

# CLINICAL GUIDELINE FOR THE MANAGEMENT OF PATIENTS ON ANTICOAGULANT MEDICINES IN INPATIENT UNITS

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<b>CLINICAL GUIDELINE SUMMARY</b>
Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital.
This clinical guideline describes the requirements for the safe prescribing and monitoring of oral and injectable anticoagulants, including the direct-acting oral anti-coagulants (DOACs), on in-patient units within the Trust
<b>The Trust monitors the implementation of and compliance with this clinical guideline in the following ways;</b>
Trust-wide Clinical Audit Programme; Datix Report monitoring

Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

**The Director responsible for monitoring and reviewing this Clinical Guideline is the Executive Medical Director**

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INPATIENT UNITS CLINICAL GUIDELINE**

**ESSEX PARTNERSHIP UNIVERSITY NHS FOUNDATION TRUST**

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### Assurance Statement

The purpose of this procedural guideline is to minimise the risks associated with the management and use of anticoagulant therapy in inpatient units across Essex Partnership NHS Foundation Trust.

### 1.0 INTRODUCTION

- 1.1 Patients admitted to in-patient units in the Trust, both in Mental Health and Learning Disabilities and in Community Health Services, may already be taking warfarin or other oral anticoagulant for a condition which may or may not be related to their admission. Several in-patient units within the Community Hospitals in the Community Health Services in Essex occasionally initiate warfarin for patients in their care. Patients may also be admitted on injectable Low Molecular Weight Heparin (LMWH) or have this medicine initiated on admission. Irrespective of whether or not the anticoagulant was initiated by a Trust-employed physician, the Trust has a duty of care to ensure that the patient is managed appropriately and receives their anticoagulant therapy safely during their episode of care with EPUT.
- 1.2 This guideline describes actions to be taken to ensure the safe use of oral and injectable anticoagulants in patients admitted to EPUT In-Patient Units, according to NPSA Patient Safety Guidance<sup>1</sup> and Patient Safety Alert (PSA) Harm from using Low Molecular Weight Heparins when contraindicated. (January 2015)<sup>2</sup>
- 1.3 In March 2007, The National Patient Safety Agency (NPSA) issued a Patient Safety Alert No18 recommending actions that can make anticoagulant therapy safer, having identified that Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital (See Appendix 1).
- 1.4 Under the CQC Inspection Framework there are 13 Fundamental Standards of Care<sup>3</sup>, below which care must never fall, one of which is “Safety”, which states:  
“You must not be given unsafe care or treatment or be put at risk of harm that could be avoided. Providers must assess the risks to your health and safety during any care or treatment and make sure their staff have the qualifications, competence, skills and experience to keep you safe.”
- 1.5 To ensure Trusts are compliant with the Fundamental Standards, the CQC uses Key Lines of Enquiry (KLOEs)<sup>4</sup> that directly relate to the five key questions – are services safe, effective, caring, responsive and well-led? Medicines Management is covered under Safety S4: How does the service provider ensure the proper and safe use of medicines, where the service is responsible?

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- 1.6 The following subcategories are applicable to this Guideline and anticoagulant use:
- 1.6.1 S4.2 - Are medicines appropriately prescribed, administered and/or supplied to people in line with the relevant legislation, current national guidance or best available evidence?
  - 1.6.2 S4.3 - Do people receive specific advice about their medicines in line with current national guidance or evidence?
  - 1.6.3 S4.4 - How does the service make sure that people receive their medicines as intended, and is this recorded appropriately?
  - 1.6.4 S4.6 - Are people receiving appropriate therapeutic drug and physical health monitoring with appropriate follow-up in accordance with current national guidance or evidence?

### **2.0 SCOPE**

- 2.1 This guideline covers the use of warfarin and other coumarins, (also known as Vitamin K Antagonist (VKA) anticoagulants), Direct-Acting Oral Anticoagulants (DOACs) and prophylactic and treatment doses of Low Molecular Weight Heparin for patients admitted to in-patient units within EPUT. It does not cover administration of anticoagulants in the community setting by community nursing staff.

