Royal Devon University Healthcare NHS Foundation Trust

Title
Management of oral anticoagulants in elective surgery

Reference Number: RDF2473-24
Date of Response: 23/04/24

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

I note that the FOI request online (reference FOI4522) refers to speciality specific guidance in orthopaedics for management of oral anticoagulants in elective surgery (paragraph 13.1). Please can you provide a copy of this guidance?.

Please find attached the following:

- Foot-Ankle-VTE-Risk-Assessment-and-Treatment_Jan2023-002_Redacted
- Venous-Thromboprophylaxis-VTE-in-Adults-Policy_Redacted
- VTE-Prophylaxis-for-Elective-Orthopaedic-Surgery-V

Please note: two of the enclosed documents have been redacted as they contained staff names and details. The disclosure of staff names and details would breach the first data protection principle and fail to meet any of the relevant conditions set out in Schedule 2 of the Data Protection Act (DPA) 2018. The first principle in the DPA requires that disclosure must be fair and lawful, and, in particular, personal data shall not be processed unless at least one of the conditions in Schedule 2 is satisfied. The staff concerned would not have expected their names to be disclosed in the public domain and so disclosure would not be 'fair' in the manner contemplated by the DPA. Furthermore, disclosure would not satisfy any of the conditions for data processing set out in Schedule 2 of the DPA. In particular, we do not consider that there is a legitimate interest in disclosure in this case. There is no public interest in making information about our staff available in this way contrary to what would have been their legitimate expectation at the time the information was gathered.

Royal Devon University Healthcare
NHS Foundation Trust

Protocol for:
Foot & Ankle Orthopaedic Surgery VTE Risk Assessment and Treatment

SUMMARY

This protocol provides information on the requirement for VTE risk assessment and proposed treatment guidelines for standard and high risk foot and ankle orthopaedic surgery patients.

PUBLICATION DETAILS

Authors of Clinical Guideline	*Foot & Ankle surgical team:* [redacted]
Division/ Department responsible for Clinical Guideline	Surgical Services Division Trauma & Orthopaedics
Contact details	[redacted]
Version number	1.0
Replaces version number	N/A
Date written	January 2023
Consultation undertaken with	Emergency Department, Pharmacy
Approving body and date approved	Trauma & Orthopaedics Governance Group: 07/02/2023
Review date	07/09/2025
Expiry date	07/02/2026
Date document becomes live	07/08/2023

Please note: *a national multicentre trial "FATE STUDY" is ongoing investigation to rate of DVT and management strategies in UK F&A practice – and this protocol may change once this study is completed.*

VTE Risk Assessment and Treatment

Foot and ankle day case surgery in which the patient will be weight bearing post operatively and not in a plaster cast represents a low surgical risk for DVT, however they will need a DVT assessment for personal risk factors (such as previous PE, coagulopathy etc). The level of risk will be determined by the surgeon and documented in the operative note 'post op care plan'.

LOW SURGICAL RISK PROCEDURES (not exhaustive)

- Scarf osteotomy
- 1st MTP fusion
- Ankle arthroscopy
- Lesser toe surgery
- Morton's neuroma excision
- Toe amputation
- Cheilectomy
- Ganglion excision
- Soft tissue surgery
- Toe nail surgery
- Metalwork removal from foot/ankle
- Tendon repairs in the foot
- Plantar fibroma removal
- Plantar fascia release
- 1st MTP joint replacement

- Mobilise as soon as practical (no requirement to wait for block to wear off)

  If the patient has personal risk factors then consider:

- Dalteparin 5000units 8hrs post-op if still in hospital and whilst hospital inpatient (see appendix 1 for dosing) – switching to:

  - Aspirin 150 mg for 6 weeks to commence on discharge *(where aspirin intolerant, consider substituting Dalteparin or Rivaroxaban 10mg OD instead for six weeks or until fully weight bearing)*

Standard risk

FOOT AND ANKLE SURGERY IN BELOW KNEE CAST

- Mobilise as soon as practical (no requirement to wait for block to wear off)
- Consider contralateral Calf pumps if on bedrest/elevation until mobile
- Dalteparin 5000units 8hrs post-op if in hospital *(see appendix 1 for dosing)* and whilst hospital inpatient – switching to:
    - Aspirin 150 mg for 6 weeks to commence on discharge (where aspirin intolerant, consider substituting Dalteparin or Rivaroxaban 10mg OD instead for six weeks or until fully weight bearing).

High risk

FOOT AND ANKLE SURGERY IN BELOW KNEE CAST

(e.g. previous PE/DVT, malignancy history, clotting disorder)

- Mobilise as soon as practical (no requirement to wait for block to wear off)
- Consider contralateral Calf pumps if on bedrest/elevation until mobile
- Dalteparin 5000units 8hrs post-op if in hospital (see appendix 1 for dosing) and then one of:
    - Continue Dalteparin for 6 weeks, OR
    - Rivaroxaban 10mg once daily (discuss option with consultant) for 6 weeks.
        - NB: Rivaroxaban may be considered in patients who are unable to tolerate subcutaneous injections or unable to self/peer-administer at home following lower limb immobilisation when all other options have been exhausted. Its use for such indications is unlicensed.

Clopidogrel: If a patient is already taking clopidogrel 75mg at home, continue clopidogrel monotherapy unless high risk then consider adding in low molecular weight heparin. Seek advice from consultant in this situation.

Patients will be reviewed in clinic in 2 weeks' and further VTE prophylaxis prescribed then if they continue to be non-weight bearing.

Appendix 1 Dalteparin Dosing:

Weight / CrCl	**<50kg**	**50-99kg**	**100-149kg**	**>150kg**	**CrCl <20ml/min**
Dalteparin Dose	2500 units OD	5000 units OD	5000 units 12 hourly	7500 units 12 hourly	Consider reducing to 2500 units OD

ASSOCIATED TRUST POLICIES

Venous Thromboprophylaxis in Adults Policy

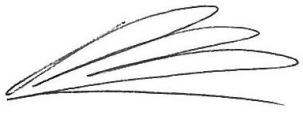
Venous Thromboprophylaxis in Adults Policy

Post holders responsible for Policy:	[redacted], VTE Prevention Group Chair
Author of Policy:	[redacted], VTE Prevention Group Chair
Division/ Department responsible for Procedural Document:	VTE Prevention Group
Contact details:	[redacted]
Date of original document:	May 2009
Impact Assessment Performed:	Yes
Approving body and date approved:	Clinical Effectiveness Committee: 10 January 2019
Review date & (frequency of further reviews):	June 2022 (3 ½ years)
Expiry date:	January 2023
Date policy becomes live:	4 February 2019 (version 4.1: 9 May 2019)

Please *specify* standard/criterion numbers and tick ✓ other boxes as appropriate.

Monitoring Information		**Strategic Directions: Key Milestones**	
Patient Experience		Waiting	
Assurance Framework	✓	Privacy and Dignity	
Monitor/Finance/Performance		Efficiency and Effectiveness	
CQC Regulations / Outcomes:	Outcome 4 Outcome 16	Delivery of Care Closer to Home	
		Infection Control	
NHSLA Risk Management Standards for Acute Trusts		5.9	
NHSLA CNST Maternity Clinical Risk Management Standards:			
Other (please specify):			
Note: This policy has been assessed for any equality, diversity or human rights implications			

Full History		Status: Final	
Version	**Date**	**Author Title**	**Reason**
1.1	Mar 2009	Consultant Vascular Surgeon	Creation
2.1	Feb 2012	VTE Committee Chair Medical Director	Update
2.2	Jan 2013	VTE Group Chair	Update
2.2.1	July 2013	VTE Group Chair	
3.0	Apr 2015	VTE Group Chair	Update
3.1	Dec 2016	VTE Group Chair	Minor Revision to T&O table
4.0	Nov 2018	VTE Group Chair	Update: References (including NICE NG89), associated Trust Policies, new template. Sections: 3.7, 9, clinical table appendices.
4.1	May 2019	VTE Group Chair	Amend incorrect information in Appendix 4A-BMI table

Associated Trust Policies/ Procedural Documents:	• VTE Prophylaxis Following Acute Stroke. • Venous Thromboembolism - Obstetric Prophylaxis. • Orthopaedic Shoulder and Elbow Surgery VTE Guideline (incl. risk stratification). • Anticoagulation Policy. • ICU Clinical Guideline for VTE (Feb 2018) • Reversal of Anticoagulation Policy. • Essential Learning Policy. • Clinical Audit Policy. • Injectable Medicines Policy • Employee Training, Education and Development Policy (Oct 2017)
Key Words	VTE, thromboembolism, thromboprophylaxis, DVT, PE, clot, prevention, dalteparin, prophylaxis, LMWH, heparin
In consultation with: October 2018:	VTE Prevention Group (clinical leads) Patient Safety and Mortality Group Associate Medical Directors Divisional Directors Assistant Directors of Nursing Governance Managers Quality Assurance 23/10/2018 Clinical Effectiveness Committee 10/01/2019
Contact for Review:	Chair, VTE Prevention Group
Executive Lead Signature:	 Adrian Harris, Medical Director

CONTENTS

KEY POINTS OF THIS POLICY

Patients, on admission, receive an assessment of VTE and bleeding risk using the clinical risk assessment tool.

