompanied by a copy of the warfarin prescription chart(s).
8 If unsure or concerned about the patient's anticoagulation, refer to the anticoagulation practitioners.

NOMOGRAM FOR WARFARIN SLOW START REGIMEN

Day 1

Baseline prothrombin time <2 seconds prolonged
Start 2mg warfarin/day at 6pm
Repeat INR in 7 days

Day 8

INR <2

Continue present dose warfarin.
Repeat INR in 7 days.

INR >2

Warfarin sensitive.
Discuss with anticoagulation practitioners (RHH ext. 13820, NGH ext. 14399).

Day 15

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

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	3.0-4.0	1mg/day
3.0-4.0	1mg/day	------	------

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

Recheck INR after a further week and adjust dose as below

Day 21

INR <2

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

INR 2-3

Continue present dose of warfarin.
Repeat INR in 7 days.
Fine tune warfarin dose if INR fluctuates.

INR >3

Fine tune warfarin dose / omit doses if necessary.

By the time the patient has been taking warfarin for 6 weeks the INR should be in the therapeutic range.
Fine tuning of the warfarin dose by using alternate day regimens (e.g. 2mg/3mg alternate days) can be used if INR fluctuating.
Discuss any queries with the anticoagulation practitioners (RHH ext. 13820).
Any bleeding complications must be discussed with a haematology registrar (bleep via switchboard).

Appendix 6

Guidelines for using vitamin K for the management of over-anticoagulation (INR >5.0)

For those providers using NPT, instructions on appropriate further testing when high INR results are recorded is given at paragraph 18.10 onwards, page 12.

Always ask patient about signs of bleeding; if any of the following are present, arrange admission to hospital.

- bruising
- epistaxis
- haematuria
- fresh blood in stools
- melaena
- any other signs of bleeding
- recent fall
- head injury
- confusion
- elderly / frail

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. Discuss with the on-call haematology doctor Omit warfarin. Give oral vitamin K (Konakion® MM Paediatric 2mg in 0.2ml); 1-2mg as advised by haematologist. 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.*

INR 6.0 – 8.0 (with no bleeding or minor bleeding, e.g. epistaxis)	
High risk[1] patients	Omit warfarin. Discuss with the on-call haematology doctor Consider giving oral vitamin K (Konakion® MM Paediatric 2mg in 0.2ml); 1-2mg as advised by haematologist. Repeat INR test following day. Restart warfarin at reduced dose.
Low risk patients	Omit warfarin. Restart warfarin at reduced dose.
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.	

If the primary care provider is not the patient's registered GP, they should complete the Patient Over-anticoagulation Report (Appendix 7) and send a copy to the patient's registered GP.

Vitamin K Protocol

Konakion® MM Paediatric (phytomenadione 10mg/ml) 0.2ml ampoules should be used to manage high INRs in the community as per the protocol below. Although this product is licensed for several routes of administration this protocol refers to oral use, which is off licence for this indication.

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

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

How to obtain Konakion® MM Paediatric

All providers of the anticoagulation monitoring service must purchase this product on initiation of the service.

Practices may purchase this from a local community pharmacist on receipt of a signed order.

When two ampoules remain or the product is out of date stock should be re-ordered.

Clinical governance

Ensure the expiry date of Konakion MM Paediatric™ is checked regularly as per practice protocol for checking expiry dates of drugs.

Any near misses or adverse incidents should be reported. Please refer to section 22 for details.

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 7

Patient Over-Anticoagulation Report

Dear Dr._____ Date: _____

Your patient _____
Patient Name Patient Number

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

His/Her INR reading today was _____

This reading is possibly due to:_____

_____

_____

Previous two INR readings, dates and doses were:

Date: INR: Dose:

Date: INR: Dose:

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

( ) Patient sent to the anticoagulation department at _____ hospital.

( ) Patient has been admitted to _____ by the hospital anticoagulation team

( ) Vitamin K given by _____

( ) Sent home with the following instructions:

_____

_____

_____

Additional Relevant Information

_____

_____

_____

Signed: _____ **Name:** _____

GP Practice / Pharmacy: _____

Appendix 8

Anticoagulation monitoring service

Definition of different levels of service as per service specification.

Level of service	Definition	Provider's action
Level 3	Self-testing of INR by patient or venous laboratory sample for INR check.	Provider then assesses INR result provided by the patient or laboratory and doses the patient.
Level 4	Near patient testing as per provider using approved meter e.g. Coaguchek® or MicroINR®.	Provider checks INR and doses the patient.
Level 5	Initiating a vitamin K antagonist (VKA) anticoagulants (i.e. warfarin, acenocoumarol or phenindione) for non-urgent anticoagulation e.g. AF as per slow loading protocol. See Appendix 5 for further details.	Provider initiates VKA, Warfarin is the commonly prescribed VKA anticoagulant. This will include appropriate patient counselling and written information i.e. printed dosing sheet or completion of yellow book.

Appendix 9

Near patient testing devices currently available and NICE guidance.