### **3.0 PURPOSE**

- 3.1 This guidance has been developed for use by clinicians managing patients receiving oral anticoagulants, to ensure safe practice when prescribing, dispensing, administering and monitoring anticoagulant medicines

### **4.0 DEFINITIONS/GLOSSARY**

Oral Anticoagulants: warfarin, Phenindione; acenocoumarol

DOACs – Direct-acting Oral Anticoagulants (formerly known as NOACs): rivaroxaban; dabigatran; apixaban; edoxaban

Injectable Anticoagulants: Low molecular weight heparins

LMWH – Low Molecular Weight Heparin (tinzaparin, enoxaparin, dalteparin)

UFH – unfractionated Heparin

INR – International Normalised Ratio

## **5.0 TRAINING AND COMPETENCE**

Healthcare organisations must ensure that staff who prescribe, adjust the dosage, dispense, prepare, administer, monitor and discharge patients on anticoagulant therapy have received adequate training to ensure they have the necessary work competences to undertake their duties safely<sup>5</sup>.

### **5.1 Prescribers**

- 5.1.1 All prescribers who initiate, continue or adjust dosage of anticoagulants shall have the necessary work competencies as defined by the NPSA <sup>5</sup> ([www.npsa.nhs.uk/health/alerts](http://www.npsa.nhs.uk/health/alerts)):  
Competency no. 1 “Initiating anticoagulant therapy”  
Competency no. 2 “Maintaining oral anticoagulant therapy”  
Competency no. 5 “Preparing and administering heparin therapy”
- 5.1.2 Prescribers should assess their current level of competence and improve their knowledge and understanding by completion of appropriate educational packages such as the MHRA e-learning Module “Oral Anticoagulants” ( Link: <https://www.gov.uk/government/publications/e-learning-modules-medicines-and-medical-devices/e-learning-modules-medicines-and-medical-devices#oral-anticoagulants>) or BMJ e-learning packages “Starting patients on anticoagulants”, “Maintaining patients on anticoagulants”.
- 5.1.3 In the Mental Health Setting, with the exception of prophylaxis for VTE, initiation of any anticoagulant should only be undertaken by or under the advice of the local acute trust.

### **5.2 Registered Nurses**

- 5.2.1 Nursing staff who are authorised to administer medications under CLPG13 Safe and Secure Handling of Medicines Clinical Procedural Guideline may administer anticoagulants.
- 5.2.2 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”<sup>5</sup>

### **5.3 Pharmacists**

- 5.3.1 Pharmacists shall ensure that the INR is safe prior to dispensing oral anticoagulants for patients being discharged.
- 5.3.2 Pharmacists working on in-patient units shall take an active advisory role in monitoring INR results in patients and advising on use of medicines to minimise the impact on INR and the risks of bleeding from increased INR or VTE from reduced INR. Advice on Interactions between medicines co-prescribed with direct-acting oral anticoagulants and appropriate prescribing should also be provided.

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5.3.3 Pharmacy staff dispensing other medicines for patients maintained on anticoagulants must not assume that additional INR tests have been arranged and the anticoagulant clinic informed. When dispensing or noting the discontinuation of an interacting medicine, it is safe practice for healthcare professionals to check that these additional safety precautions have been taken.

### **6.0 RESPONSIBILITIES**

6.1 It is the responsibility of line managers to ensure that staff who prescribes, dispense, administer, monitor or discharge patients on anticoagulants have sufficient knowledge to fulfil their responsibilities - see Safe and Secure Handling of Medicines CLPG13

### **7.0 PRESCRIBING ORAL ANTICOAGULANTS (EXCLUDING DOACS)**

#### **7.1 Patients admitted on anticoagulants**

7.1.1 Patients may be admitted on oral anticoagulants, where an Acute Trust, GP or other provider organisation has initiated therapy. Such patients are the clinical responsibility of EPUT whilst in the care of the Trust and as such their anticoagulant therapy should be appropriately monitored and managed.

7.1.2 Check that they already have an Oral Anticoagulation Therapy Book (Yellow Book) and provide a new one if required, ensuring all relevant sections at the front are completed.

7.1.3 Before prescribing, check to establish that patient's INR has been monitored and is at a safe level for the prescription to be written. Contact the Anticoagulant service for advice if the INR is significantly outside the target range.