Patients are re-assessed within 24 hours of admission for risk of VTE and bleeding.

Patients at risk of VTE are offered VTE prophylaxis (mechanical and/or with medicines) which may be extended beyond the admission period for some patient groups.

Patients/carers are offered information on VTE prevention during the admission and discharge processes.

Patients provided with anti-embolism stockings have them fitted and monitored.

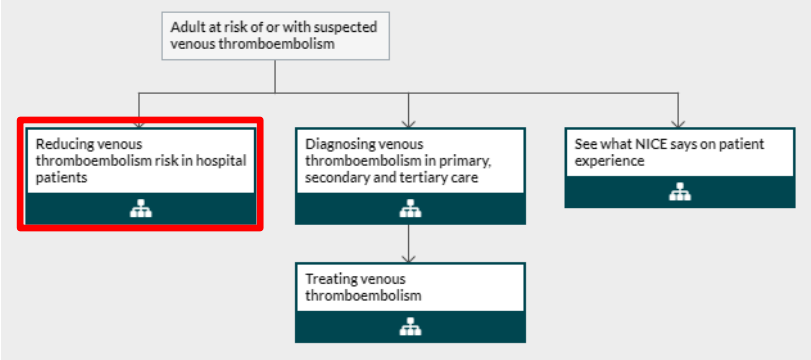


Fig 1 - NICE Venous Thromboembolism Pathway

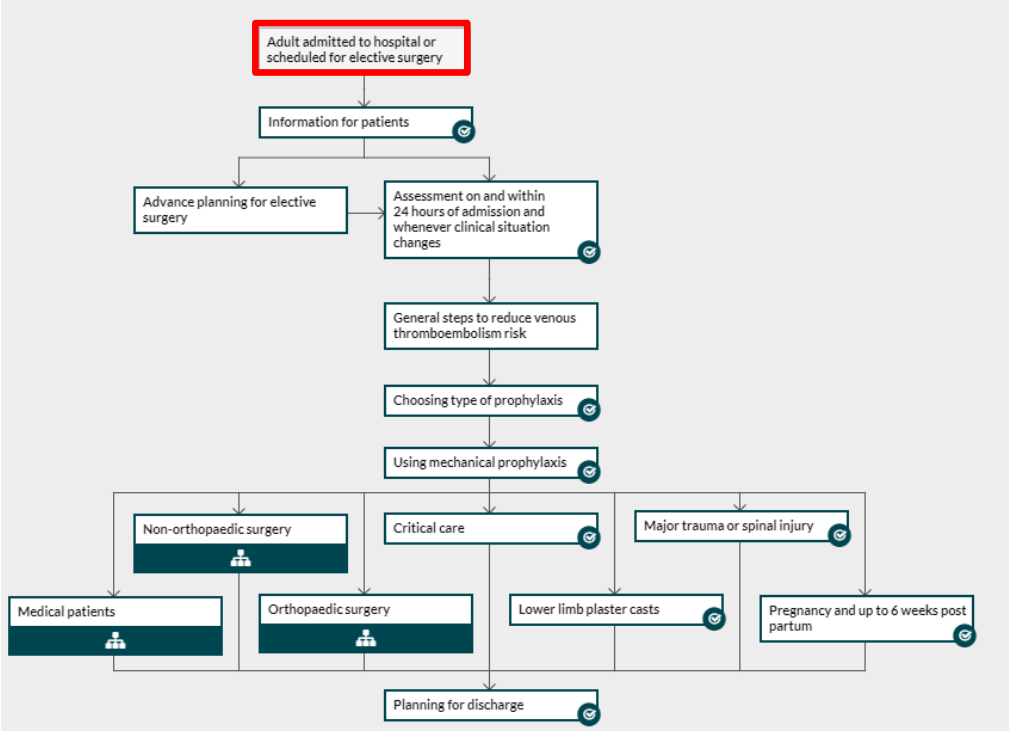


Fig 2 - NICE VTE Pathway: Reducing the risk of venous thromboembolism in hospital patients

1. INTRODUCTION

1.1 It has been estimated that 25,000 people die from venous thromboembolism (VTE) in hospitals in England each year, including both medical & surgical patients.

1.2 The National Institute of Health and Clinical Excellence (NICE) produced an updated clinical guideline: "Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital" (NICE, 2015 June); a NICE Quality Standard: "Venous thromboembolism – prevention" (NICE QS3, 2010); and a NICE Pathway (see fig.1 and fig.2 above).

1.3 **Failure to comply with this policy could result in disciplinary action.**

2. PURPOSE

2.1 This policy describes risk assessment, information for patients, and measures for prophylaxis against VTE that should be used for all patients admitted to the Royal Devon & Exeter NHS Foundation Trust (hereafter referred to as "the Trust").

2.2 The Trust's implementation and approach to the NICE Quality Standard for VTE prevention (QS3) (NICE QS3, 2010), is detailed throughout this policy. The seven key statements in the QS3 are:

- Medical, surgical or trauma patients have their risk of VTE and bleeding assessed using a national tool as soon as possible after admission to hospital.
- Patients who are at increased risk of VTE, are given information about VTE prevention on admission to hospital.
- Patients provided with anti-embolism stockings have them fitted and monitored in accordance with NICE guidance.
- Medical, surgical and trauma patients have their risk of VTE reassessed at consultant review or if their clinical condition changes. Patients assessed to be at risk of VTE are offered VTE prophylaxis in accordance with NICE guidance.
- Patients/carers are offered verbal and written information on VTE prevention as part of the discharge process.
- Patients are offered extended (post hospital) VTE prophylaxis in accordance with NICE guidance.

2.3 The recommendations in this policy are based on NICE Guideline NG89. (NICE NG89, 2018)

2.4 The standards described in this policy will form the basis for audit of practice in risk assessment, information for patients, and measures prescribed and used for prophylaxis against VTE in the Trust.

2.5 Like NICE guidance, this policy does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient. It is recommended that any departures from the measures stipulated in this policy should be clearly documented.

2.6 The appropriate summaries of product characteristics (SPC) should be used for information on the licensed indications, doses, timing and administration of pharmacological prophylaxis.

2.7 This policy refers to prophylaxis in adults (over 16 years of age). There is currently no clear national guidance for children. For guidance for obstetric & stroke patients refer to the relevant policies on the Trust intranet.

3. DEFINITIONS

3.1 The following definitions should be used to guide staff involved in thromboprophylaxis in adults.

3.2 **Venous Thromboembolism (VTE)** is a condition in which a blood clot (thrombus) forms in a vein. It most commonly occurs in the deep veins of the legs; this is called deep vein thrombosis (DVT). The thrombus may dislodge from its site of origin to travel in the blood – a phenomenon called embolism. Thrombus which is carried through the veins lodges in the lungs: this is a pulmonary embolus (PE).

3.3 **Venous Thromboprophylaxis** encompasses all methods to reduce the risk of a VTE occurring which includes one or more of: general measures, mechanical, and pharmacological methods.

3.4 **VTE assessment** is a process by which a patient's risk for developing a VTE is considered. This process is partly facilitated by the assessment tool provided by DoH (see Appendix 1A).

3.5 **LMWH** – Low molecular weight heparin e.g. dalteparin.

3.6 **UFH** – Unfractionated heparin.

3.7 **HIT** – Heparin induced thrombocytopenia.

3.8 **IPCD** - Intermittent pneumatic compression devices.

3.9 **FID** – Foot impulse devices**.**

3.10 **GCS** - Graduated compression stocking.

