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Dear Colleagues

This guidance is currently under review by the author.

NHS Grampian Guidance For Extended Pharmacological Venous Thromboembolism (VTE) Prophylaxis In General Surgery – Version 1

This document has been risk assessed by the author and deemed appropriate to be used during this review period. A copy of the risk assessment can be provided on request.

If you have any queries regarding this, please do not hesitate to contact the Medicines Guidelines and Policy Group (MGPG) email at gram.mgpg@nhs.scot

Yours sincerely



Lesley Coyle
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NHS Grampian Guidance For Extended Pharmacological Venous Thromboembolism (VTE) Prophylaxis In General Surgery

Co-ordinators: Specialist Clinical Pharmacist (Surgery)/ Consultant Colorectal Surgeon	Consultation Group: See page 10	Approver: Medicines Guidelines and Polices Group
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Version 1

Executive Sign-Off

This document has been endorsed by the Director of Pharmacy and Medicines Management

Signature:  _____

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Corporate: Senior Managers
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Unit Operational Managers

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Review: This policy will be reviewed in three years or sooner if current treatment recommendations change.

Responsibilities for review of this document: Specialist Clinical Pharmacist (Surgery)/
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NHS Grampian Guidance For Extended Pharmacological Venous Thromboembolism (VTE) Prophylaxis In General Surgery

Contents	Page No
1 Introduction	2
1.1 Objectives	3
2 VTE Prophylaxis Use and Dosing	3
2.1 Exclusion Criteria and Contraindications.....	4
2.2 Cautions.....	4
3 Documentation	4
4 Patient Advice and Counselling.....	5
5 Method of Administration	5
6 Adverse Effects	5
7 Interactions ^{5,6,7,8}	6
8 Supplying Dalteparin	6
9 Monitoring Requirements and Precautions	7
9.1 Renal Impairment.....	7
9.2 Hepatic Impairment	7
9.3 Platelet Monitoring	7
9.4 Potassium	7
9.5 Porcine.....	8
9.6 Bleeding	8
9.7 Antiplatelets.....	8
9.8 Extremes of Body Weight.....	8
10 Anti-embolism Stockings.....	9
11 References.....	9
12 Distribution list.....	10
13 Acknowledgements	10

NHS Grampian Guidance For Extended Pharmacological Venous Thromboembolism (VTE) Prophylaxis In General Surgery

1 Introduction

All general surgical patients should be assessed to evaluate an individual patient's risk of thrombosis and bleeding, also taking procedural risk factors into consideration. The locally agreed venous thromboembolism (VTE) risk assessment tool¹ should be completed for each patient on admission to hospital and re-assessed regularly and whenever the clinical situation changes^{2,3}. For elective procedures, patients should have their initial VTE risk assessment conducted at their pre-assessment clinic appointment. The appropriate chemical and mechanical thromboprophylaxis are prescribed and given to the patient during their admission in all elective and emergency general surgical cases. The primary users of this document are the surgeons, nurses and allied professionals caring for major abdominal surgical procedures. This document will be used in secondary care where major resections are undertaken and is aimed at assessing the requirement for extended pharmacological VTE prophylaxis prescriptions at the point of patient discharge.

Major abdominal and pelvic surgery carries a high risk of VTE and risk remains elevated weeks following surgery⁴. VTE prophylaxis with low molecular weight heparin (LMWH) is effective at preventing VTE and is associated with little or no increase in the rates of clinically important bleeding. Recent evidence indicates that, following major abdominal or pelvic surgery, prolonged thromboprophylaxis with LMWH significantly reduces the risk of VTE compared to thromboprophylaxis during hospital admittance only, without increasing bleeding complications or mortality⁴.

Extending pharmacological VTE prophylaxis to 28 days postoperatively should be considered for people who have had emergency or elective, major abdominal or pelvic surgery. The assessment will be carried out by the primary surgeon responsible for the care of the patient.

Example surgeries include, but are not limited to:

- Right hemicolectomy
- Extended right hemicolectomy
- Left hemicolectomy
- Sigmoid colectomy
- Hartmann's resection
- High anterior resection
- Low anterior resection
- Abdomino perineal excision of rectum and anus
- Proctectomy
- Subtotal colectomy
- Small bowel resections

The decision to prescribe extended pharmacological VTE prophylaxis should be made on a case by case basis and will be assessed by the medical team during the post-operative recovery of the patient. Particular attention should be paid to assessing the risk of bleeding in individual patients.

