Trust Policy

University Hospitals Plymouth NHS Trust

Anticoagulation: Safe prescribing, dispensing and administration of oral and parenteral anticoagulants

Issue Date	Review Date	Version
May 2021	May 2024	5

Purpose

To manage the inherent risks to patients from the use of anticoagulant therapy when prescribing, administering or dispensing these medicines by ensuring safe systems of working and clear responsibilities. This policy meets or exceeds the requirements of NPSA safer practice notice no.18 – Actions to make anticoagulant therapy safer.

Who should read this document?

All prescribers and nursing staff. All pharmacists and other pharmacy staff involved in dispensing or in advising patients about their medicines.

Key Messages

Anticoagulants are associated with a high risk of patient harm if therapy is not managed appropriately. All those involved with prescribing, administering or dispensing anticoagulants or in prescribing medicines for patients already taking anticoagulants must ensure they have the knowledge to do so safely and must be aware of their responsibilities as laid out in this document.

Core accountabilities	
Owner	Charlotte Carvell - Anticoagulant Specialist Pharmacist
Review	Thrombosis Committee
Ratification	Medical Director – Mark Hamilton
Dissemination (Raising Awareness)	Via Trust-wide information channels under the responsibility of Charlotte Carvell and Huw Rowswell
Compliance	Huw Rowswell - Thrombosis Special Nurse, Steve Mumford - Medicines Safety Officer, Medicines Governance Committee

Links to other policies and procedures

TRW.MMA.POL.265.3 Medicines Management Policy

Version History

1	September 2012	Initial Document
2	March 2015	Minor amendments and additions made regarding following aspects: 1. Use of novel oral anticoagulant agents (section 8). 2. Typical doses of acenocoumarol and phenindione (section 5.1.2).
3	March 2016	Amendments made to wording in sections 5.1.1 and 5.1.2 in consultation with Livewell Southwest in response to Coroner's report. Terminology update – DOAC replaces NOAC
4	July 2018	Additional information in section 9 relating to use of DOACs

5	May 2021	Format updated, references to electronic inpatient prescribing added where appropriate, information on DOACs updated (minor changes)

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available in the Document Library. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

The National Patient Safety Agency (NPSA) issued a Safer Practice Notice in March 2007 titled "Actions that can make anticoagulant therapy safer". It provides guidance for all NHS staff involved in the prescribing, dispensing and administration of oral and parenteral anticoagulants. A joint working group was formed which included representatives from PHNT and PTPCT and local actions agreed for each of the nine action points required by the NPSA alert.
This policy provides guidance for all staff involved in the prescribing, dispensing and administration of oral and parenteral anticoagulants in UHP to ensure compliance with the NPSA safety notice.

2 Purpose

The purpose of this policy is to provide robust and safe systems to manage the inherent risks to patients from the use of anticoagulant therapy. It meets or exceeds the minimum requirements of the NPSA safer practice notice no.18 with respect to risk assessment, safe procedures, training and audit.

The guidance covers the following key areas:

- Prescribing responsibilities for doctors and non-medical prescribers: initiation, continuation, monitoring and discontinuation of anticoagulant therapy
- Competency of all staff involved with anticoagulant administration or supply
- Safe systems for documenting results and treatment, including effective communication on discharge and the checking by prescribers, pharmacists and nurses that the INR is safe before dispensing or administration
- Promotion of safe practice by re-checking the INR following changes of medication or patient condition
- Providing the patient with appropriate information at commencement of therapy, at discharge from secondary care and throughout the course of treatment
- Standardisation of the strength of intravenous (IV) unfractionated heparin in use.
- Requirement for audit to ensure the guidance is achieving its objectives.

Specific clinical guidance is provided on PHNT Staffnet (see references).

3 Definitions

For the purposes of this policy "oral anticoagulation" is defined as coumarins (warfarin, acenocoumarol) and phenindione. These anticoagulants require monitoring of INR results and dose adjustment according to response.
Direct Oral Anticoagulant agents (DOACs) are covered in section 9. Sections of the document that do not specifically mention DOACs are not applicable to these agents.