3.11 **NOAC** – the 'non-vitamin K antagonist oral anticoagulants' (previously called new or novel oral anticoagulants) e.g. dabigatran, rivaroxaban, apixaban (see section 9.4.8.1). (NICE, 2014)

4. DUTIES AND RESPONSIBILITIES OF STAFF

4.1 The **Medical Director** is responsible for ensuring the Trust has effective assessment, prophylaxis and monitoring processes for the management of VTE; and is the executive signatory for this policy.

4.2 **Associate Medical Directors** and **Clinician Leads** are responsible for ensuring that detailed policies are in place, which specify VTE prophylaxis measures for patients managed in their specialist areas, in accordance with the principles of NICE CG92 and other relevant guidelines.

4.3 **Consultants** are responsible for ensuring application of VTE policies to all patients under their care, and for providing training to more junior grade medical staff as required.

4.4 **Doctors** (or other nominated health care professionals in a service) are responsible for undertaking, documenting and reviewing VTE risk assessments using the appropriate Trust approved documentation (normally the national tool).

4.5 **Prescribers (medical and non-medical)** are responsible for prescribing VTE prophylaxis for patients under their care as identified in the service in which they are working.

4.6 **Nurses** are responsible for ensuring that patients receive appropriate VTE prevention as prescribed, and that mechanical prevention is applied and monitored in accordance with NICE guidance.

4.7 **Managers** with responsibility for staff, to whom this policy applies, are responsible for ensuring that relevant staff are aware of and adhere to this policy; and that a system is in place to keep staff up to date with any changes.

4.8 **Clinical Effectiveness Committee (CEC)** provides the strategic direction for, and assurance of, effective management of risk within the Trust and determines priorities for action. CEC analyses reports from the VTE Prevention Group and escalates issues or provides assurance where appropriate to the Governance Committee.

4.9 The Patient Safety Group is responsible for ensuring that: this policy is up to date and reflects national guidance including the NICE VTE Quality Standard; the mandatory submission of UNIFY2 VTE data reflects clinical practice; and that reports are regularly provided to the Safety & Risk Committee on these aspects.

5. TRAINING

5.1 It is the responsibility of the Divisional Management Teams, Associate Medical Directors, Assistant Directors of Nursing and Departmental Heads to ensure that all staff in their areas who are involved in VTE assessment / treatment are familiar with the procedures and documentation and have received the appropriate training. It is essential that all staff caring for patients are skilled in the necessary competencies. The evidence of this training can be found on the staff members ESR (electronic staff record). Staff groups requiring VTE training and update frequency are identified on the Trust training needs analysis (TNA) which can be found on the Trust Intranet.

6. ASSESSMENT OF RISK FOR VTE

6.1 All patients should be assessed for their risk of VTE, using the DoH 'Venous thromboembolism (VTE) risk assessment' tool (see Appendix 1) (DoH, 2010). For all other patients the assessment should be done as part of the admission process. Assessment includes questions to detect any bleeding tendency, which might influence the methods of prophylaxis that are used.

6.2 VTE risk assessments should be documented clearly in the patient's notes.If risk assessment for VTE and bleeding has been undertaken as part of an pre-admission clinic e.g. for elective patients, it should be documented clearly and reviewed/verified on admission.

6.3 The VTE risk of patients may change during their hospital stay and should be reassessed if their condition changes or if, for example, they require major surgery which had not been anticipated.

6.4 Procedures undertaken by radiologists may be associated with an increased risk of VTE. This risk should be assessed by the referring speciality team and appropriate prophylaxis considered. The risk assessment and any VTE prophylaxis prescribing remains the responsibility of the referring Consultant's Team.

7. WHAT TO DO IF A VTE IS SUSPECTED

7.1 Diagnosis should be carried out according to the Trust clinical pathway guideline on DVT (Deep Vein Thrombosis) and PE (Pulmonary Embolism) and therapy initiated where appropriate. Therapy may, in appropriate cases, be initiated in anticipation of diagnosis. See separate relevant Trust guideline for details (see section 14.0).

8. INFORMATION FOR PATIENTS ABOUT VTE RISK AND PROPHYLAXIS

8.1 Whenever practical, patients/carers should be offered verbal and written information on VTE prevention as part of the admission process, encompassing:

- Risks and possible consequences of VTE.
- Importance of VTE prophylaxis and its possible side effects.
- Correct use of VTE prophylaxis (e.g. anti-embolism stockings, intermittent pneumatic compression devices or foot impulse devices).
- How patients can reduce their risk of VTE (such as keeping well hydrated and, if possible, exercising and becoming more mobile).

8.2 Two generic VTE risk and prophylaxis leaflets are available for use in the Trust and are available on the Trust internet/intranet sites and from Health Information. Written information should also be included in all relevant procedure- and condition-specific advice booklets.

8.3 The use of Oestrogen containing hormonal contraception and hormone replacement therapy (HRT) is not recommended in women who are immobile for a prolonged period following surgery or illness. Patients should be advised to stop Oestrogen containing contraceptives and HRT four weeks before major surgery. Women undergoing minor surgery and most day surgery may continue with Oestrogen containing contraceptives. There is no need to discontinue Progesterone only methods of contraception in these circumstances. Patients stopping such contraceptives should be advised to take other contraceptive precautions to cover this period. Tamoxifen should normally be stopped 2 weeks before surgery and restarted at an appropriate time post-surgery.

8.4 Patients/carers should be offered verbal and written information on VTE prevention as part of the discharge process, including information about:

- Signs and symptoms of deep vein thrombosis and pulmonary embolism
- Correct and recommended duration of use of VTE prophylaxis at home (if discharged with prophylaxis).
- Importance of using VTE prophylaxis correctly and continuing treatment for the recommended duration (if discharged with prophylaxis)
- Signs and symptoms of adverse events related to VTE prophylaxis (if discharged with prophylaxis).
- Importance of seeking help and who to contact if they have any problems using the VTE prophylaxis.
- Importance of seeking medical help if deep vein thrombosis, pulmonary embolism or other adverse events are suspected.
- Immobility associated with continuous travel of more than 3 hours during the 4 weeks after surgery or serious illness may increase the risk of deep venous thrombosis (DVT).

9. PROPHYLAXIS AGAINST VTE

9.1 These include general measures; graduated compression stockings and intermittent pneumatic compression devices (the latter two often combined as “mechanical prophylaxis” but in practice better considered separately); pharmacological prophylaxis; and other measures. Details of the measures used in each specialty for particular groups of patients are shown in Appendix 4.

9.2 **GENERAL MEASURES**

9.3 Immobility is a significant risk factor for VTE and all patients should be encouraged to mobilise; leg exercises should be arranged for those who are immobile in bed. Surgical patients should be mobilised as soon as possible after operation.

9.4 Dehydration is a risk factor for VTE and patents should not be allowed to become dehydrated during their stay in hospital.

9.5 Regional or local anaesthesia should be considered for suitable patients, because it reduces the risk of VTE compared with general anaesthesia.

9.6 **MECHANICAL PROPHYLAXIS**

9.7 This includes both graduated compression stockings and intermittent pneumatic compression devices.

9.8 **GRADUATED COMPRESSION STOCKINGS (ANTI-EMBOLISM STOCKINGS)**

9.9 Patients should be checked for their suitability to wear graduated compression stockings (they are contraindicated, for example, in many patients with peripheral arterial disease or diabetic neuropathy). Staff trained in the use of graduated compression stockings should show patients how to wear them correctly and monitor their use. (NICE 2010)

9.10 Below knee stockings should normally be used. NICE guidance advises either below knee or above knee stockings. It is the consensus of clinicians in the Trust that thigh-length stockings are uncomfortable for patients; they tend to fall down; and proper compliance with their use is poor. The published evidence of any advantage of thigh-length over below-knee stockings is not conclusive. Taking all this into account, below-knee stockings will normally be used.

9.11 Patients should be advised whether and for how long they should continue to wear graduated compression stockings after discharge from hospital.

9.12 For the management of stroke patients refer to the Trust Policy on the Trust intranet here.

9.13 **INTERMITTENT PNEUMATIC COMPRESSION DEVICES**

9.14 These include intermittent calf or foot compression devices. When prescribed, they should be used for as much of the time as possible and practical. They may be used instead of, or as well as, graduated compression stockings.

9.15 **PHARMACOLOGICAL PROPHYLAXIS**

9.16 The most common method of pharmacological prophylaxis employed in the Trust is subcutaneous injection of the low molecular weight heparin (LMWH) - dalteparin. It should be used in accordance with its SPC. Any deviations from the SPC should be clearly documented, with reasons, in the patient's clinical notes.