1.1 Objectives

The aim of this document is to provide guidance to medical, nursing and pharmacy staff on prolonged thromboprophylaxis following emergency or elective, abdominal or pelvic surgery in order to reduce the risk of post-operative venous thromboembolism.

2 VTE Prophylaxis Use and Dosing

Dalteparin sodium is the LMWH of choice in NHS Grampian and should be given as below in the majority of patients. The NHS Grampian Risk Assessment for Venous Thromboembolism (VTE)¹ should be used to assess risk in these patients at the point of admission.

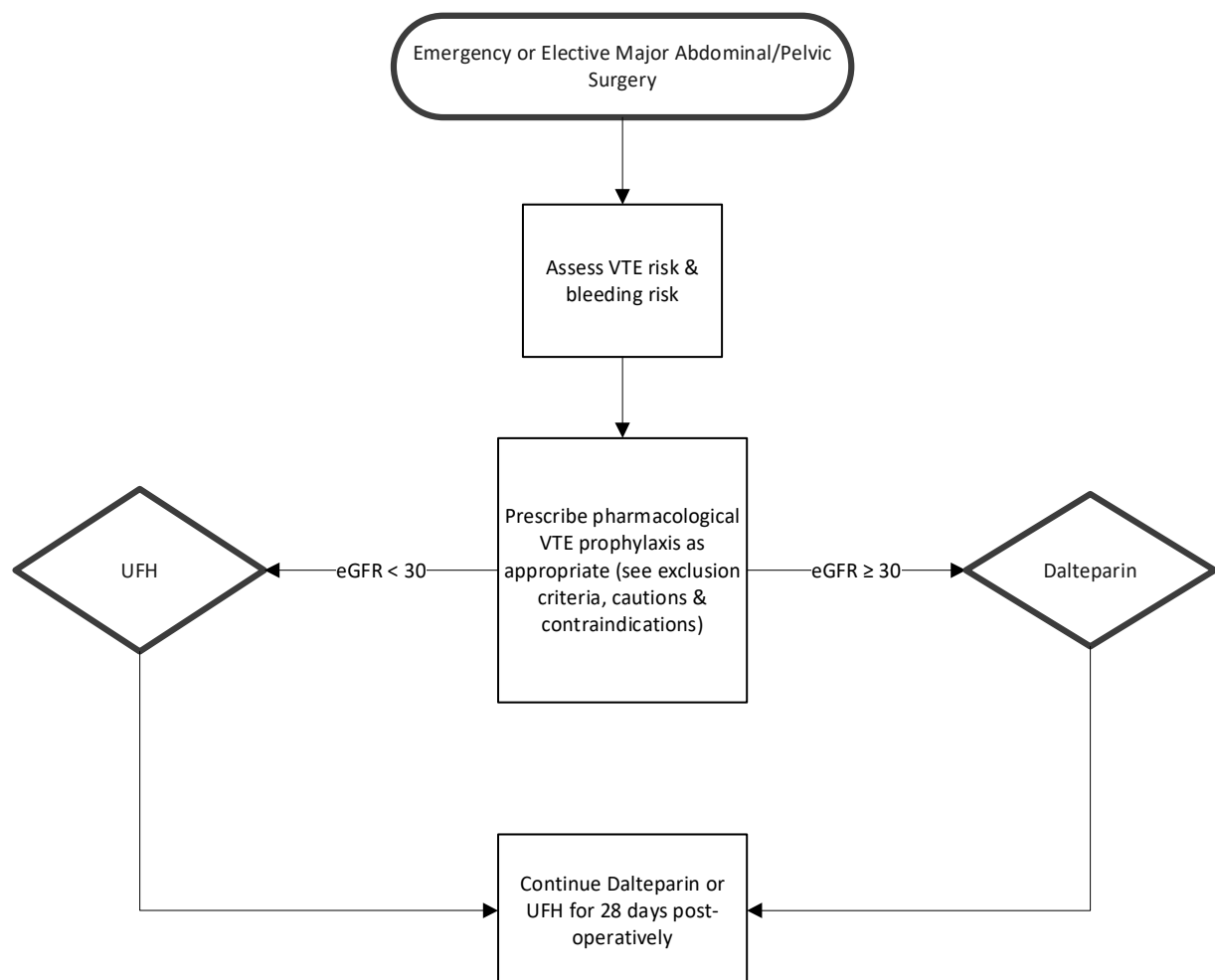
Moderate risk patients = DALTEPARIN 2500 units subcutaneous once daily

