

Guidelines for Venous Thromboprophylaxis for patients attending the Orthopaedic Trauma and Elective service

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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

Review date: **November 2024**

Changes made:

Updated guidance to include Enoxaparin as the LMWH of choice reflecting the change across the trust

KEY WORDS

Arthroplasty, Deep Venous Thrombosis, DVT, MSK, Musculoskeletal, Orthopaedics, PE, Prevention, Pulmonary embolism, THR, Thromboembolism, Thromboprophylaxis, TKR, Total Hip Replacement, Total Knee Replacement, Trauma Guideline, VTE.

1 INTRODUCTION

This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for Venous Thromboprophylaxis for patients attending the Orthopaedic Trauma and Elective service.

2 POLICY AIMS

To provide guidance for staff as regards the appropriate measures to be implemented to aid in the prevention of venous thrombosis in patients attending the Trauma and Orthopaedic unit at UHL NHS Trust.

3 POLICY SCOPE

This policy applies to all staff involved in the care of patients in the trauma and Orthopaedic unit of UHL NHS Trust, this includes day-case patients, inpatient elective and inpatient trauma patients.

4 DEFINITIONS

DVT: deep venous thrombosis, blood clot in the lower leg venous system.

PE: Pulmonary embolism, blood clot in the lungs, potentially fatal.

Thromboembolism: either of the above events

Thromboprophylaxis: measures taken to prevent DVT and PE.

5 ROLES AND RESPONSIBILITIES

- a) Executive lead will be the current MSK clinical director
- b) Guideline ratified by MSK consultant body and approved by CMG board
- c) This document applies to all staff within the MSK unit

6 POLICY STATEMENTS, STANDARDS, PROCEDURES AND ASSOCIATED DOCUMENTS

GUIDELINES FOR ALL PATIENTS ADMITTED TO THE ORTHOPAEDIC UNIT
(NB this does not apply to day-case patients- see below)

a) All patients to have documentation of risk assessment for thrombosis filed in the case notes or completed on the electronic prescribing system.

(Appendix 1).

This is now an integral part of the admission notes and the initial VTE assessment will be filled in by appropriately trained staff as part of the admission process, if risk factors are identified the responsible doctor will prescribe the appropriate thromboprophylaxis. Nursing staff will perform daily checks of stockings.

b) All patients to be given written information on blood clot recognition and prevention.

Copies of approved leaflet are available free from the print room and are available on all Orthopaedic wards, pre-assessment and fracture clinic.

c) All patients to be kept adequately hydrated.

Intravenous fluids should be prescribed if appropriate, especially where a patient is likely to be nil by mouth for a prolonged period of time. Otherwise, oral fluids should be encouraged by all staff.

d) All patients to be mobilised at the earliest opportunity.

Patients are encouraged to mobilise as early as possible and to perform regular leg exercises when confined to bed or chair.

e) Intra-operatively.

Where possible, regional anaesthetic techniques should be employed, and operative time kept to a minimum

f) Post operatively.

For those procedures of long duration or that are categorised as high risk, or for patients with risk factors LMWH should be given until discharge unless extended out of hospital thromboprophylaxis is warranted. Extended TP is warranted in the following circumstances:

- 1) Total hip replacement (see appropriate section)
- 2) Total knee replacement (see appropriate section)
- 3) Fractured neck of femur (see appropriate section)
- 4) Lower limb immobilisation where risk of VTE outweighs the risk of TP (see appropriate section)

Anti-embolism stockings:

All patients to have below knee Anti-embolism stockings AES (unless contra-indicated). **Exceptions** include Neck of Femur Fracture (NOF), THR and TKR patients (see separate sections below), patients having upper limb procedures where the total operative and anaesthetic time is less than 90 minutes and patients having local anaesthetic procedures where their usual mobility is not impaired post-operatively. To be worn until mobility is back to baseline or for up to 6 weeks post operatively.