9.17 Timing of administration of dalteparin should take account of the possible use of regional anaesthesia. Guidance has been agreed with the Anaesthetic Department and is shown in section 12.0.

9.18 If using pharmacological VTE prophylaxis for medical patients, it should be started as soon as possible and within 14 hours of admission, where appropriate. (NICE NG89, 2018)

9.19 For patients who have concerns about receiving animal products such as heparins, synthetic alternatives e.g. fondaparinux should be considered based on clinical judgement and after discussing their suitability, advantages and disadvantages with the patient (NICE, 2015 June)

9.20 Aspirin is considered to be an option for VTE prophylaxis but only in a limited number of clinical situations (NICE NG89, 2018). See Appendix 4C & D, for details of aspirin therapy in orthopaedics.

9.21 At the time of approval, aspirin did not have a UK marketing authorisation for these indications. Prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the GMC prescribing guidance here.

9.22 Heparin-induced thrombocytopenia (HIT) is a rare but serious immune-mediated side-effect of heparin (including LMWH) therapy which develops between 4-14 days of treatment (earlier if previously exposed to heparin). The most serious complication of HIT is life or limb-threatening thrombosis. The guidelines for HIT monitoring were modified in 2012 (British Society of Haematology, 2012).

9.23 To obtain a baseline for comparison a pre-treatment platelet count should be checked in ALL patients who will be receiving any type of heparin (seek haematology advice where concerns about abnormal results).

- Medical, surgical and obstetric patients receiving LMWH prophylaxis DO NOT require further monitoring of the platelet count after baseline, with the exception of cardiopulmonary bypass patients and surgical patients who have received heparin within the last 100 days.
- Patients receiving unfractionated heparin (UFH) should have a platelet count checked every 2-4 days until day 14 or until heparin is stopped.
- Immediate cessation of therapy is indicated if there is a fall in the platelet count of 50% or more, thrombosis or skin necrosis. Alternative anticoagulation is mandatory in patients with HIT, even without evidence of thrombosis – contact haematology for urgent advice.

9.24 Hyperkalaemia can occur as a result of inhibition of aldosterone secretion by heparins. Patients with diabetes mellitus, chronic renal failure, acidosis, raised plasma potassium or those taking potassium sparing drugs seem to be more susceptible. The risk of hyperkalaemia appears to increase with duration of therapy. Plasma-potassium should be measured in patients at risk before starting therapy and monitored regularly thereafter, particularly if treatment is prolonged beyond about 7 days.

9.25 **DALTEPARIN USE IN SPECIAL POPULATIONS (GUIDANCE).**

Renal impairment

9.26 There is no clear consensus approach on how to manage patients on prophylactic dalteparin in patients with severe renal impairment (creatinine clearance <30mls/min).

9.27 NICE recommends UFH or LMWH as options for patients with renal failure and where necessary that the dose of LMWH and UFH the dose could be reduced. Dose reductions decisions should be based on multidisciplinary or senior opinion, or in locally agreed protocols. (NICE NG89, 2018). Local advice is described below.

9.28 Dalteparin is considered to be well tolerated at prophylactic doses in end stage renal failure and although it does not normally need to be dose-adjusted (unlike high/treatment dose schedules) it should be used with caution (DunleavyA, 2014). Dose reductions may be considered in severe renal impairment and minor bleeding (discontinue in cases of major bleeding). (ASHP, 2011) (Schmidt P, 2009) (Tincani E, 2006) (HAT Committee (UKCPA), 2017) (Hull R, 2014).

9.29 For prolonged dalteparin courses (>10days) in patients with chronic severe renal impairment (<30mls/min), monitoring anti-Xa levels should be considered, especially when there is concern about accumulation/bleeding. (Douketis J, 2008) (ASHP, 2011) (HAT Committee (UKCPA), 2017) (Pfizer Limited, 2016 May). Monitoring should be discussed with a haematologist.

9.30 To monitor anti-Xa activity in a patient with renal impairment receiving prophylactic Dalteparin, a pre-dose (trough) sample should be taken to assess for accumulation. Samples should be taken into a coagulation (citrate) tube and a 'heparin anti-Xa assay' requested from the laboratory. No guidelines exist for dose adjustment of prophylactic dalteparin, but given that the accepted peak reference range for prophylactic doses is <0.1-0.3 units/dL, a trough level in the range <0.1-0.3 units/dL is clearly elevated and indicates accumulation. Dose adjustment or an increased dose interval should be considered and discussed with a haematologist.

9.31 Any deviations from the SPC should be clearly documented, with reasons, in the patient's clinical notes. When dosing patients undergoing renal replacement therapies, advice should be sought from a nephrologist.

Extremes of weight

9.32 There are no specific licensed dose adjustments of dalteparin for patients with extremes of weight, although the manufacturer does recommend considering monitoring anti-factor-Xa levels in patients who are 'thin' or 'clinically obese'. (Pfizer Limited, 2016 May) However, specific dose weight adjusted schedules have been suggested for some patient groups (Royal College of Obstetrics & Gynaecologists, 2009) (HAT Committee (UKCPA), 2015 Dec) and adjustments may be considered in exceptional circumstances. (American College of Chest Physicians, 2012) (Hull R, 2014).

9.33 Any deviations from licensed dosing should be clearly documented in the patient notes with the rationale. Specialities may consider recommendations for their patient groups (see Appendix 4).

10. OTHER PHARMACOLOGICAL AGENTS

10.1 There are a number of other drugs which have also been assessed as appropriate options for VTE prophylaxis by NICE, which are not in widespread use in the Trust at this time.

10.2 These include:

Drug	NICE Ref	Indication(s)
Dabigatran	TA157 (2008)	Total hip/knee replacement in adults.
Rivaroxaban	TA170 (2009)	Total hip/knee replacement in adults.
Fondaparinux	CG92 (2010)	Multiple (see product datasheet)
UFH	CG92 (2010)	Multiple (in renal impairment only)
Apixaban	TA245 (2012)	Total hip/knee replacement in adults.

11. OTHER MEASURES

11.1 The use of vena cava filters should be considered in patients with existing or recent (within 1 month) VTE when anticoagulation therapy is contraindicated.

11.2 NICE has also considered a *battery powered, disposable neuromuscular electrostimulation* (or Geko^{TM}) device for VTE prevention in people who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. Refer to the guidance online for more information. (NICE (MTG19))

11.3 EXTENDED PROPHYLAXIS

11.4 Extended prophylaxis should be used in selected patients after their discharge from hospital, as set out in the policies of each specialist area in Appendix 4. Relevant information regarding specific indications and dosing schedules can be found within the Summary of Product Characteristics (SPC).

11.5 Supply of LMWH after discharge for fixed length courses of extended prophylaxis, will normally be supplied by the RD&E pharmacy from the discharge summary or medication chart.

11.6 For patients who require extended prophylaxis and cannot administer LWMH themselves, information will be provided for relatives who are able to assist with this task. Where there is no suitable relative/carer who can assist at home with administration, the team responsible for discharge will liaise with community nursing services to arrange home visits for injections to be administered.

11.7 Patients/carers will be offered verbal and written information on extended prophylaxis at discharge where appropriate (NICE QS3, 2010) as outlined in section 8. For patients using injectable prophylaxis at home e.g. dalteparin; the patient/carer should be given information and the necessary equipment to administer and dispose of these items safely and effectively. Mini sharps bins are available as part of the Trusts Extended Prophylaxis packs.

11.8 Patients' General Practitioners should be notified (e.g. on the discharge summary), when patients have been discharged with VTE prophylaxis to be used at home.

12. ADMINISTRATION OF PHARMACOLOGICAL PROPHYLAXIS WITH RELATION TO EPIDURAL/SPINAL ANAESTHESIA.

12.1 Prophylaxis with low molecular weight heparin (LMWH) should not be given within the 12 hours before insertion of a spinal or epidural; or within the first 4 hours after insertion.

12.2 Removal of epidurals should be performed at least 12 hours after the most recent dose of LMWH.

13. TO BE USED IN CONJUNCTION WITH

- Applicable national or local speciality VTE prevention guidelines.
- Current summary of product characteristics (aka data sheets) for the medications relevant to this policy.