4 Duties

It is the responsibility of all staff prescribing, administering or dispensing anticoagulant agents to ensure their knowledge and competencies are up-to-date and adequate for the duties they are performing.
Prescribers have overall responsibility for clearly documenting the decision to start oral anticoagulant treatment and communicating this to the patient and GP.

5 Training and Competencies

5.1 Prescribers

All prescribers that initiate, continue or adjust dosage of anticoagulants must have the necessary work competencies to undertake their work safely.

The competencies are defined by the NPSA (www.nrls.npsa.nhs.uk/resources/type/alerts/)

- Competency no. 1 “Initiating anticoagulant therapy”
- Competency no. 2 “Maintaining oral anticoagulant therapy”
- Competency no. 5 “Preparing and administering heparin therapy”

Practitioners should assess their current level of competence and improve their knowledge and can improve their understanding by completion of the following BMJ e-learning packages (same website as above):

- Starting patients on anticoagulants
- Maintaining patients on anticoagulants.

Anticoagulation is included in the following e-learning packages as part of the medicines management module:

- Doctor’s induction – information about the relevant sections of the drug chart, discharge forms and completion of Yellow Books. Also a strong recommendation to complete the BMJ learning packages and a link to the BMJ learning website.
- Any changes to policy or procedures relating to anticoagulants or any specific problems highlighted by audits or clinical incident reports will be included in the update training medicines management module for prescribers as applicable. Update training modules are reviewed annually.

5.2 DVT Clinic Staff

Registered nurses that work in the DVT clinic administer, supply or adjust dosage of oral anticoagulation, including DOACs, working within a Patient Group Direction (PGD).
Practitioners must have the necessary competency regarding initiation of anticoagulant therapy as above and also NPSA competency no. 4 “Dispensing oral anticoagulants”.

All nursing staff working under this PGD must complete the BMJ e - learning packages and provide a copy of the certificate to their line manager as proof that this has been completed.

5.3 Nursing Staff

Nursing staff who are authorised to administer medications under the Trust Medicines Management Policy may administer anticoagulants.
The medicines management e-learning completed by new nursing staff includes information about use of the relevant sections of the drug chart and use of EPMA.

It is the responsibility of line managers to ensure that staff who administer or discharge patients on anticoagulants have sufficient knowledge to fulfil their responsibilities under this policy. The BMJ e-learning packages (see 5.1) can be used to improve knowledge of anticoagulation.

Nurses who are required to prepare or administer heparin therapy need to have appropriate knowledge of heparin as defined by the NPSA competency no.5 ““Preparing and administering heparin therapy” (see section 5.1) and have completed the appropriate Trust IV administration training (see Medicines Management Policy).

5.4 Pharmacists and Pharmacy Technicians

Pharmacists involved in clinically screening prescriptions for anticoagulants and counselling patients should also complete the e-learning packages referred to in 5.1 above.

All pharmacists will be asked to print off the certificates from the BMJ website to show that they have completed the e-learning packages and pharmacists new to the Trust will be required to complete these as part of their departmental induction. Completion will be confirmed by line managers as part of the annual appraisal process.

Pharmacy technicians and preregistration pharmacists may counsel patients on warfarin therapy if they have completed local competency training.

6 Oral Anticoagulation requiring INR monitoring

Clinical guidelines to aid prescribing are available in the Trust Document Library and in the Plymouth Area Joint Formulary (PAJF). Sections of these guidelines are also reproduced in the inpatient drug prescription and administration record (DPAR) and can be accessed directly from EPMA prescribing screens.

6.1 Prescriber Responsibilities

For inpatients, oral anticoagulants should be prescribed on the "Oral Anticoagulation Prescription & Record Card" section of the paper DPAR or on the electronic inpatient prescribing system (EPMA) where this is available.