Contra-indication to AES:

Severe peripheral vascular disease

Insensate leg (numbness) due to local anaesthesia block, neuropathy, diabetes etc

Cellulitis

Dermatitis

Massive oedema

Leg/foot ulcers

Gangrene

Fragile "tissue paper" skin

Severe Cardiac failure

Allergy to the material of manufacture

Major limb deformity preventing correct fit

Day Case Patients

- a) All patients to be given written information on blood clot recognition and prevention.
- b) All patients to be kept adequately hydrated.
- c) All patients to be mobilised at the earliest opportunity.

These patients generally have few risk factors and mostly undergo procedures of short duration that are low risk for thrombosis and therefore do not require routine thromboprophylaxis. An agreed list of upper limb and/or local anaesthetic procedures of short duration where patients mobilise fully post procedure are deemed so low risk for VTE that no routine VTE precautions are required.

HOWEVER it is the duty of the consultant in charge of the patient to decide if mechanical or chemical thromboprophylaxis is appropriate for individual patients who have risk factors or are undergoing high risk or prolonged surgery.

Transfer between trauma and elective units (or via versa)

When a patient is transferred between units the thromboprophylactic measures a patient is already on should continue unchanged unless the patients clinical condition or risk of thrombosis/bleeding has changed in which case they should be reviewed. LMWH should not be withheld pre-operatively unless within 12 hours of a procedure.

ON DISCHARGE/TRANSFER:

Ensure patient information leaflet is provided appropriately

If discharge is to patient's home- re-assess thrombosis risk and provide extended thromboprophylaxis if necessary.

If discharge is to another institution/ward/care home- document that ongoing thromboprophylaxis is or is not required (detail the length of course and agent needed if ongoing TP is required) and suggest re-assessment of VTE risk on arrival other institution/ward

TRAUMA UNIT

See above section- guidelines for all patients admitted to the Orthopaedic Unit

The following patients are classified as high risk for venous thrombosis and should be routinely given chemical thromboprophylaxis unless contra-indicated:

- a) Fractured neck of femur/proximal femur (also see below)
- b) Polytrauma
- c) Pathological fractures (unless bleeding tendency)
- d) PMH or strong FH (1st degree relative) of thrombo-embolic disease
- e) Pelvic and acetabular fractures
- f) Femoral shaft fractures
- g) Prolonged (>3 days) bed rest

Chemical thromboprophylaxis; Enoxaparin see Appendix A (press Alt + back arrow to return here from Appendix A)

To be continued until fully mobile or until discharge

Contraindications and warnings, LMWH.

Hyperkalaemia: LMWH can cause hypoaldosteronism, which may result in hyperkalaemia. Potassium should be monitored before and during treatment, particularly in patients at risk of high potassium e.g. renal impairment, ACE inhibitors, Angiotension II receptor blockers, potassium sparing diuretics etc.

Heparin induced thrombocytopenia (HIT): is a rare side effect of LMWH. HIT predisposes patients to an increased risk of VTE. Platelet count should be performed before treatment is started and during treatment. Thrombocytopenia usually occurs between the 5th and 14th day of treatment. If HIT is suspected, stop LMWH and refer urgently to local haematologist for further management. Seek specialist advice before further prescription of LMWH in patients with history of HIT.

Dosage may need to be reduced to lower the risk of haemorrhage due to drug accumulation in severe renal impairment, elderly patients, and patients with extremes of body weight.

Contraindications include:

- Major bleeding disorders including active peptic ulcer, severe liver disease, severe thrombocytopenia
- Acute haemorrhagic stroke
- Acute bacterial endocarditis
- Hypersensitivity to LMWH

Prescription of LMWH

Currently the LMWH of choice for UHL is Enoxaparin however alternative LMWH formulations may be considered in times of shortage or on the advice of pharmacy. Before prescribing LMWH a platelet count and CrCl should be obtained. Prescription should only occur if platelet count is $>75 \times 10^9/L$ and if CrCl is $<30 \text{ ml/min}$ a reduced dose as per appendix 1 should be used.