14. ARCHIVING ARRANGEMENTS

14.1 The original of this policy will remain with the author, Medication Safety and Deputy Chief Pharmacist. An electronic copy will be maintained on the Trust Intranet (HUB) document library here , P – Policies, V – VTE.

14.2 Archived electronic copies will be stored on the Trust's "archived policies" shared drive, and will be held indefinitely. A paper copy (where one exists) will be retained for 10 years.

15. PROCESS FOR MONITORING COMPLIANCE WITH AND THE EFFECTIVENESS OF THE POLICY

15.1 To evidence compliance with this policy, the following elements will be monitored:

What areas need to be monitored?	Evidenced by	Where will this be reported and by whom?
95% of patients have a completed VTE assessment on admission to hospital, using the clinical criteria of the national tool.	Electronic VTE assessment data capture (Unify2 submission)	Data analyst team. Ward 2 Board dashboard
95% of patients have a current completed VTE assessment.	NHS *Patient Safety Thermometer* Audit	Data analyst team. Ward 2 Board dashboard

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APPENDIX 1A: A RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

DH Department of Health

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

Mobility – all patients (tick one box)	Tick		Tick		Tick
Surgical patient		Medical patient expected to have ongoing reduced mobility relative to normal state		Medical patient NOT expected to have significantly reduced mobility relative to normal state	
Assess for thrombosis and bleeding risk below				**Risk assessment now complete**	

Thrombosis risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age > 60		Hip or knee replacement	
Dehydration		Hip fracture	
Known thrombophilias		Total anaesthetic + surgical time > 90 minutes	
Obesity (BMI >30 kg/m²)		Surgery involving pelvis or lower limb with a total anaesthetic + surgical time > 60 minutes	
One or more significant medical comorbidities (eg heart disease;metabolic,endocrine or respiratory pathologies;acute infectious diseases; inflammatory conditions)		Acute surgical admission with inflammatory or intra-abdominal condition	
Personal history or first-degree relative with a history of VTE		Critical care admission	
Use of hormone replacement therapy		Surgery with significant reduction in mobility	
Use of oestrogen-containing contraceptive therapy			
Varicose veins with phlebitis			
Pregnancy or < 6 weeks post partum (see NICE guidance for specific risk factors)			

Bleeding risk			
Patient related	**Tick**	**Admission related**	**Tick**
Active bleeding		Neurosurgery, spinal surgery or eye surgery	
Acquired bleeding disorders (such as acute liver failure)		Other procedure with high bleeding risk	
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR >2)		Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours	
Acute stroke		Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Thrombocytopaenia (platelets< 75x10⁹/l)			
Uncontrolled systolic hypertension (230/120 mmHg or higher)			
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)			

APPENDIX 1B: A RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

All patients should be risk assessed on admission to hospital. Patients should be reassessed within 24 hours of admission and whenever the clinical situation changes.

STEP ONE

Assess all patients admitted to hospital for level of mobility (tick one box). All surgical patients, and all medical patients with significantly reduced mobility, should be considered for further risk assessment.

STEP TWO

Review the patient-related factors shown on the assessment sheet against **thrombosis** risk, ticking each box that applies (more than one box can be ticked).

Any tick for thrombosis risk should prompt thromboprophylaxis according to NICE guidance.

The risk factors identified are not exhaustive. Clinicians may consider additional risks in individual patients and offer thromboprophylaxis as appropriate.

STEP THREE

Review the patient-related factors shown against **bleeding risk** and tick each box that applies (more than one box can be ticked).

Any tick should prompt clinical staff to consider if bleeding risk is sufficient to preclude pharmacological intervention.

Guidance on thromboprophylaxis is available at:

National Institute for Health and Clinical Excellence (2010) Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in patients admitted to hospital. NICE clinical guideline 92. London: National Institute for Health and Clinical Excellence.

http://www.nice.org.uk/guidance/CG92

This document has been authorised by the Department of Health
Gateway reference no: 10278

DH Department of Health

1

APPENDIX 2: VTE RISK ASSESSMENT (ADULT DRUG CHART)

RISK ASSESSMENT TOOL FOR VENOUS THROMBOEMBOLISM

See DoH website for full tool

Patient name: .....
NHS no: .....
Hospital no: .....
DOB: .....
Affix Patient ID Label

MOBILITY

Patient or admission related	Tick
Surgical patient	
Medical patient expected to have ongoing reduced mobility relative to normal state	
Medical patient NOT expected to have significantly reduced mobility relative to normal state - this risk assessment is complete if this option is ticked. Reassess at 24 hours and regularly thereafter	

THROMBOSIS RISK

Patient or admission related	Tick
Active cancer or cancer treatment	
Age >60 years	
Dehydration	
Known thrombophilias	
Obesity (BMI >30kg/m²)	
One or more significant medical comorbidities (e.g. heart disease; metabolic, endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)	
Personal history or first-degree relative with a history of VTE	
Use of hormone replacement therapy	
Use of oestrogen-containing contraceptive therapy	
Varicose veins with phlebitis	
Pregnancy or <6 weeks post partum (see NICE guidance for specific risk factors)	
Significantly reduced mobility for 3 days or more	
Hip or knee replacement (planned)	
Hip fracture	
Total anaesthetic + surgical time >90 minutes	
Surgery involving pelvis or lower limb with a total anaesthetic + surgical time >60 minutes	
Acute surgical admission with inflammatory or intra-abdominal condition	
Critical care admission	
Surgery with significant reduction in mobility	

BLEEDING RISK

Patient or admission related	Tick
Active bleeding	
Acquired bleeding disorders (such as acute liver failure)	
Concurrent use of anticoagulants such as warfarin (with INR >2), apixiban (Eliquis®), dabigatran (Pradaxa®), edoxoban (Lixiana®), rivaroxaban (Xarelto®), or other	
Acute stroke (see guidelines)	
Thrombocytopaenia (platelets <75 x 10^9/l)	
Uncontrolled systolic hypertension (230/120mmHg or higher)	
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)	
Neurosurgery, spinal or eye surgery	
Other procedure with high bleeding risk	
Lumbar puncture/epidural/spinal anaesthesia expected within the next 12 hours	
Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hours	
Other factor associated with higher bleeding risk - please describe:	

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE)

All patients should be risk assessed on admission. Please reassess within 24 hours of admission and whenever clinical situation changes. Complete either treatment decision box or indicate that no prophylaxis is required below.

STEP ONE
Assess all patients admitted to hospital for level of **mobility** (tick one box). All surgical patients, and all medical patients with significantly reduced mobility, should be considered for further risk assessment.

STEP TWO
Review the patient-related factors shown on the assessment sheet against **thrombosis** risk, ticking each box that applies (more than one box can be ticked). Any tick for thrombosis risk should prompt thromboprophylaxis according to NICE guidance. The risk factors identified are not exhaustive. Clinicians may consider additional risks in individual patients and offer thromboprophylaxis as appropriate.

STEP THREE
Review the patient-related factors shown against **bleeding risk** and tick each box that applies (more than one box can be ticked). Any tick should prompt clinical staff to consider if bleeding risk is sufficient to preclude **pharmacological** intervention.

INITIAL ASSESSMENT: Based on local guidelines: ☐ Treatment required ☐ No prophylaxis indicated Details:	Date & Time DD/MM/YY HH:MM Signature & Grade:
24-HOUR RE-ASSESSMENT: Based on **local guidelines**: ☐ Treatment required ☐ No prophylaxis indicated Details:	Date & Time DD/MM/YY HH:MM Signature & Grade:

Continue to reassess risk and document risk / prophylaxis requirements regularly and every time the clinical situation changes

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APPENDIX 3: VTE RISK ASSESSMENT (PAEDIATRIC DRUG CHART)

VTE RISK ASSESSMENT & PROPHYLAXIS GUIDANCE

Use on all children >40kgs (in specialist areas e.g. Oncology, please discuss with patient's consultant before prescribing)

Patient name: .....
NHS no: .....
Hospital no: .....
DOB: .....
Affix Patient ID Label

- General preventative measures should be undertaken in all patients. These include: adequate hydration, particularly peri- and post-operatively, early mobilisation and removal of CVLs as soon as possible.
- Older girls on the combined oral contraceptive pill undergoing planned surgery - consider stopping oral contraceptive pill for 4 weeks pre-operatively, especially if there are other risk factors.
- Mechanical prophylaxis (graduated compression stockings, intermittent pneumatic compression and venous foot pumps), are practicable only in older children (>40kg).
- Eash patient must be assessed individually. The following is guidance only and not intended to replace clinical judgement.