Blood for INR tests must be taken in the morning and the result checked and daily dose prescribed before 14.00 where ever possible. Dosing should not be left for the out-of-hours cover team to complete

On DPAR: All relevant parts of the anticoagulation chart should be completed, including patient details (an addressograph sticker may be used), drug, indication, target INR and intended duration of therapy.
For each dose the date, drug and INR result (if available) need to be completed, as well as the dose and prescriber's signature. Doses must be prescribed in mg.
To ensure that the anticoagulant doesn't get overlooked during drug administration rounds the drug should also be written in the regular section of the drug chart with "see anticoagulant prescription" written in the additional information box and the dosage left blank.

On EPMA: Relevant details of indication, target INR and intended duration must be completed in the prescribing record. Previous INR results and doses can be reviewed on screen and daily dose prescribed. The audit trail allows the prescriber to be identified.

6.1.1 Initiation of Treatment

Prescribers should carry out a risk assessment of the benefits versus the risks of therapy for individual patients before starting oral anticoagulation. This should include considerations made regarding choice of agent where DOACs may be an option. The risk assessment should be documented in the patient's medical notes.
Baseline clotting screen should be performed before starting any anticoagulant and renal function and LFTs should be assessed for patients starting DOACs.

If oral anticoagulation is to be commenced as an outpatient the patient's GP must be contacted and must agree that they are happy to commence therapy. This should be for the minority of cases – most patients where a decision to start anticoagulation has been made while an inpatient should commence their therapy while in hospital.

For all inpatients include the indication for treatment on the DPAR or on EPMA.

The co-prescribing of anti-platelet agents with oral anticoagulants needs very careful safety evaluation as this will significantly increase the risk of bleeding. The indication for anti-platelet

therapy and patient risk factors should be assessed for individual patients and decisions on whether anti-platelets are to stop or continue documented in the medical notes. Ensure anti-platelet therapy is stopped on the inpatient administration chart and reason for discontinuation stated.

When a patient is commenced on an anticoagulant they must receive appropriate verbal information and be provided with a yellow oral anticoagulation pack entitled “Oral Anticoagulant Therapy – Important information for patients” (commonly referred to as a “Yellow Book”).
The information in the Yellow Book should be fully explained to the patient (ward pharmacists will be checking the patient understands this information – see below). The record book should have all relevant sections at the front completed.

Loading regimens are included on the DPAR/EPMA and in clinical guidelines. **INR tests MUST be performed daily for at least the first four days of treatment.**
For patients being started on warfarin for stroke prevention in AF or where there are risk factors for bleeding the lower dose loading regimen should be used.

For the initial treatment of deep-vein thrombosis a low molecular weight heparin (enoxaparin) is started at treatment dose (1.5mg/kg) daily together with warfarin. The LMWH needs to be continued for at least 5 days (unless INR > 3) and until the INR>= 2 for 24 hours then stop (see oral anticoagulant guidelines for full details).

Where a DOAC is chosen as the oral anticoagulant this should not overlap with LMWH treatment. Specific product information for the DOAC should be referred to for details on how to switch between different anticoagulants.

6.1.2 Continuation of Prescribing

For existing patients, check that they already have a yellow book and provide a new one if required, ensuring all relevant sections at the front are completed. Sign in the relevant section of the anticoagulant page of the DPAR when this has been done or record in comments section on EPMA.

Frequent changes in dose should be avoided, although prescribers should beware of other factors which may affect INR and monitor more frequently if necessary (see clinical guidelines).

Prescribers should simplify regimens for patients so that where possible:

- The least number of tablets need to be taken each day
- Constant daily dosing is employed rather than alternating doses

For patients with raised INR, refer to clinical guidelines - INR result, bleeding risk factors or presence of bleeding and risk to patient of reversing anticoagulant therapy should be considered and reversal agents given where indicated. **Any serious bleeding associated with anticoagulation must be reported using the Datix incident reporting system.**

Any significant change in clinical presentation in a patient on warfarin should trigger an immediate INR test and repeat INRs may be necessary whilst the patient remains unwell.

Where patients on DOACs have a significant change in clinical presentation bleeding should be considered and immediate haemoglobin checks carried out. A change in renal function can also result in accumulation of active drug and DOACs may need to be dose reduced or withheld until renal function recovers.