Monitoring of prophylactic dose LMWH

Current British Haematological Society guidance is that routine monitoring of platelet count in Orthopaedic patients receiving prophylactic dose LMWH is unnecessary.²²

Fractured Neck of Femur:

- 1) Enoxaparin as above continued for 35 days
- 2) Anti-embolism stockings (AES) are not required.**
- 3) Mechanical Thromboprophylaxis in theatre (Flow-Tron Boots) unless contra-indicated.

Spinal Injuries

As per the spinal protocol

Chemical thromboprophylaxis if appropriate only after discussion with a spinal consultant

Mechanical thromboprophylaxis to be routinely applied (AES or IPCD)

Fracture Clinic:

Patients attending fracture clinic with lower limb immobilisation (plaster casts, braces and external fixators) either de novo or as an outpatient should routinely be screened for VTE risk using the L-Trip scoring system (see appendix B). Most patients attending via the UHL Emergency Department will have already had this assessment however it should not be presumed that this had automatically occurred and the notes of each patient should be checked for compliance, if no assessment is identified a full VTE risk L-Trip assessment should be made.

Patients with lower limb immobilisation should be provided with the trust VTE leaflet to inform them of the risk of VTE and identify symptoms to look out for, the following patient categories should be offered **LMWH** thromboprophylaxis for 42 days:

- 1) L-Trip score of 9 or above
- 2) History of previous VTE
- 3) Achilles tendon rupture/equinus cast
- 4) Known thrombophilia

Patient information leaflets regarding risk vs benefit of LMWH prophylaxis are available in fracture clinic and should be given to each patient when offering LMWH.

ELECTIVE UNIT

See above section- guidelines for all patients admitted to the Orthopaedic Unit

1) Stop Warfarin 5 days pre surgery and follow “Warfarin Bridging Therapy for Elective Surgery” (document available via insite)

2) Stop NSAIDS/Clopidrogel/oral anticoagulants (if appropriate)

These are to be stopped 4 days pre-operatively or 7 days for Aspirin and Clopidrogel if it is considered the intended procedure is at high risk of bleeding (eg. THR/TKR, some spinal procedures). Clinical indications for these agents need to be considered and advice on peri-operative manipulation should be sought from the appropriate speciality (e.g. Cardiology in patients with drug eluting cardiac stents).

3) Stop Oestrogen containing oral contraceptive pills 4 weeks pre-operatively/either stop HRT or cover with LMWH

Progesterone only contraceptives (mini pill, implanted devices) do not need to be discontinued. Patients need to be warned to take other contraceptive measures. Currently HRT does not need to be stopped pre-operatively (it may be stopped 4 weeks prior to surgery) but if it is continued then LMWH should be given as TP.

4) At Operation:

- a) consider the use of inflatable boots or calf compression if AES are not applied
- b) remove anti-embolic stockings on operated leg only for TKR and operations on the lower leg. For THR- removal is at the discretion of the operating surgeon

5) Post Operation:

- a) reapply anti-embolic stocking at earliest opportunity if indicated
- b) follow chemical thromboprophylaxis policy as below

For operations considered moderate/high risk for thromboembolism (eg, combined anaesthetic and operative time>90 mins in lower limb surgery, prolonged upper limb surgery)

Enoxaparin SC once daily until discharge (NB remember extended TP in THR/TKR and fractured neck of femur).

(see appendix A)

Spinal Surgery:

All patients to be risk assessed and to have mechanical prophylaxis. Chemical prophylaxis at the discretion of the operating surgeon/consultant in charge.

Thromboprophylaxis for Total Hip replacement

THR: Enoxaparin s/c daily at 6pm on day of surgery, continued for 10 days then Aspirin 150mg once daily for 28 days. (see appendix A)

CONTRAINDICATIONS: aspirin

- known allergy
- age under 12 years (risk of Reye's syndrome)
- active peptic ulceration; history of recent gastrointestinal bleeding
- history of recent intracranial bleeding
- bleeding disorders including haemophilia, von Willebrand's disease, thrombocytopenia and severe liver disease.