1. Assess VTE risk → Assess bleeding risk (✔ boxes)
2. If VTE risk high, assess bleeding risk (✔ boxes)
3. Balance risk VTE/bleeding (clinical decision)
4. Prescribe appropriately (✔ boxes)

Table 1: Risk Factors for VTE		Score	✔Adm	✔24hr
Age	Infant <6/12 (Note 1)	0		
	6/12 - pre-adolescent (Note 2)	0		
	Adolescence onwards	2		
Congenital disorders	Congential heart disease	1		
	Certain metabolic disorders (Note 3)	1		
	Certain malformations (Note 4)	1		
Pre-existing major medical conditions	Inflammatory disorders (Note 5)	1		
	Connective tissue disorders (Note 6)	1		
	Previous VTE	1		
	Thrombophilic conditions (congenital and acquired) (Note 7)	1		
Current major medical conditions	Critical care admission	1		
	Indwelling Central Venous Line (CVL)	1		
	Active malignancy	1		
	Severe/ongoing sepsis	1		
	Major trauma/burns	1		
	Prolonged immobility, i.e. mobility significantly reduced >3 days, or ongoing reduction in mobility relative to normal state	1		
	Pregnancy	1		
	Obesity (BMI >30kg/m²)	1		
	Temporary cessation of antiplatelet or anticoagulant treatment, e.g. peri-operatively (see bridging plan if available)	1		
	Thrombophilic drugs, e.g. combined oral contraceptives, asparaginase	1		
Total Score	**1-2 = Low risk 3-5 = Medium risk 6+ = High risk**			

Table 2: Risk Factors for bleeding	✔Adm	✔24hr
Active bleeding		
Known bleeding disorder (e.g. acute liver failure or haemophilia)		
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR >2)		
Lumbar puncture/epidural/spinal anaesthesia within the previous 4 hrs or expected within next 12 hrs		
Acute stroke or risk of central nervous system bleeds e.g. head injury or previous subarachnoid bleed		
Thrombocytopenia (platelets <75 x 10^9/l)		
Uncontrolled systolic hypertension (?mmHg)		

Table 3: VTE Assessment for Surgical Patients (see Table 1 & Table 2)			✔Adm	✔24hr
Surgery	Score	Precautions and Risk		
Surgery less than 30 mins	Any score	General preventative measures		
General surgery greater than 30 mins	1-2	General preventative measures		
	3-5	Graduated compression stockings (GCS)		
	6+	GCS & Fragmin		
Major orthopaedic surgery	1-2	General preventative measures		
	3-5	GCS & Fragmin		
	6+	GCS & Fragmin		
Medical/ICU		Guidance		
Low risk patients	1-2	General preventative measures		
		Graduated compression stockings if intubated & ventilated >48 hrs		
Medium risk patients	3-5	Consider Fragmin (GCS if Fragmin unsuitable)		
High risk patients	6+	Fragmin (GCS if Fragmin unsuitable)		

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APPENDIX 4: SPECIFIC MEASURES TO BE USED BY EACH SPECIALTY GROUP

Page	Appendix Subsection	Speciality Summary
21	5A	Acute Surgery (incl. upper & lower GI, Urology and Vascular)
22	4B	Gynaecology
23	4C	Orthopaedics: elective (also refer to shoulder guideline via Trust intranet)
24	4D	Orthopaedics: trauma
25	4E	Medicine
26	4F	Patients with Cancer, Central Venous Catheters or receiving Palliative Care.

APPENDIX 4A: ACUTE SURGERY

Acute Surgery (including upper & lower GI, Urology, Vascular & Thoracic)	
Complex abdominal and pelvic surgery for malignant disease.	• General measures • Mechanical: – Compression stockings **OR** intermittent pneumatic calf compression. – Continue until no significantly reduced mobility relative to normal or anticipated mobility. • Pharmacological: – Add where risk of VTE outweighs risk of bleeding. – LMWH (dalteparin 5000units daily*). Continue for 28 days after operation with platelet monitoring (may continue for longer in selected cases on an individual basis).
All other abdominal and pelvic surgery.	• General measures. • Mechanical: – Compression stockings – May consider intermittent pneumatic compression on an individual patient basis. – Continue until no significantly reduced mobility relative to normal or anticipated mobility. • Pharmacological: – Add where risk of VTE outweighs risk of bleeding – LMWH (dalteparin 5000units daily*) Continue until discharge (may continue for longer on an individual basis).
Open vascular surgery or major endovascular procedures (including aneurysm repair).	• General measures • Pharmacological: – Consider where risk of VTE outweighs risk of bleeding – LMWH (dalteparin 5000units daily*) – Continue until discharge (may continue for longer on an individual basis). • Mechanical: – Consider where pharmacological prophylaxis is contraindicated. – Compression stockings **OR** intermittent pneumatic calf compression. Continue until no significantly reduced mobility relative to normal or anticipated mobility.
Table approved at Surgical Division Governance Group 28/11/2018	

APPENDIX 4A: ACUTE SURGERY continued

Lower limb amputation	• General measures • Pharmacological: − Consider where risk of VTE outweighs risk of bleeding − LMWH (dalteparin 5000units daily*) − Continue until discharge (may continue for longer on an individual basis). • Mechanical: – Consider intermittent pneumatic compression on the contralateral leg if pharmacological prophylaxis is contraindicated Continue until no significantly reduced mobility relative to anticipated mobility.
• Laparoscopic day case surgery Day case groin surgery, including: adult patients having groin hernia repairs and scrotal surgery.	• General measures. Compression stockings for 5 days.
All other patients without any VTE risk factors and having operations with total time <90 minutes (or < 60 mins lower limb or pelvis) including all day cases having minor surgery under local anaesthesia with minimal reduced mobility expected.	General measures only.
Table approved at Acute Surgical Governance Group 28/11/2018	

***** Consider dalteparin dose reduction to 2500units daily for patients <50kg or with a GFR <30ml/min, or dose increase in patients with raised BMI (see below).

100-150kg	>150kg
5000 units twice daily	7500 units twice daily

APPENDIX 4B: GYNAECOLOGY

Gynaecology	
Highest risk: • Complex abdominal and pelvic surgery for malignant disease:	• General measures • Compression stockings (consider intermittent pneumatic calf compression) • Dalteparin 5000units daily - continued for 28 days (In selected cases this may need to be continued e.g. continuing chemotherapy)
High risk: • Inpatient surgery lasting >30 minutes • One or more patient related risk factors (as in NICE guideline 92) • Patients admitted as emergencies and/or for investigation, with one or more risk factors as above	• General measures • Compression stockings (consider intermittent pneumatic calf compression) • Dalteparin 5000units daily – until discharge
Intermediate risk: • Day surgery patients having procedures lasting longer than 30 minutes	• General measures • Compression stockings • Single dose of dalteparin in theatre
Low risk: • Patients without any risk factors having operations under general anaesthesia lasting under 30 minutes	• General measures • Compressions stockings
Table approved at Gynaecology Governance Group 9th June 2017	

APPENDIX 4C: ORTHOPAEDICS: elective

Orthopaedics: elective	

High risk HIP & KNEE replacement
 	
(e.g. previous PE/DVT, malignancy history, clotting disorder)
	Regional anaesthesia when possible
	• Calf pumps until mobile (for knees- foot pump on operated limb side).
	• Dalteparin 5000units 8hrs post-op and then one of:
	  ○ Warfarin (target INR 2-2.5) for 6 weeks to start the day following surgery,(continue dalteparin until INR therapeutic),
	  ○ Continue dalteparin for 6 weeks, **OR**
	  ○ Rivaroxaban 10mg once daily (discuss option with consultant):
	  ▪ For 5 weeks in HIPS
	  ▪ For 6 weeks in KNEES

Standard risk HIP & KNEE replacement	• Calf Pumps until mobile (for knees, use foot pump on operated limb side). • Dalteparin 5000units* 8 hours after surgery and whilst hospital inpatient (applies to acute and community settings), switching to - • Aspirin 150 mg for 6 weeks to commence on discharge (where aspirin intolerant, consider substituting dalteparin or rivaroxaban instead for two-four weeks (TKR) or five weeks (THR)).
Hip Arthroscopy	• Dalteparin 5000units* 6-8hrs post-op, then daily until discharge.
Spinal Surgery/Fractures: **Standard risk** **High risk**	• Calf pumps until mobile. • Calf pumps until mobile. • Consider dalteparin 5000units starting 48hrs after surgery until discharge. Requires careful consideration of the bleeding/VTE risks - discuss with consultant.
Foot and Ankle	Please refer to specialist departmental guidance.
Shoulder Surgery[$]	• No specific treatment unless high risk co-morbidities exist (see hip/knee).
Table approved at Trauma & Orthopaedic Governance Group 31/05/2018	

[$]Please see 'Clinical Guideline for: VTE Prophylaxis for Shoulder and Elbow Surgery' for detail regarding risk stratification.