Phenindione and acenocoumarol are rarely used and will only be commenced by a haematology consultant although patients visiting the area may be admitted on either of these agents. Prescribers may therefore be unfamiliar with their usage. Close monitoring of INR is recommended when restarting these agents or adjusting dosage. Acenocoumarol loading doses are usually 6mg

then 4mg and maintenance doses between 1-8mg daily. Phenindione loading doses are usually 200mg then 100mg and maintenance doses between 50-150mg daily.

6.1.2.1 Drug Interactions

As so many drugs have a potential, but unpredictable, interaction with oral anticoagulants, **ANY change in medication (addition or subtraction) should trigger a repeat INR within 2 - 4 days**, with dosage adjustment and further testing as necessary. See Oral Anticoagulation Guidelines for details.

The following drugs that induce Cytochrome P450 liver enzymes may be responsible for an interaction (increased clearance of anticoagulant) that **may take up to 2 or 3 weeks to take effect** [reference no.4]:

- Barbiturates (including Phenobarbital and Primidone)
- Carbamazepine
- Nevirapine
- Phenytoin
- Rifampicin or Rifabutin
- St Johns Wort

If any of the above drugs are combined with an oral anticoagulant, INR tests should be performed at weekly intervals after any new prescription or change in dose until stabilised. If any of these drugs are reduced in dose or stopped, remember that the INR may rise and this may also take 2 - 3 weeks to become apparent.

6.1.2.2 Peri-operative Management

For elective patients, a decision must be made during the pre-assessment process regarding whether to stop oral anticoagulant and the patient/carer must be provided with written information about when to stop their treatment. Appropriate bridging therapy must be planned, including arrangements for administration if LMWH is prescribed.

For patients who require emergency surgery, consider reversal of anticoagulation, taking into account the risk of delayed surgery and bleeding risks.

Post-operatively all surgical patients should recommence anticoagulation as soon as bleeding risk and absorption of oral medication allow. Appropriate bridging should continue until oral anticoagulant has been reinstated and, for coumarins, target INR is reached.

6.1.3 Discharge

The aim should be for most patients to reach a stable INR within target range before discharge.

When a patient on anticoagulants is discharged the prescribing doctor MUST complete the “Oral Anticoagulant Discharge Information” form electronically on e-discharge or on paper if e-discharge is unavailable. This form will be forwarded to the patient’s GP practice by pharmacy. EPMA will auto-complete parts of the form, but the form should be checked and the remaining sections completed on e-discharge.

Completing the discharge form may not remove the need to discuss the patient with the GP or to arrange for INR tests to be taken. Where INR is unstable or not in therapeutic range the GP should be contacted in addition to the form being completed. Use of the acute GP service may be considered for patients with sub-therapeutic INR to allow safe discharge (see clinical guidelines). If you are considering discharging patients for outpatient anticoagulation the referral route for this is via the HOT clinic hosted in the Acute GP Service (AGPS) based on MAU Thrushel. Patients must be assessed as safe for discharge by a senior doctor and be mobile and able to attend on a daily basis.

Particular care should be taken when discharging a patient close to weekends or public holidays to ensure blood tests can be arranged at an appropriate interval after discharge.

The patient's Yellow Book MUST be updated with INR results and doses and the patient made aware of what dose to take and when their next INR test is due.

- For the sake of clarity, the Yellow Book should include the dose as the total in milligrams and not solely as a multiple of tablets e.g. "6 mg (2 x 3 mg tablets) daily".
- 500 microgram warfarin tablets should be used to prevent the need to halve tablets. Take great care to avoid confusion between 500 microgram and 5 mg on the prescription (avoid the use of the description 0.5 mg).
- Patients will not normally be issued with both 5 mg and 500 microgram tablets.

6.2 Pharmacist Responsibilities

Yellow Books are supplied from Derriford Pharmacy and will be held as ward stock in all areas where they are commonly required. Ward stock supplies will be reordered or topped-up in the same way as stock drugs supplied from pharmacy.