High risk patients = DALTEPARIN 5000 units subcutaneous once daily

By definition, such procedures are either moderate or high risk so there is no “low risk” patients in these cohorts.

Where there is significant renal impairment (estimated Glomerular Filtration Rate (eGFR) <30 ml/min), dalteparin should be avoided and unfractionated heparin (UFH) sodium prescribed alternatively. Refer to [Section 9.1](#) for further information.

See [Section 9](#) for advice on VTE prophylaxis in instances of renal and hepatic impairment, those that cannot receive porcine based medicines, and in extremes of body weight/body mass index.



2.1 Exclusion Criteria and Contraindications

This guideline does not apply to the following groups of patients who should **not** receive extended pharmacological VTE prophylaxis:

- < 16 years old
- Pregnancy or breastfeeding (out with scope of this guidance document - discuss with consultant surgeon and seek advice from obstetrics in individual patient cases)
- Patients who are admitted to hospital on anticoagulation
- Platelets <75 x 10⁹/L
- Known hypersensitivity to LMWH and/or heparins
- History of immunologically mediated heparin induced thrombocytopenia (HIT)
- Severe uncontrolled hypertension
- Acute gastroduodenal ulcer
- Cerebral haemorrhage
- Known haemorrhagic diathesis or other active haemorrhage
- Serious coagulation disorders
- Acute or sub-acute septic endocarditis
- Haemorrhagic pericardial effusion and haemorrhagic pleural effusion
- Injuries to and operations on the central nervous system, eyes and ears
- Recent stroke (<3 months) unless due to systemic emboli

2.2 Cautions

Dalteparin should be used with caution⁵ in patients in whom there is an increased risk of bleeding complications, e.g. following surgery or trauma, haemorrhagic stroke, severe liver or renal failure, thrombocytopenia or defective platelet function, uncontrolled hypertension, hypertensive or diabetic retinopathy, patients receiving concurrent anticoagulant/antiplatelet agents.

3 Documentation

The decision to commence extended VTE prophylaxis could take place at any time in the patient pathway but should be recorded in the operation note as a minimum standard. This treatment option should be discussed with the patient as part of the pre-operative consent process (or post-operatively in the event of emergency admission or an unexpected surgical procedure).

Timely identification of a patient's eligibility for extended VTE prophylaxis allows ward nursing staff to train patients/carers in safe administration of dalteparin/UFH at the earliest opportunity. This helps patients/carers gain competence and confidence in correctly administering dalteparin/UFH and avoids delays in discharge.

The Prescription and Administration Record (PAR) should also be annotated to indicate if the patient is to receive extended VTE prophylaxis. Any decisions or changes relating to VTE prophylaxis should be documented in the patient's case notes.

The patient's GP should be notified via the Core Discharge Document (CDD) that the patient has been discharged with extended pharmacological VTE prophylaxis to administer at home.

4 Patient Advice and Counselling

Patients should receive information^{2,3} about VTE risk and how to reduce risk both during admission and on discharge from hospital.

Patients who are discharged with VTE prophylaxis must be given verbal and written information³ regarding:

- How to use VTE prophylaxis correctly (i.e. method of administration and disposal of pharmacological prophylaxis) and who to contact if they have problems using this. If patients or relatives/carers are unable to administer or use dalteparin/UFH correctly, alternative arrangement should be made for these individuals, e.g. district nurses administer instead.
- Signs and symptoms of adverse events related to VTE prophylaxis and what to do if these occur.
- The importance of continuing treatment for the recommended prescribed duration.

5 Method of Administration

Dalteparin should be injected into the abdominal subcutaneous tissue, or into the lateral part of the thigh once daily at the same time of day (typically in the evening). The site of administration should be rotated.