APPENDIX 4D: ORTHOPAEDICS: trauma

Orthopaedics: trauma	
Pelvic Fractures	• Dalteparin 5000units on admission until discharge, in discussion with consultant.
Fractured Neck of Femur	• Foot/Calf pumps until mobile. • Dalteparin 5000units* whilst inpatient, switching to • Aspirin 150mg for 6-weeks from discharge home unless inappropriate[&].
Lower Limb Fractures: Lower Limb Plaster Casts Above- Knee Casts	• Consider dalteparin. • Dalteparin 5000units whilst immobilised.
Upper Limb Fractures/Surgery	• High Risk: consider dalteparin for high VTE risk patients e.g. in malignancy (discuss with consultant). • Low Risk: nil
Table approved at Trauma & Orthopaedic Governance Group 31/05/2018	

*****For standard risk procedures & hip arthroscopies, consider dalteparin dose reduction to 2500units for LOW BMI patients.

[$] The Clinical Policy Committee recommend that individual Providers should be given the option to include **aspirin** as part of a multimodal VTE prophylaxis strategy following appropriate individual risk assessment and patient consultation. Where the decision is taken not to align policy with NICE recommended options, Trusts must ensure that their VTE prophylaxis policy is ratified through the appropriate Clinical Risk Committee. Providers must ensure that patients can make an informed choice to elect to receive NICE recommended options if they would prefer.

At time of writing this has been signed off by the Executive Group of NEW Devon CCG, but the QEIA (Quality and Equality Impact Assessment) approval is still outstanding but due April 2015.

APPENDIX 4E: MEDICINE

Medicine excluding stroke (2017)	
Based on the *Department of Health's* Risk Assessment for VTE Tool	
High risk, including: • Age >60 years • Previous pulmonary embolism or deep vein thrombosis • Active cancer • Acute/chronic lung disease • Acute/chronic inflammatory disease • Chronic heart failure • Lower limb paralysis (excluding acute stroke) • Acute infectious disease, e.g. pneumonia • BMI >30kg/m2 – or alternative risk factors (as in NICE guideline NG89 – see appendix 1) – or surgical risk factors as above	• General measures including early mobilisation where appropriate • LMWH at enhanced dose (dalteparin 5000units daily subcutaneously) • Consider compression stockings if: – pharmacological intervention inappropriate – risk deemed particularly high
Low risk, including: • Fully ambulatory patients without any risk factors	• General measures • Review risk if clinical situation changes

The majority of medical patients should receive appropriate venous thromboprophylaxis. However, *pharmacological* interventions may be inappropriate, for example in patients with:	
• Haemophilia/other known bleeding disorder • Known platelet count <75 x 10^9/L • Acute stroke in previous month (haemorrhagic or ischaemic) • Blood pressure >230 systolic or 120 diastolic • Severe liver disease (prothrombin time above normal or known varices)	• Severe renal disease • Active bleeding • Major bleeding risk • Anticoagulant therapy or anti-platelet therapy • Neurosurgery, spinal surgery or eye surgery • Other procedure with high bleeding risk • Lumbar puncture/spinal/epidural in previous 4 hours
Table approved at Medical Division Governance Group	

APPENDIX 4F: PATIENTS WITH CANCER, CENTRAL VENOUS CATHETERS OR RECEIVING PALLIATIVE CARE

Patients with Cancer, Central Venous Catheters or Receiving Palliative Care.

Immobile patients receiving treatment for cancer should receive pharmacological prophylaxis unless there are contraindications e.g. thrombocytopenia (see below).

Consider offering prophylaxis to patients receiving palliative care if there is potentially reversible acute pathology, but do not offer routinely if in terminal care or on an individualised end-of-life care plan. Review decision daily.

High risk, including: • Age >60 years • Previous PE or DVT • Concurrent acute infectious disease e.g. pneumonia • BMI >30kg/m2 – or medical risk factors as above – or surgical risk factors as above	• General measures including early mobilisation where appropriate • LMWH (dalteparin 5000 units daily subcutaneously) • Consider compression stockings or other mechanical means of prophylaxis if pharmacological intervention is contraindicated (see below)
Low risk, including: • Fully ambulatory patients without any additional risk factors	• General measures • Review risk if clinical situation changes
Special considerations: • Risk of VTE increased with certain drugs e.g. Lenalidomide, Thalidomide, etc.	• Consider extended anticoagulant prophylaxis e.g. with full dose Warfarin
Exclusions from risk assessment audit (i.e. assessed as 'low risk' cohort): Day case transfusions, chemotherapy, IVIG, Pamidronate infusions, intrathecal chemotherapy, venesection, bone marrow examination, and stem cell collection, UNLESS additional risk factors as above.	
Pharmacological interventions may be contraindicated in patients with:	
• Haemophilia/other known bleeding disorder • Known platelet count <100 • Acute stroke in previous month • (haemorrhagic or ischaemic) • Blood pressure >200 systolic or 120 diastolic • Severe liver disease (prothrombin time above normal or known varices)	• Severe renal disease • Active bleeding • Anticoagulant therapy or anti-platelet therapy • Neurosurgery, spinal surgery or eye surgery • Other procedure with high bleeding risk • Lumbar puncture/spinal/epidural in previous 4 hours
Table approved at Chemotherapy Governance Group 17/05/2018	

APPENDIX 5: COMMUNICATION PLAN

The following action plan will be enacted once the policy has been approved.

Staff groups that need to have knowledge of the strategy/policy	All clinical staff involved in care and treatment of all patients: doctors, nurses, pharmacists and physiotherapists
The key changes if a revised policy/strategy	General policy revision including addition of aspects from new updated NICE guidance NG89 (March 2018) Revised wording around advice for dalteparin dosing in special populations (renal impairment and extremes of body weight) so in line with NG89. Aspirin commentary updated in line with NICE guidance. Update of speciality specific VTE prevention tables with approval dates in relevant Trust governance groups. Addition of paediatric risk assessment form from the paediatric prescription medication and administration chart. Update of citations/references to most recent versions and index.
The key objectives	This Policy describes risk assessment information for patients, and measures for prophylaxis against venous thromboembolism which should be used for all patients admitted to the hospital.
How new staff will be made aware of the policy and manager action	Local induction
Specific Issues to be raised with staff	Ensure all relevant staff are familiar with this policy.
Training available to staff	Managers and senior clinicians are responsible for ensuring that staff are adequately trained in their area(s) of expertise as set out in the Trust TNA.
Any other requirements	
Issues following Equality Impact Assessment (if any)	No negative impacts.
Location of hard / electronic copy of the document etc.	Trust Intranet (Policies A-Z, under "**V**")

APPENDIX 6: EQUALITY IMPACT ASSESSMENT TOOL

Name of procedural document	VENOUS THROMBOPROPHYLAXIS (VTE) FOR ADULTS POLICY
Directorate and Service Area	Trust-wide
Name, job title and contact details of person completing the assessment	[redacted]. VTE Group Chair. j[redacted]
Original Date:	January 2012, revised June 2017

The purpose of this tool is to:

- **identify** the equality issues related to a policy, procedure or strategy
- **summarise the work done** during the development of the document to reduce negative impacts or to maximise benefit
- **highlight unresolved issues** with the policy/procedure/strategy which cannot be removed but which will be monitored, and set out how this will be done.

1. **What is the main purpose of this policy / plan / service?**
   Outlines the broad strategies of the Trust within the VTE prevention national agenda.

2. **Who does it affect?** Please tick as appropriate.
   Carers ☐ Staff ☒ Patients ☒ Other (please specify)

3. **Who might the policy have a 'differential' effect on, considering the "protected characteristics" below?**

Protected characteristic	Relevant	Not relevant
Age	☒	☐
Disability	☒	☐
Sex - *including: Transgender, and Pregnancy / Maternity*	☐	☐
Race	☐	☐
Religion / belief	☐	☐
Sexual orientation – *including: Marriage / Civil Partnership*	☐	☐

4. **Apart from those with protected characteristics, which other groups in society might this document be particularly relevant to…** (e.g. those affected by homelessness, bariatric patients, end of life patients, those with carers etc.)?