The pharmacist clinically screening a prescription for anticoagulants should consider whether the dose, drug and route are appropriate for the patient. **Any problems, including significant drug interactions will be discussed with the prescriber and appropriate action taken.**

It is the pharmacist clinically checking the prescription (inpatients, patients being discharged and outpatients) who is responsible for checking that the patient has a current Yellow Book and/or alert card. If the patient does not have an up-to-date book a new one should be supplied and filled out by the pharmacist or by a pre-registration pharmacist or pharmacy technician who has been assessed as competent.

Competent pre-registration pharmacists or pharmacy technicians can counsel patients on anticoagulant therapy (either on the wards or when handing out prescriptions in pharmacy).

6.2.1 Clinical Screening of Inpatient Prescriptions

The ward pharmacist should check the anticoagulant prescription. Missing details should be clarified and completed as necessary including addition of the indication for the anticoagulant.

Pharmacists will ensure that the oral anticoagulant is written in the regular section of the paper DPAR (see 6.1).

It is the ward pharmacist's responsibility to ensure the information in the Yellow Book has been completed and to keep it up-to-date during the admission. Patients on DOACs should hold an alert card (see section 9).
The pharmacist should also check the patient's understanding of the information in the Yellow Book and give the patient (or carer if applicable) the opportunity to ask questions about their anticoagulant therapy wherever possible. There is a space on the anticoagulation page of the DPAR to indicate when the patient has been counselled. On seeEHR indicate in the pharmacy section of CPL that the patient has been counselled.

Ward pharmacists should monitor prescriptions for inpatients taking oral anticoagulants on a daily basis (Monday to Friday) and check whether INR results are available and the dose has been adjusted accordingly. **Any concern about frequency of blood tests or dose should be discussed with the prescriber.**

6.2.2 Dispensing and Discharge Procedures

Patients should be provided with the strengths of oral anticoagulant necessary for them to take their prescribed dose. Pharmacists and medicines management technicians screening prescriptions or ordering supplies should:

- Supply ONLY those strengths required by the patient for the current dose regimen. Order or endorse the prescription with the strengths required. Do not automatically issue 1mg, 3mg and 5mg strengths of warfarin.
- Use 500 microgram tablets when required to prevent patients having to halve tablets, which some patients find is difficult to do and which can lead to inaccuracies in dosage.
- When dispensing, great care should be taken to avoid mix ups between 500 micrograms and 5 mg tablets. Individual patients should NOT usually be issued with both of these strengths.
- Dispensing labels should state “take as directed” and should not include a specific dose.

For discharge prescriptions the screening pharmacist MUST check that an “Oral Anticoagulant Discharge Form” has been completed by the prescriber **and check the information on this form is up-to-date, complete and consistent with the information available from other sources (e.g. Yellow Book, clinical information section of e-discharge summary)**. The prescriber should be contacted if necessary to resolve any queries. Amendments to the form should be made if required.
A copy of the Discharge Form and the anticoagulant prescription page of the DPAR will be faxed to the patient’s GP surgery and copies retained in pharmacy.

If the pharmacist clinically screening the prescription has access to the Yellow Book (or has issued a new one) at the point of screening the pharmacist should ensure that all details in the front of the book, INR results and doses are filled out.

Oral anticoagulants with variable dosage will not usually be dispensed into compliance aids.

6.3 Nursing Responsibilities

Oral anticoagulants should be administered on the 2 p.m. drug administration round whilst the patient is an inpatient. This is to ensure that warfarin dosing is decided by the medical team looking after the patient and not left for the night cover to complete. If the dose is not prescribed by this time the medical team should be contacted in the afternoon to prescribe the dose as soon as possible. After discharge the patient can take their dose in the evenings at around 6 p.m.

6.3.1 Administration of Oral Anticoagulants

Before administering warfarin or any other oral anticoagulant to a patient, the nurse should check:
- The patient’s identity as per Medicines Management Policy
- The dose to be given for that day has been completed by the doctor
- The dose to be given for that day has not already been administered
- A recent INR test has been performed and the result is either within target or the doctor has adjusted the dose if the INR is outside of target – INR test should be performed more frequently if patient is acutely unwell and within 2 - 4 days of any change in other medication

The nurse administering the dose should complete the dose given, the time given and their initials on paper DPAR. EPMA will record this information when dose is marked as administered.
If the nurse is concerned about the dose or frequency of blood tests this should be discussed with the prescribing doctor.