Patients should be supine (lying flat on back) and the total length of the needle should be introduced at a 90 degree angle into the thick part of a skin fold, produced by squeezing the skin between the thumb and forefinger; the skin fold should be held throughout the injection⁵.

6 Adverse Effects

Potential adverse effects^{5,6} associated with dalteparin include the following:

INCIDENCE	ADVERSE EFFECT
Common (≥1/100, <1/10)	Mild thrombocytopenia (type 1) Subcutaneous haematoma at the injection site Pain at the injection site Haemorrhage Transient elevation of transaminases
Uncommon (≥1/1000, <1/100)	Hypersensitivity Urticaria Pruritus
Rare (≥1/10 000)	Skin necrosis Transient alopecia Priapism Hyperkalaemia Osteoporosis (in long term treatment)
Not Known	Immunologically-mediated heparin-induced thrombocytopenia (type 2) Intracranial bleeds Anaphylactic reactions Prosthetic cardiac valve thrombosis Retroperitoneal bleeds Rash Hypoaldosteronism Spinal or epidural hematoma

Monitor for adverse effects and report any suspected adverse reactions to the MHRA via Yellow Card Scheme (www.mhra.gov.uk/yellowcard).

7 Interactions^{5,6,7,8}

The anticoagulant effect of dalteparin can be **enhanced** by antiplatelets, non-steroidal anti-inflammatory drugs (NSAIDs), other anticoagulants and by some antidepressants. If concomitant use is essential, risk of bleeding should be closely monitored.

Certain herbal medications and nutritional supplements can increase risk of bleeding and should be avoided while on 28 day extended courses of pharmacological VTE prophylaxis post operatively. Example agents include, but are not limited to, Chondroitin, Feverfew, Fish oils, Garlic, Ginger, Ginkgo, Ginseng, and Vitamin E^{9,10}.

Increased risk of hyperkalaemia should be considered when dalteparin is administered alongside other medicines known to increase potassium levels, i.e. NSAIDs, trimethoprim, Angiotensin-converting enzyme (ACE) inhibitors, Angiotensin II receptor blockers.

The anticoagulant effect of dalteparin can be **reduced**^{5,8} by antihistamines, cardiac glycosides, tetracycline, ascorbic acid, quinine, high dose penicillin and smoking. Through the clinical significance of such predicted interactions is unclear, International Normalised Ratio (INR) monitoring may be considered with concurrent use⁸.

For more information regarding potential drug interactions, please consult the British National Formulary (BNF), and Stockley's Drug Interactions available via www.medicinescomplete.com and NHS Grampian intranet page.

8 Supplying Dalteparin

Extended therapy should be prescribed on the CDD at the same dose as the inpatient stay to cover the remainder of the 28 post-operative days.

A supply of both 2500 unit/0.2mL and 5000 unit/0.2mL prefilled dalteparin injections are available as over-labelled medicines in the majority of the general surgical wards in Aberdeen Royal Infirmary (ARI). Dalteparin can be also be dispensed from ARI and Dr Gray's pharmacy.

Patients should be directed to the Patient Information Leaflet (PIL) contained within the supply of dalteparin and advised to read this thoroughly.

All patients receiving dalteparin for self or carer administration should also be provided with a sharps disposal bin at the same time as their supply of dalteparin. The dispensing pharmacy (or in the case of over-labelled stock the ward) must ensure that the patient has a blue lided sharps bin with a yellow body, is aware of how to use and store it and how to dispose of it (via community pharmacy) once their medication course is complete.

9 Monitoring Requirements and Precautions

9.1 Renal Impairment

Caution is required when using any LMWH in patients with any degree of renal impairment, especially severe renal impairment^{5,7}. These patients should be assessed on a case by case basis, with advice sought from consultant surgeon, renal and haematology teams as appropriate.

In the case of significant renal failure (eGFR <30mL/min), dalteparin should be avoided and use of unfractionated heparin (UFH) sodium should be considered alternatively at a dose of 5000 units subcutaneously 12 **hourly**. In high VTE risk patients, unfractionated heparin (UFH) sodium at a dose of 5000 units subcutaneously 8 **hourly** may be used.