#### **7.2 Initiation of Oral Anticoagulant Treatment**

7.2.1 Prescribers shall carry out an assessment of the benefits versus the risks of therapy for individual patients before starting oral anticoagulation.

7.2.2 Patients shall receive appropriate verbal information at the start of therapy 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. The Yellow book should have all relevant sections at the front completed. Yellow Books can be ordered from Chelford court Pharmacy, or local Anticoagulant Clinics. (N.B. not all anticoagulant clinics use the Yellow Book, instead preferring to give patients a letter of information.)

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Foreign language versions of the Patient Information booklet (Yellow Book) are available to download from [here](#) in the following languages:

- Arabic
- Bengali
- Cantonese
- French
- Gujarati
- Polish
- Punjabi
- Somalian
- Tamil
- Urdu
- Welsh

7.2.3 There should be a “stop” or “Review” date clearly indicated

### 7.3 All Prescribing

7.3.1 A clear indication for the anticoagulant therapy must be recorded in the patient notes and/or on the Prescription Administration Chart (Drug Chart).

7.3.2 Prescribe doses in mg (milligrams) and not numbers of tablets.

7.3.3 Avoid use of both 5mg and 500 microgram (0.5mg) Warfarin tablets together.

7.3.4 Prescribe the least number of tablets needed to be taken each day

7.3.5 Prescribe a constant daily dose where possible

7.3.6 Where possible, avoid prescribing medicines which have clinically significant interactions with anticoagulant therapy. When prescribing a medicine with clinically significant interactions for a patient established on anticoagulant therapy, appropriate additional INR blood testing shall be arranged. (Seek advice from a pharmacist e.g. for short courses of medicines.) For frequency of testing for specific medicines seek advice from local acute trust anticoagulation service. See current BNF<sup>6</sup> for information on interaction medicines

7.3.7 Where a regularly prescribed medicine with clinically significant interactions is discontinued, arrangements shall be made for additional INR blood tests. The Anticoagulant clinic must be informed that an interacting medicine has been discontinued. For frequency of testing for specific medicines seek advice from local acute trust anticoagulation service.

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### 7.4 Administration of oral anticoagulants to In-Patients

7.4.1 Before administering oral anticoagulants, check in health records or in the patient's Outpatient Anticoagulation Therapy booklet:

- The target INR and duration of therapy intended for the patient
- The patient's INR has been monitored and is at a safe level for administration to proceed. Contact the anticoagulant service for advice if the INR is significantly outside the target range.

7.4.2 Maintain the dose stated by the anticoagulant service and/or prescriber unless this has been changed by a registered prescriber or a healthcare professional working in an anticoagulant service and is confirmed in writing

7.4.3 Check with the patient and/or carer that they understand the contents of the Outpatient Anticoagulation Therapy booklet. Explain any aspect that the patient is unsure about, from the Outpatient Anticoagulation Therapy booklet. Record the event in the patient's health record.

7.4.4 Records of Administration of Anticoagulants

7.4.4.1 Record administration in the appropriate section of the In-Patient Prescription & Administration Record Chart or Additional Anticoagulant Chart as applicable.

7.4.4.2 Record administration as the number of milligrams administered and not numbers of tablets.

### 7.5 Monitoring INR Levels

7.5.1 Maintain the monitoring intervals specified by the anticoagulant service supervising treatment.

7.5.2 All patients INR levels should be maintained below 5.

7.5.3 Where INR levels are above 5, seek urgent advice from the local Acute Trust Anticoagulation Service.

7.5.4 All services administering oral anticoagulants should have access to Phytomenadione injection 10mg/ml (Vitamin K injection which can be administered orally). Patients with an INR >5.0 but who are not bleeding should have 1–2 doses of warfarin withheld and their maintenance dose should be reduced. Oral vitamin K may be given to patients with an INR of 5.0–8.0 if they are judged to be at high risk of bleeding. The cause of the elevated INR should be investigated. Patients with an INR >8.0 and who are not bleeding should receive 1–5 mg of oral vitamin K. (unlicensed use)<sup>7</sup>. Intravenous vitamin K produces a more rapid correction of the INR than oral vitamin K and should be used in preference in the bleeding patient. Advice on

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appropriate use of reversal agents should be sought from the Acute Trust Haematologist.