	CoaguChek®	**MicroINR®**
NICE guidance	Yes DG14	Yes MIB257
Availability	Widely	Widely
Sample size	>8 microlitre	3 microlitre
Internal QC checks	Yes	Yes
Individually wrapped test strips	No	Yes
Time within which test strip should be used once taken out of original packaging	Within 10mins	Up to 6 hours
Bluetooth compatible	Yes	Yes
Limitations of use	Anaemic and PCV Not compatible if haematocrit outside of 25-55% range	Anaemic and PCV Not compatible if haematocrit outside of 25-55% range
Cost of test strips	24 strips £72.38*	25 strips £71.25*
Cost of machine	£299*	£395*
Payment plan option	Yes- 12- or 24-months interest free	Available on request
QC solutions and recommended frequency of testing	Patients self- testing INR not required to check, due to internal QC checks. HCP need to check with every new pot of test strip or as per local guidance. See section 23.4	No recommended frequency as internal QC in place. QC solutions available for provider own use, if required.
Training provided by company	Primary care- remote training offered via MS Teams. Quick guides, training manuals and training certificates available on request. Self-testing: training DVD provided to patient. Freephone access to CoaguChek® care line (0808 100 7666) including one to one telephone/Facetime training and free technical support is available, if required.	On request online or face to face training available for both patients and HCPs. Company checks device appropriate for patient prior to sale.
Is device refundable	**Only if faulty.** Patient should watch the DVD FIRST and only open the device packaging once happy to proceed with the meter.	**Only if faulty.** This should not be required as the company checks appropriateness of the device prior to patient purchasing the meter.
Manufacturer and contact details	Roche Diagnostics Limited Customer Services: 0808 100 9998 CoaguChek® Orders: 0808 100 7666 To book training email: burgess_hill.pocetraining@roche.com	Prospect Diagnostics. Peter Tomlinson Peter.Tomlinson@prospectdiagnostics.co.uk 01246 292 955

*price checked with manufacturer at the time of writing. June 2021.

Appendix 10

Competency Assessment for Healthcare Professionals Monitoring INR.

A. Knowledge and understanding of vitamin K antagonist anticoagulant therapy

Name of Practitioner: …… GMC/GPC/NMC
Date: ……

Legislation, regulations and guidelines	Completed: Practitioner initial and date
1. Is familiar with NPSA Alert 18 on oral anticoagulation, the BSH guidelines and local policies. See section 3 of SOP and SCCG intranet for relevant policies.	
2. Is up to date with appropriate national guidance e.g. NICE guidance on stroke prevention in AF	
3. Has undertaken an approved anticoagulation training course as recommended in the SOP or by SCCG.	
4. Completes relevant BMJ anticoagulation modules see section 14 of SOP.	
5. Has a working understanding of risk management, patient safety principles and causes of medication errors.	
Clinical knowledge	**Completed: Practitioner initial and date**
1.Understands the principles of anticoagulation therapy, the indications and doses for anticoagulation therapy, the recommended duration of treatment.	
2. Demonstrates understanding of the clinical conditions for which anticoagulation is indicated.	
3. Has an understanding of the mode of action of anticoagulants.	
4. Has knowledge of the side effects of anticoagulants, how to recognise them and manage them.	
5. Has knowledge of contra-indications of anticoagulants.	
6. Has an understanding of the normal parameters for routine investigations.	
7.Has knowledge of a recommended computerised dosing support software eg INRstar.	
8. Has an understanding of patient concordance and the impact of this on therapy.	
9. Has knowledge of procedures for dealing with very high INRs and reversal of warfarin.	
Practice Support	
1. Has a mentor for support and development in this role.	
2. Aware of own limitations of knowledge and experience, and the importance of not operating beyond these. Able to explain the implication of accountability when undertaking advanced practice.	

Appendix 10 (cont'd)

B. Monitoring of vitamin K antagonist anticoagulant therapy

Performance criteria and Patient management	Completed: Practitioner initial and date
1. Able to obtain relevant clinical details from patient for INR monitoring.	
2. Able to undertake and document measurement of the INR in accordance with local and national guidelines.	
3. Able to accurately record results, inform patient of their **dosage** and other relevant information needed for patients current and future management.	
4. Has ability and clinical judgement to use a computerised dosing support software eg INRstar as a tool for safe dosing and setting of follow-up appointments.	
5. Is able to dose and set follow-up appointments **manually** according to agreed guidelines if a computerised dosing support software eg INRstar cannot be used.	
6. Able to identify patients who need referral to the haematologist, their GP or other healthcare professional.	
7.Able to provide on-going education and support to patients.	
8. Is alert to any potential increased bleeding risk and take appropriate action.	
9. Is alert to any potential drug, food or alcohol interaction and take appropriate action.	
10. Communicates next **appointment** clearly to the patient in written and verbal form.	
11. Ensures all relevant documentation is clearly completed.	
12. Able to use, maintain and clean NPT device as per manufacturers guidance and local policy.	

I have sufficient knowledge and understanding to undertake the practice of monitoring warfarin anticoagulation.
Name of practitioner: Signature of Practitioner: Date:
This practitioner has successfully met all the criteria for assessment
Assessor comments:
Name of assessor: Signature of Assessor: Date:

Appendix 11

Useful Contacts

STHFT anticoagulation clinics

Royal Hallamshire	Switchboard	Tel: 0114 271 1900
Northern General	Switchboard	Tel: 0114 243 4343

Up-to-date contact list can be accessed via the STH Anticoagulation and Thrombosis Prevention Directorate Page on the intranet
http://nww.sth.nhs.uk/NHS/SpecialisedMedicine/Haematology/AntiCoagulationAndThrombosisPrevention/

NHS Sheffield CCG

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