For more information regarding UFH, please consult the BNF and Summary of Product Characteristics (SmPC) via www.medicines.org.uk.

9.2 Hepatic Impairment

Patients with severe chronic hepatic impairment (assessed by Child's Pugh score) may require dose adjustment of dalteparin and careful monitoring⁴.

In these circumstances, patients should be assessed on a case by case basis, with advice sought from consultant surgeon, and haematology team as appropriate.

9.3 Platelet Monitoring

Immune mediated heparin induced thrombocytopenia (HIT) may occur in a small proportion of patients, typically 5 - 10 days after starting treatment with LMWH or UFH¹¹. Risk of HIT is greater using UFH than LMWH.

Due to risk of HIT, all patients should have their platelets checked before initiating heparin and then regularly thereafter while an inpatient. Assuming that the platelet count is normal (range 150-400 x10⁹/l) on day of discharge **and** that the patient's platelets have not dropped by 30% or more from baseline, further monitoring of platelets when on dalteparin is not required in the absence of clinical indication. However, all patients receiving UFH require monitoring **every 3 days** up until prophylaxis is discontinued. It will be the responsibility of the secondary care team to communicate with the secondary care hub or the General Practice about organising this monitoring in the community before the point of discharge.

If thrombocytopenia (platelets <150 x 10⁹/l) develops or if platelet count drops by 30% or more and/or the patient develops new thrombosis or skin allergy¹¹, HIT should be considered. If HIT is confirmed/strongly suspected, stop heparin and seek advice from the on-call haematologist.

9.4 Potassium

LMWH can suppress adrenal secretion of aldosterone resulting in hyperkalaemia, particularly in those with diabetes mellitus, chronic renal failure, pre-existing metabolic acidosis, a raised plasma potassium and/or taking potassium sparing drugs⁵.

Plasma potassium should be measured in patients at risk before starting dalteparin therapy and monitored regularly while an inpatient. Assuming that the potassium level is normal at discharge, further monitoring of potassium is not required in the absence of clinical indication.

9.5 Porcine

LMWH and UFH are derived from porcine based heparin and if patients have concern regarding, or cannot receive an animal based medicine, FONDAPARINUX 2.5mg subcutaneously once daily, is porcine free and should be considered alternatively.

In these circumstances, patients should be assessed on a case by case basis, with advice sought from consultant surgeon, and haematology as appropriate.

For more information regarding fondaparinux, please consult the BNF and SmPC via www.medicines.org.uk.

9.6 Bleeding

If mild bleeding occurs, it is generally sufficient to discontinue LMWH or UFH as the half-life of both agents is short. In cases of excessive bleeding, stop LMWH/UFH and seek urgent advice from the on-call haematologist.

9.7 Antiplatelets

Aspirin or other antiplatelet agents are not considered adequate prophylaxis for VTE.

In most circumstances and where clinically appropriate, it is considered reasonable to continue aspirin alongside extended pharmacological thromboprophylaxis. Patients should be advised about increased risk of bleeding and what to do if this occurs.

In patients taking any other kind of antiplatelet drug (e.g. clopidogrel or ticagrelor), confirm the indication for therapy, and consider risk/benefit of withholding the antiplatelet and re-starting this on cessation of dalteparin. In these individual circumstances, patients should be assessed on a case by case basis, with advice sought from consultant surgeon, relevant speciality (depending on indication for antiplatelet) and haematology as appropriate.

9.8 Extremes of Body Weight

For the majority of patients, a standard dose of dalteparin provides adequate prophylaxis against VTE balanced against bleeding risk. In individuals who are very over or underweight, prescribe a prophylactic dose of dalteparin as per Body Mass Index (BMI). Please refer to the NHS Grampian Surgical Risk Assessment for Venous Thromboembolism (VTE)¹ for further information.

BMI < 30 kg/m² = 2500 units dalteparin once daily

BMI ≥ 30 kg/m² = 5000 units dalteparin once daily

10 Anti-embolism Stockings

There is no requirement to wear anti-embolism stockings on discharge in patients who are receiving extended VTE prophylaxis.

National guidance advises that for abdominal surgery, anti-embolism stockings need only be worn until the person no longer has significantly reduced mobility relative to their normal or anticipated mobility³.

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