6.3.2 Discharge

If a pharmacist or doctor has not already done so, the nurse must ensure that the records in the yellow book are up-to-date and complete when the patient is discharged.

The nurse issuing the discharge medication to the patient must check that the current dose and when this dose is due to be taken has been communicated to the patient or carer. The nurse should also confirm that the patient has understood the information in the yellow book or ensure

relevant information is passed on to the patient's carers. The yellow book must be sent with the patient at discharge.

7 Intravenous Unfractionated Heparin

Where an infusion of unfractionated heparin is required the use of a standard ready-to-use 1000 units/ml preparation is mandatory. Changes in dose (usually based on APTT ratio) should be made by adjusting the rate of administration. Monitoring for heparin induced thrombocytopenia should also be carried out (see clinical guidelines).

A specific infusion chart is available within UHP and must be used to prescribe and record administration and dose adjustment for intravenous heparin infusions.

Specialist areas e.g. haemodialysis, critical care areas, cardiothoracic theatres should only use standard 1000 units/ml products and base any specialist protocols in use in these areas on this concentration of heparin. The need for dilution prior to administration should be avoided wherever possible.

No other strengths of intravenous unfractionated heparin will be stocked in ward areas, except line flushes which must only be held by limited areas in agreement with a senior pharmacist.

8 Low Molecular Weight Heparins

Prescribed doses of low molecular weight heparins (LMWHs) for the treatment of a thromboembolic event are dependent on the weight of the patient and renal function.

- A patient's weight MUST be used as the basis for calculating the required treatment dose of LMWH. The weight must be accurately recorded in kilograms (kg) on the front of the DPAR (when in use) or in the appropriate icon on EPMA as well as in the medical notes.
- Patients should be weighed and their renal function checked at the start of therapy and, where applicable, during treatment.
- If this information is unavailable do not delay the first dose, but ensure these parameters are checked as soon as possible and the next dose adjusted accordingly.

Clinical guidelines are available on Staffnet which include advice on dosage and monitoring.
Essential information such as dose, weight, renal function, indication and duration of treatment must be communicated at transfers of care, including on discharge prescriptions.
Patients discharged on LMWH should be encouraged to self-administer if possible and can be taught how to do this by a nurse. If a District Nurse is required to administer the injection the ward nurse will make arrangements with the appropriate community team and the prescriber must complete a blue community prescription card.
All patients discharged on LMWH must be supplied with a sharps bin.

9 Other anticoagulants including Direct Oral Anticoagulants (DOACs)

A number of "fixed dose" **oral anticoagulant** agents have been licensed for indications including prevention of VTE after orthopaedic surgery, stroke prevention in patients with AF and DVT treatment or prevention. These agents are direct thrombin inhibitors (e.g. dabigatran) or inhibitors of factor Xa (e.g. rivaroxaban, apixaban, edoxaban). **INR monitoring is not required with these drugs**.

These agents should only be used at licensed doses, for licensed indications and where NICE have made a positive recommendation for the use.

When considering initiating an anticoagulant or choosing between agents a risk assessment should be carried out. Factors to consider include:

- Renal function,
- Risk factors for serious bleeding,
- Interacting medications – e.g. dabigatran is contraindicated with certain medications and requires dose adjustment with others,
- Previous anticoagulant use and whether INR has been well controlled,
- An informed discussion of risks and benefits should take place with the patient before any anticoagulant therapy is initiated or the agent already in use is switched to a different agent.

Where initial treatment dose differs from maintenance dose duration of initial regimen and continuing dosage must be clearly stated on the prescription and discharge letters.

Patients on DOACs must be provided with a patient alert card to carry. This can be the product specific card provided by the manufacturer (usually with the patient tablet pack) or a completed "yellow card". Yellow cards are available separately from the "yellow book" packs for this purpose.