None in addition

5. **Do you think the document meets our human rights obligations?** ☒

Feel free to expand on any human rights considerations in question 6 below.

A quick guide to human rights:
• ***Fairness –*** *how have you made sure it treat everyone justly?* • ***Respect –*** *how have you made sure it respects everyone as a person?* • ***Equality –*** *how does it give everyone an equal chance to get whatever it is offering?* • ***Dignity –*** *have you made sure it treats everyone with dignity?* • ***Autonomy –*** *Does it enable people to make decisions for themselves?*

6. Looking back at questions 3, 4 and 5, can you summarise what has been done during the production of this document and your consultation process to support our equality / human rights / inclusion commitments?

Discussed with Equality lead. No adjustments to Policy required. Also referred to: ***RD&E VTE GROUP*** ***National Guidance (NICE NG89)***

7. If you have noted any 'missed opportunities', or perhaps noted that there remains some concern about a potentially negative impact please note this below and how this will be monitored/addressed.

"Protected characteristic":	*n/a (none identified)*
Issue:	*n/a*
How is this going to be monitored/ addressed in the future:	*n/a*
Group that will be responsible for ensuring this carried out:	*n/a*

Document Control

Title			
VTE Prophylaxis for Elective Orthopaedic Surgery Policy			
Author			**Author's job title** Pharmacist
Directorate Surgery & Theatres			**Department** Orthopaedics
Version	**Date Issued**	**Status**	**Comment / Changes / Approval**
0.1	Apr 2016	Draft	Initial version for consultation
1.0	Feb 2017	Final	Approved by DTG and Executive Group of NEW Devon CCG
2.0	June 2018	Final	Changes made to prophylaxis strategies in line with NICE guideline
Main Contact			**Tel: Direct Dial** **Tel:** **Email:**
Lead Director Associate medical director for planned care			
Superseded Documents None			
Issue Date June 2018	**Review Date** June 2021		**Review Cycle** Three years
Consulted with the following stakeholders: • Orthopaedic Consultants • Drug and Therapeutics Group • Pharmacy			
Approval and Review Process • DTG • Executive Group of NEW Devon CCG			
Local Archive Reference G:\Compliance\Policies and procedures\Published policies\Orthopaedics **Local Path** Orthopaedic folder **Filename** VTE Prophylaxis for Elective Orthopaedic Surgery Policy			
Policy categories for Trust's internal website (Bob) Orthopaedics, Surgery & Theatres			**Tags for Trust's internal website (Bob)** Hip replacement, Knee replacement, VTE prophylaxis

CONTENTS

1. Purpose

1.1. The purpose of this document is to detail the process for preventing venous thromboembolic events post operatively in elective orthopaedic surgery.

1.2. The policy applies to all trust staff involved.

1.3. Implementation of this policy will ensure that:

- Appropriate VTE prophylaxis is provided during admission and discharge

2. Definitions

2.1. VTE – Venous thromboembolism – blood clot in the deep veins

2.2. THR – total hip replacement

2.3. TKR – total knee replacement

2.4. OD – Once daily

3. Responsibilities

3.1. Orthopaedic surgeons – ensure appropriate VTE prophylaxis is documented on the operation note in accordance with current guidance and ensure that deviation from NICE guidance is discussed with the patient and documented appropriately in the notes.

3.2. Junior doctors – Ensure VTE prophylaxis is appropriately prescribed during admission and on discharge and ensure that a discussion has taken place with the patient where NICE guidance is not followed.

3.3. Nursing staff – ensure VTE prophylaxis is prescribed by doctor post operatively and check against operation note.

3.4. Pharmacists – Ensure VTE prophylaxis is appropriately prescribed during admission and discharge.

4. VTE prophylaxis recommendations:

Elective Hip replacement

Standard Risk	• Foot pumps until mobile • **Enoxaparin** (Clexane) –subcutaneously OD. Starting 8 hours post-operatively for 10 days. 40mg if eGFR>= 30ml/min 20mg if eGFR<30ml/min • Then **aspirin** 150mg orally, OD for 28 days after enoxaparin course complete • **Lansoprazole** 30mg OD while patient taking aspirin
High Risk Previous PE/DVT, Clotting disorder, history of malignancy Allergy to aspirin	• Use Standard risk protocol as default • Selected patients should be offered **rivaroxaban** instead of enoxaparin and aspirin in line with NICE guidance. • 10mg OD started 6-10 hours after surgery for 35 days. • Rivaroxaban has shown a lower incidence of VTE in trials, but is associated with a higher bleeding risk than Enoxaparin/aspirin.
Other options	• Patients who are not suitable for the above may be offered: • Enoxaparin daily for 28 days post operatively • Apixaban within its licensed indications Patients on direct oral anticoagulants prior to admission for non-orthopaedic indications will generally be on higher doses than the licensed Orthopaedic VTE prevention doses. As such a clinical decision should be made regarding whether to continue on their normal anticoagulation or adjust their dose in line with orthopaedic licensing.

Elective knee replacement

Standard Risk	• **Aspirin** – 150mg orally, OD for 14 days post-operatively • **Lansoprazole** 30mg OD while patient taking aspirin
High Risk Previous PE/DVT, Clotting disorder, history of malignancy Allergy to aspirin	• Use Standard risk protocol as default • Selected patients should be offered **rivaroxaban** in line with NICE guidance. • 10mg started 6-10 hours after surgery OD for 14 days. • Rivaroxaban has shown a lower incidence of VTE in trials, but is associated with a higher bleeding risk than Enoxaparin/aspirin. **Or – if eGFR<30** • Anti-embolism Stockings until discharge • **Enoxaparin** (Clexane) –subcutaneously OD. Starting 8 hours post-operatively for 14 days. 40mg if eGFR>= 30ml/min 20mg if eGFR<30ml/min
Other options	• Patients who are not suitable for the above may be offered: • Enoxaparin daily for 14 days post operatively • Apixaban within its licensed indications Patients on direct oral anticoagulants prior to admission for non-orthopaedic indications will generally be on higher doses than the licensed Orthopaedic VTE prevention doses. As such a clinical decision should be made regarding whether to continue on their normal anticoagulation or adjust their dose in line with orthopaedic licensing.

Other Surgery

Elective Non-arthroplasty orthopaedic knee surgery	For high risk patients and total anaesthesia time greater than 90 minutes offer VTE prophylaxis if VTE risk outweighs bleeding risk **Enoxaparin** (Clexane) – 8 hours after surgery for 14 days.
Foot and Ankle orthopaedic surgery	Consider pharmacological prophylaxis for patients that meet one of the following criteria: • Patients requires immobilisation – Consider stopping prophylaxis if immobilisation continues beyond 42 days • Total anaesthesia time greater than 90 minutes • Patient VTE risk outweighs risk of bleeding For these patients consider the use of **enoxaparin** while at elevated VTE risk
Elective spinal surgery	Offer mechanical prophylaxis • Anti-embolism stockings until discharge Consider **enoxaparin** for patients whose risk of VTE outweighs risk of bleeding. Start 14-48 hours postoperatively and continue until discharge

5. Monitoring Compliance with and the Effectiveness of the Policy

Standards/ Key Performance Indicators

5.1. Key performance indicators comprise:

- Nosocomial VTE numbers

Process for Implementation and Monitoring Compliance and Effectiveness

5.2. Orthopaedic teaching.

5.3. Detail here the monitoring process:

- Yearly audit

6. Equality Impact Assessment

6.1. The author must include the Equality Impact Assessment Table and identify whether the policy has a positive or negative impact on any of the groups listed. The Author must make comment on how the policy makes this impact.

Table 1: Equality impact Assessment

Group	Positive Impact	Negative Impact	No Impact	Comment
Age			x	
Disability			x	
Gender			x	
Gender Reassignment			x	
Human Rights (rights to privacy, dignity, liberty and non-degrading treatment)			x	
Marriage and civil partnership			x	
Pregnancy			x	
Maternity and Breastfeeding			x	
Race (ethnic origin)			x	
Religion (or belief)			x	
Sexual Orientation			x	

7. References

- NG89 - Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism [CG89] Published date: March 2018

8. Associated Documentation

- Trust Anticoagulation Policy
- Trust medicines policy