CAUTIONS

- asthma;
- uncontrolled hypertension (risk of intracranial bleeding); and previous peptic ulceration

AES are not required with the above regime

Thromboprophylaxis for Total knee replacement

TKR: Aspirin 150mg PO once daily at 6pm on the day of surgery, continued for 14 days.

(see cautions and contra-indications above)

AES are not required with the above regime

Oral Contraceptive pill/HRT ⁽¹⁾

Current guidance from the Royal College of Obstetricians and Gynaecologists recommend stopping Oestrogen containing oral contraceptive pills 4 weeks before planned surgery. In the emergency situation chemical thromboprophylaxis should be given on admission and until fully mobile or until removal of lower leg casts.

Progestogen only pills (and most implanted contraceptives) do not appear to increase the risk of DVT and therefore do not need to be discontinued before surgery.

Hormone replacement therapy may increase the risks of thrombosis and the guidance here is either to stop HRT 4 weeks prior to surgery or, if it is continued, (there is no clear advice that it has to be stopped pre-op) then chemical thromboprophylaxis should be given.

Patients with prior history of VTE

Patients undergoing THR/TKR seek haematological advice.

All other patients/procedures: discuss individual circumstances with haematologist for peri-operative plan.

Patients taking Warfarin

NICE guidance and haematology advice recommend an INR of <1.5 as the safe level to proceed with surgery, the Warfarin bridging policy is available on Insite for those patients where it is deemed necessary to continue with some form of thromboprophylaxis. Although this is the general recommendation the actual decision to proceed with surgery rests with the operating surgeon and the Consultant in charge of the patient where the INR is above 1.5 (for example there are reports of TKR being

done in patients who are fully anticoagulated where the risks of stopping warfarin outweigh the risks of bleeding), advice from the Haematologist on call should be sought in such circumstances.

In the emergency situation advice can be obtained from the Haematologist on call and it may be appropriate to reverse the effects of Warfarin pre-operatively, again the aim should be to obtain an INR<1.5.

Patients taking “new” oral anticoagulants

In recent years oral anticoagulants acting on different parts of the clotting cascade have become available, the ones commonly in use are Rivaroxaban and Dabigatran but other agents are also appearing on the market (e.g. Apixaban). In general if it is appropriate to stop these agents pre-operatively (this decision will need to be made considering the risks/benefits for each individual patient) then it is recommended that before surgery is undertaken at least **3 half lives should have elapsed where the bleeding risk is standard and 5 half lives to have elapsed where the bleeding risk is high**. In the emergency situation and where bleeding is problematic (e.g. In the polytrauma patient) then advice on reversal of these agents should be sought from the Haematologist on call (activated charcoal and dialysis may be appropriate as well as specific “antidotes” such as FEIBA, Novoseven, Anti-IIa and Anti-Xa, Tranexamic acid can also be considered). The half-life for some agents is listed below:

Rivaroxaban: 7-11 hours

Dabigatran: 14-17 hours

In general therefore stopping these agents 4-5 days pre-operatively (if appropriate) should reduce the bleeding risk.

New unit guidelines specifically relating to NOAC management during surgery are available on Insite ref C10/2017

Inpatients with lower limb immobilisation:

For patients admitted to the unit either electively or via the trauma unit who will have lower limb immobilisation upon discharge an L-Trip VTE risk assessment (Appendix B) should be made before discharge to identify those patients who should be offered extended LMWH thromboprophylaxis for 42 days post application of cast, these will include:

- 1) L-Trip score of 9 or above
- 2) Achilles tendon surgery/equinus cast
- 3) Known thrombophilia
- 4) Previous history of VTE

L-Trip scoring sheets are available in the following formats:

Trauma unit:

Printed in the admission booklet and consultant ward round sheet to be filled in during the “A or B” consultant ward round process in those patients who will be discharged with some form of lower limb immobilisation.

Elective unit:

Available through pre-assessment clinics, in theatres 9 A and B and via ward clerks on elective inpatient wards.