There were no specific antidotes available for these agents, however there are now agents which are licensed for use in limited situations for some of these medications. Clinical guidelines regarding management of anticoagulation during the peri-operative period and actions to take in the event of major bleeding are available in the Trust Document Library.

Where a patient is prescribed one of these anticoagulants care must be taken that anticoagulant therapy is not unintentionally duplicated. It is NOT necessary to overlap treatment with LMWH and DOACs for example. Care should also be taken when switching a patient between anticoagulants and advice sought from haematology or pharmacy if appropriate.

All anticoagulants must be prescribed on the DPAR/EPMA for inpatients. The discharge letter must state indication and duration for all newly initiated anticoagulants and include any parameters relevant to the choice of dose e.g. renal function, weight.

Other anticoagulants may be used within the Trust for specified indications or in particular circumstances. For example, fondaparinux is used for patients with acute coronary syndromes or danaparoid and argatroban are available for when a patient has HIT diagnosed. Local clinical guidelines and product information should be consulted to ensure these anticoagulants are used safely.

10 Overall Responsibility for the Document

Overall responsibility for this document lies with the Thrombosis Committee.

11 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed and ratified by the Thrombosis Committee to include the Lead Haematologist for Anticoagulation and Thrombosis, Thrombosis specialist nurse, Senior Clinical Pharmacists with an interest in anticoagulation.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes and ratified by the Thrombosis Committee.

12 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

13 Monitoring Compliance and Effectiveness

Every 2 years the following parameters from the NPSA audit checklist ("Audit of safety indicators") will be audited retrospectively over a period of one month for coumarin anticoagulants using the information on the faxed discharge forms and DPAR copies held in pharmacy/EPMA and INR results from the iLab system:

For all patients starting on oral anticoagulants

- % patients developing INR > 5.0
- % patients following loading protocol
- % patients with therapeutic INR at discharge
- % patients not issued with patient-held written information pack (yellow book)
- % patients discharged without a date for next INR test
- % patients with unknown diagnosis, target INR or duration
- % patients with inappropriate target INR for diagnosis

For patients established on oral anticoagulants before admission

- % patients developing INR > 5.0 and those developing INR > 8.0
- % INR results > 1.0 below target range (e.g. INR < 1.5 if target 2.5)
- % INR results within target range
- % patients with unknown diagnosis, target INR or duration
- % patients with inappropriate target INR for diagnosis
- % patients without patient-held written information (yellow book)
- % patients discharged without a date for next INR test

Every 3 months there will also be a review of patient safety incident data (drawn from Datix) involving anticoagulants over the preceding 3 months. This data will be reviewed for common themes. Data will also include any reported incidents relating to bleeding associated with anticoagulants.

These audits will be reported back to the Medicines Governance and Thrombosis Committees.

Audit of safety indicators and clinical incidents will also take place in primary-care and learning points from both primary and secondary care shared where applicable. A working group, with representatives from primary and secondary care, will be reconvened if necessary to ensure compliance with NPSA patient safety alert 18 and to discuss any issues for use of anticoagulants across the interface.

Training: Individual training is monitored through the HR personnel and training records

14 References and Associated Documentation

1. National Patient Safety Agency (NPSA) Safer Practice Notice no. 18 (Mar 2007) “Actions that can make anticoagulant therapy safer”
2. Plymouth Area Joint Formulary www.plymouthformulary.nhs.uk
3. BNF (Current Edition)
4. Stockley’s Drug Interactions 9th Edition 2010
5. Keeling D. et al. Guidelines on oral anticoagulation with warfarin – fourth edition. British Journal of Haematology August 2011: 154: 311-324
6. SPC Sintrom (acenocoumarol) 4mg tablets. Novartis. Accessed 12/11/2014
7. SPC Phenindione 10mg tablets. Amdipharm. Accessed 12/11/2014
8. BCSH Guideline: Safety indicators for inpatient and outpatient oral anticoagulant care. 2007. www.bcshguidelines.com
9. Local clinical guidelines:
   Adult oral anticoagulation guidelines
   DVT guidelines
   PE treatment guideline
   Suspected PE in pregnancy
   LMWHs in secondary care
   Guidelines for the use of LMWHs in primary care
   Guideline for intravenous unfractionated heparin administration
   HIT Guidelines
   Unstable coronary artery syndromes
   Peri-operative management of warfarin (contained in Pre-operative assessment guidelines)
   Peninsula Heart & Stroke Network Guidance: Dabigatran & Rivaroxaban for the prevention of stroke and systemic embolism in AF
   Peninsula Heart & Stroke Network Factsheet: Rivaroxaban for treatment and prevention of DVTs
   Treatment of severe bleeding in patients on DOACs