### **7.6 Discharge**

- 7.6.1 Inform the Anticoagulant service supervising treatment that the patient is to be discharged and make arrangements for monitoring of the INR after the patient has been discharged.
- 7.6.2 Provide this information to the patient and record the date in the Outpatient Anticoagulation Therapy booklet (Yellow Book).
- 7.6.3 Ensure the patient has adequate stock of oral anticoagulant tablets, in the strengths the patient is familiar with, until a further supply can be obtained.
- 7.6.4 Where the INR is unstable or not in therapeutic range the GP should be contacted in addition to the form being completed, if discharging into the community.
- 7.6.5 When discharging a patient close to weekends or public holidays take care to ensure blood tests can be arranged at an appropriate interval after discharge.
- 7.6.6 Ensure the Outpatient Anticoagulation Therapy booklet (Yellow Book) is up to date and give this back to the patient or carer or goes with the patient if they are transferred to the care of another provider.
- 7.6.7 The nurse issuing the discharge medication to the patient must check that the current dose and administration time 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.
- 7.6.8 Ensure that the Discharge Summary has been written up with appropriate doses.
- 7.6.9 Ensure that the Discharge Summary has the stop or review date indicated for anticoagulant therapy (except where therapy is for a long term indication such as Atrial Fibrillation (AF) and was not initiated by EPUT clinicians).

## **8.0 INJECTABLE ANTICOAGULANTS**

### **8.1 VTE Assessment**

All patients admitted to hospital should undergo a risk assessment for venous thromboembolism on admission. For Mental Health wards this would generally apply mainly to Older People's wards. Patients considered to be at high risk include those anticipated to have a substantial reduction in mobility, those with obesity, malignant disease, history of venous thromboembolism, thrombophilic disorder, or patients over 60 years. Patients with risk factors for bleeding (e.g.

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acute stroke, thrombocytopenia, acquired or untreated inherited bleeding disorders) should only receive pharmacological prophylaxis when the risk of bleeding does not outweigh the risk of venous thromboembolism. [NICE clinical guideline 89](#) provides a full list of risk factors, and gives recommendations for prophylaxis. A venous thromboembolism risk assessment checklist is also available from the Department of Health ([www.gov.uk/dh](http://www.gov.uk/dh)).

### **8.2 Prescribing Treatment Doses of Injectable Anticoagulants (LMWH, UFH)**

For continuation of established treatment, essential information such as dose, the patient's bodyweight (that the dose is calculated from), renal function and duration of treatment should have been communicated at transfer of care (e.g. discharge letter).

For initiation of treatment doses of LMWH, a VTE risk assessment must be carried out. Consideration of contra-indications, co-morbidity and drug interactions is essential, as well as local Formulary recommendations. Unfractionated heparin (UFH) should be prescribed for patients with severe renal impairment (<30 ml/min/1.73 m<sup>2</sup>), or an increased risk of bleeding (refer to current BNF and seek specialist advice as appropriate). INR monitoring is not required unless bridging with warfarin.

### **8.3 Prescribing Prophylactic Doses of Injectable Anticoagulants (LMWH)**

General medical patients who are considered to be at high risk of venous thromboembolism should be offered pharmacological prophylaxis on admission. Choice of prophylaxis will depend on the medical condition, suitability for the patient and local Formulary requirements. INR monitoring is not required

## **9.0 DIRECT-ACTING ORAL ANTICOAGULANTS (DOACS) (ALSO KNOWN AS NOACS)**

9.1 The oral anticoagulants apixaban, dabigatran etexilate, edoxaban and rivaroxaban are indicated for prophylaxis and treatment of venous thromboembolism following hip or knee replacement surgery, prophylaxis and treatment of pulmonary embolism, and prophylaxis of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Patients may be admitted whilst prescribed these medicines and continuation of therapy will be required.

9.2 Patients may be initiated on an appropriate DOAC in accordance with local CCG prescribing guidelines and Formulary requirements, if VTE assessment requires anticoagulation.