Extended (out of hospital) Thromboprophylaxis:

Extended TP is warranted in the following circumstances:

- 1) Total hip replacement (see appropriate section)
- 2) Total knee replacement (see appropriate section)
- 3) Fractured neck of femur (see appropriate section)
- 4) Lower limb immobilisation where risk of VTE outweighs the risk of TP (see appropriate section)

7 EDUCATION AND TRAINING REQUIREMENTS

There are no new skills required to implement the policy. However, TP is an integral part of the junior doctor induction teaching and is therefore already embedded in their training.

8 PROCESS FOR MONITORING COMPLIANCE

Monitoring of all HAT (hospital acquired thrombosis) is routinely carried out as part of the trusts RCA process

Regular monitoring (usually annual) of the unit VTE rates for THR/TKR

The department routinely participates in the UHL Trust wide TP audit

9 EQUALITY IMPACT ASSESSMENT

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

10 LEGAL LIABILITY

See section 6.4 of the UHL Policy for Policies for details of the Trust Legal Liability statement for Policy documents

11 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

Thromboembolic (TE) complications following Orthopaedic procedures are a cause for concern amongst Orthopaedic surgeons. Without prophylaxis (TP) the rate of radiological proven DVT following Total Hip and Knee Replacements is estimated to be 32-44% for THR and 60-66% for TKR. It must be noted however that these are radiological proven VTE and do not necessarily equate with clinically important events, the incidences of clinically important events has been substantially revised (see section below- ACCP guidelines), non-fatal pulmonary embolism 1.2-3% and 1-1.9% and fatal PE 0.3% and 0.4% respectively (2,3). Approximately 10% of pulmonary embolisms are fatal and in the long term non-fatal PE can lead to pulmonary hypertension (4). The incidence of post phlebotic limb following DVT after THR/TKR is not known and debate continues as to whether this is higher than the natural incidence in the general population (5).

It is generally accepted that prophylaxis reduces the risk of DVT (2,6) however no data exists regarding PE or death, in this respect low molecular weight heparins (LMWH)

have been shown to have superior efficacy to most other agents and are currently the agent of choice according to NICE. Although most agents that are available for the prevention of VTE (aspirin, warfarin etc) either their difficulty of use or their inferior performance make them less attractive (2,6) although recent NICE guidance (march 2018) has recognised the use of Aspirin in THR and TKR. Due to the rarity of death from PE surrogate endpoints have to be used to reflect such reductions, the assumption made is that by reducing the incidence of DVT this leads to a reduction in the incidence of PE. A study to show a significant reduction in the incidence of fatal PE would require 100,000 patients and is not a practical proposition in the real world.

Mechanical prophylaxis has been shown to be effective both in isolation and in combination with chemical TP in reducing VTE although often the studies supporting this are of poor quality or use surrogate end points. Generally, it is felt they have minimal risks attached (3,7). However, NICE has now withdrawn its advice in Fractured NOF patients, as well as THR and TKR patients, and we feel in this group of patients, the use of Anti-embolism stockings (AES) is not required.

Offset against the use of prophylaxis is the potential risks of adverse events, the main one being the risk of bleeding either from the surgical site or elsewhere. It is estimated that the risk of a major bleeding events is up to 2% with LMWH in THR and 1% in TKR (3) and that overall all-cause mortality is unchanged or reduced with prophylaxis (2,3). Heparin induced Thrombocytopenia (HIT) is also a concern although recent recommendations have downgraded the risk of this in Orthopaedic patients.

Even those individuals who remain unconvinced of the need for TP concede that high risk procedures such as hip fracture and major trauma should receive TP as the risks of thrombo-embolism outweigh the potential adverse effects such as bleeding (3). In their view THR and TKR can be considered moderate risk for VTE and decisions on TP should be made on an individual basis- if risk factors are present then the balance of evidence favours TP (the majority of patients will be over 60years old and therefore have a "significant" risk factor).