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	Anticoagulation: Safe prescribing, dispensing and administration of oral and parenteral anticoagulants
Date Finalised	March 2015, reviewed May 2021
Previous Documents	
Action to retrieve old copies	Document to be replaced on intranet by new version. No authorised paper versions in use.

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff	May 2021	IG StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Y
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Y
	Does the style & format comply?	Y
Rationale	Are reasons for development of the document stated?	Y
Development Process	Is the method described in brief?	Y
	Are people involved in the development identified?	Y
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Y
	Is there evidence of consultation with stakeholders and users?	Y
Content	Is the objective of the document clear?	Y
	Is the target population clear and unambiguous?	Y
	Are the intended outcomes described?	Y
	Are the statements clear and unambiguous?	Y
Evidence Base	Is the type of evidence to support the document identified explicitly?	Y
	Are key references cited and in full?	Y
	Are supporting documents referenced?	Y
Approval	Does the document identify which committee/group will review it?	Y
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	NA
	Does the document identify which Executive Director will ratify it?	Y
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Y
	Does the plan include the necessary training/support to ensure compliance?	Y
Document Control	Does the document identify where it will be held?	Y
	Have archiving arrangements for superseded documents been addressed?	Y
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Y
	Is there a plan to review or audit compliance with the document?	Y
Review Date	Is the review date identified?	Y
	Is the frequency of review identified? If so is it acceptable?	Y
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Y

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	12.09.2012 (reviewed May 2021 – no changes)
Title	Anticoagulation: Safe prescribing, dispensing and administration of oral and parenteral anticoagulants
What are the aims, objectives & projected outcomes?	The purpose of this policy is to provide robust and safe systems to manage the inherent risks to patients from the use of anticoagulant therapy. It meets or exceeds the minimum requirements of the NPSA safer practice notice no.18 with respect to risk assessment, safe procedures, training and audit.
Scope of the assessment	
See names and contributors above	
Collecting data	
Race	There is no evidence to suggest that there is a disproportionate impact on race regarding this policy
Religion	There is no evidence to suggest that there is a disproportionate impact on religion or belief and non-belief regarding this policy
Disability	There is no evidence to suggest that there is a disproportionate impact on disability regarding this policy
Sex	There is no evidence to suggest that there is a disproportionate impact on gender regarding this policy
Gender Identity	There is no evidence to suggest that there is a disproportionate impact on gender identity regarding this policy
Sexual Orientation	There is no evidence to suggest that there is a disproportionate impact on sexual orientation regarding this policy
Age	There is no evidence to suggest that there is a disproportionate impact on age regarding this policy
Socio-Economic	There is no evidence to suggest that there is a disproportionate impact on socio-enonomic issues regarding this policy
Human Rights	There is no evidence to suggest that there is a disproportionate impact on human rights regarding this policy
What are the overall trends/patterns in the above data?	Overall patterns and trend are not identified.
Specific issues and data gaps that may need to be addressed through consultation or further research	There are no specific equality & human rights issues and data gaps that need to be addressed through consultation and/or further research

Involving and consulting stakeholders	
Internal involvement and consultation	Thrombosis Committee
External involvement and consultation	There has been no external consultation or involvement
Impact Assessment	
Overall assessment and analysis of the evidence	This policy has no impact on equality

Action Plan

Action	Owner	Risks	Completion Date	Progress update