9.3 Patients should be monitored for signs of bleeding or anaemia; treatment should be stopped if severe bleeding occurs. However, all are dependent on the kidney for excretion and may require dose modification depending on the patient's renal function. Regular monitoring to identify and address the consequences of deterioration in kidney function over time is important. Depending on the DOAC being used body weight should also be regularly monitored and doses adjusted if necessary.

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9.4 Renal function: All DOACs should be avoided if creatinine clearance is less than 15 mL/minute. Dabigatran is contraindicated if creatinine clearance is less than 30 mL/minute. Patients prescribed DOACs should have renal function checked in accordance with Summary of Product Characteristics for individual medicines, but generally<sup>8</sup>:

- Annually if CrCl > 60ml/min
- 6-monthly if CrCl 30-60ml/min
- 3-monthly if CrCl < 30ml/min, or ≥ 75 years or expected decline in renal function
- During acute illness (dose many need to be modified)

Creatinine clearance must be used for calculating renal function using the Cockcroft and Gault equation (see below). eGFR is not a suitable alternative:

$$\text{CrCl (ml/min)} = (140 - \text{age}) \times \text{wt (kg)} \times 1.04 \text{ (female) or } 1.23 \text{ (male)} \\ \text{serum creatinine (micromol/l)}$$

9.5 No routine anticoagulant monitoring is required (INR tests are unreliable).

9.6 Antidote – there is currently no antidote to any of the DOACs with the exception of Dabigatran. Idarucizumab (Praxibind®) is licensed for use in adults treated with dabigatran etexilate (Pradaxa, Boehringer Ingelheim Limited) when rapid reversal of its anticoagulant effects is required for emergency surgery or urgent procedures or in life-threatening or uncontrolled bleeding. 9 It is only available in the acute hospital setting.

**END**

<sup>1</sup> National Patient Safety Agency. Patient Safety Alert no 18. Actions that make Anticoagulant Therapy Safer. 28.3.07. Available at: <http://www.nrls.npsa.nhs.uk/resources/?entryid45=61777&p=14> [Accessed 18.11.19]

<sup>2</sup> NHS Improvement. Patient Safety Alert. Harm from Using Low Molecular Weight Heparins when Contra-indicated 19<sup>th</sup> January 2015. Available at: <https://improvement.nhs.uk/news-alerts/harm-using-low-molecular-weight-heparins-when-contraindicated/> [Accessed 18.11.19]

<sup>3</sup> Care Quality Commission: Fundamental Standards. Available at: <http://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulations-service-providers-managers> [Accessed 18.11.19]

<sup>4</sup> Care Quality Commission. Key Lines of Enquiry. Medicines Management. October 2017 Available at: <http://www.cqc.org.uk/guidance-providers/nhs-trusts/medicines-management> [Accessed 18.11.19]

<sup>5</sup> National Patient Safety Agency. Workforce competency statements. Available at: <http://www.nrls.npsa.nhs.uk/resources/?entryid45=61790&q=0%ac2%acanticoagulant%ac2%ac> [Accessed 18.11.19]

<sup>6</sup> Joint Formulary Committee. British National Formulary. Available at <https://www.medicinescomplete.com/mc/bnf/current/index.htm> [Accessed 18.11.19]

<sup>7</sup> 3. Haemostasis and Thrombosis Task Force of the British Committee for Standards in Haematology. Guidelines on oral anticoagulation with warfarin. Fourth edition. British Journal of

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Haematology, 2011; 154:311-324. Available at: <http://www.b-s-h.org.uk/guidelines/guidelines/oral-anticoagulation-with-warfarin-4th-edition/> [Accessed 18.11.19]

<sup>8</sup> NICE Clinical Knowledge Summaries. Anticoagulation – oral June 2019. Available at <https://cks.nice.org.uk/anticoagulation-oral#!scenario> [Accessed 18.11.19]

<sup>9</sup> National Institute for Health and Care Excellence. Reversal of the anticoagulant effect of dabigatran: idarucizumab. Evidence summary [ESNM73] Published date: May 2016. Available at: <https://www.nice.org.uk/advice/esnm73/chapter/Key-points-from-the-evidence> [Accessed 18.11.19]