The time course of TE events has been documented from the global orthopaedic registry which analysed 6639 THR and 8326 TKR patients. The cumulative incidence of TE was 1.7% and 2.3% respectively, the mean time to development of TE was 21.5days for THR and 9.7days for TKR, therefore TE occurred after discharge from hospital in 75% of THR patients and 57% of TKR patients. (5)

Current Guidelines

NICE recommendations, revised 2018 (ref 2):

Nice bases its current guidance on the incidence of major VTE of:

THR: DVT 44%, PE 3%, Mortality 0.7%

TKR: DVT 60%, PE 1%, Mortality unknown

All patients to be risk assessed and given written information re: blood clots

Early mobilisation

Chemical prophylaxis with the use of fondaparinux sodium, LMWH or unfractionated heparin (UH)

Mechanical methods (not required for NOF/THR/TKR patients with certain regimes)

For THR: Dabigatran, Rivaroxaban, Fondaparinux, LMWH for 28 days or LMWH 10 days followed by Aspirin for 28 days.

For TKR: as above for 10-14 days or Aspirin for 14 days
 For #NOF: fondaparinux, LMWH or UH for 28-35 days
 For major trauma: decide if TP is appropriate then fondaparinux, LMWH or UH until the patient is no longer significantly immobile
 For plaster immobilisation: if patient at high risk then fondaparinux, LMWH or UH until cast removal or 42 days

American College of Chest Physicians 2012 (ref 9):

After revising their previous recommendations the ACCP now concede that the following rates of VTE apply for Total Joint Arthroplasty:

	Initial Prophylaxis, Postoperative Days 0-14	Extended Prophylaxis, Postoperative Days 15-35	Cumulative, Postoperative Days 0-35
No prophylaxis	VTE 2.80% (PE 1.00%, DVT 1.80%)	VTE 1.50% (PE 0.50%, DVT 1.00%)	VTE 4.3% (PE 1.50%, DVT 2.80%)
LMWH	VTE 1.15% (PE 0.35%, DVT 0.80%)	VTE 0.65% (PE 0.20%, DVT 0.45%)	VTE 1.8% (PE 0.55%, DVT 1.25%)

They recommend the use of LMWH as the best agent for TJA however acceptable alternatives include fondaparinux, apixaban, dabigatran, rivaroxaban, LDUH, adjusted-dose VKA, or aspirin.

American Academy of Orthopaedic surgeons (ref 10):

The AOA recommend the use of chemical TP in TJA however they are unable to recommend any particular regime as superior and are likewise unable to recommend the duration of prophylaxis.

British Hip Society (ref 11):

The BHS unanimously passed the motion endorsing the use of Aspirin as adequate protection against VTE.

A very recent study highlighted the use of Aspirin for extended TP in over 11,000 arthroplasty patients and concluded that Aspirin was a safe and effective method of prophylaxis (21).

Rivaroxaban and Dabigatran- new oral agents recommended by NICE.

Recently, new orally active agents (e.g., Rivaroxaban, Dabigatran) have been introduced for the prevention of TE after THR and TKR. They are both licensed for use in this respect, and both have been ratified by NICE. Whilst Dabigatran has been shown to be as effective as LMWH in reducing the incidence of TE after THR/TKR it is not superior to LMWH in this respect (12,13). Rivaroxaban however has been shown to be superior to LMWH in preventing TE (14,15,16,17) however there are concerns regarding surgical bleeding and the incidence and definition of major bleeding in some studies (17).

Compliance with NICE- Problems with Dabigatran- the experience in Leicester

Following the publication of the NICE guidelines in 2009 there was great initial enthusiasm to introduce these agents in TJA in Leicester. Dabigatran was chosen as the agent of choice in arthroplasty patients as much debate was prevalent at the time regarding Rivaroxaban which appeared to be associated with increased wound problems post operatively. The unit began the use of Dabigatran in December 2010. Immediately problems became apparent, an increase in the post operative wound leakage rate from 5% to 20% occurred and a rise in post operative surgical site infections from 8.83% to 9.63% was also noted. In addition, there were concerns raised regarding the frequency of gastro-intestinal bleeds (18,19). In the interests of patient safety, the use of Dabigatran was discontinued in May 2011. Following the adoption of the current TP policy a re-audit was carried out which confirmed the wound leak rate had reduced to 5%. (18)

This was recently published in a peer reviewed journal (20).

VTE rates in the unit

To ensure patient safety has been maintained a review of the 90 day HAT (hospital acquired thrombosis) rate was carried out with comparison between three different regimes, these are detailed below (20) for THR and TKR:

THR	Major VTE	PE	AK DVT	BK DVT
LMWH IP only	2.2%	1.1%	1.1%	0.5%
LMWH + Aspirin	0.6%	0.6%	0%	0%
TKR	Major VTE	PE	AK DVT	BK DVT
LMWH IP only	0.8%	0.3%	0.5%	0%
LMWH + Aspirin	0%	0%	0%	0%
Dabigatran	Major VTE	PE	AK DVT	BK DVT
THR	0.7%	0.5%	0.2%	0%
TKR	0.8%	0.4%	0.4%	0.7%

It can be seen therefore that local VTE rates are very low and are well within guideline values suggested by ACCP (VTE rates of 2.1-2.8% at 90 days). We follow a multi-modal regime with pre-operative, intra-operative and post operative measures all designed to reduce VTE. This has been very successful in keeping VTE rates low. In April 2019 the unit changed policy for THR and TKR to institute new NICE guidance and the unit is now NICE compliant

Monitoring:

The UHL Thrombosis Committee continues to monitor all VTE events to determine whether they are hospital acquired (HAT) through the RCA process, trends in the rate of HAT is closely observed and actions taken as necessary.

Root cause analysis (RCA) is undertaken on all HATs and results discussed at the Departmental Morbidity and Mortality meetings. Performance with risk assessment is

assessed every month and fed back to the thrombosis lead and head of service for orthopaedics for dissemination and further action as necessary.
Monthly nursing metrics assesses performance with risk assessment, use of LMWH and supply of patient information.
Updates are discussed at the departmental management meeting.

Summary:

NICE now supports the use of Aspirin for the prevention of VTE and this has been approved by the British Hip Society, The AAOS and the ACCP. The unit is now fully NICE compliant.

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Historical Orthopaedic department position on patients with lower limb immobilisation

As a unit we have carefully considered our position on giving patients extended thromboprophylaxis (TP) against blood clots (deep venous thrombosis, “DVT” or pulmonary embolism, “PE”) to those individuals with lower limb immobilisation.

We would agree that there is evidence supporting the use of TP in high-risk individuals and would recommend its use routinely in the following situations until the immobilisation is removed:

Those with a prior history of VTE (Venous Thrombo-Embolic- either DVT or PE)
Those with known thrombophilia or a strong positive family history of VTE
Achilles tendon rupture

We do not agree that routine extended TP is warranted in the remainder of patients unless their individual circumstances strongly support its use.

We have based this decision on a number of factors:

- 1) The incidence of VTE in patients with lower limb immobilisation
- 2) Review of the scientific evidence regarding the effectiveness of TP
- 3) Review of the evidence of harm from TP
- 4) Review of data from our own department
- 5) National practice
- 6) National and international guidance

The incidence of VTE in patients with lower limb immobilisation

A review of the NHS database looking at elective and trauma cases of **88,241** patients showed rates of **0.12% DVT**, **0.17% PE**, and 0.37% mortality after ankle fracture. For hindfoot fusions the rates were **0.03% DVT**, **0.11% PE** and 0.11% mortality. The authors of this paper state “there is no evidence that thromboprophylaxis reduces this risk, and these national data suggest that prophylaxis is not required in most of these patients”¹

Other studies have also found that the rate of CIVTE after lower limb immobilisation is low:

Author	Rate	Patient numbers
Jameson ¹	0.22%	88,241
Dyall ²	1.1%	2,155
Selby ³	1.9%	265
Wukich ⁴	0.7%	1,000
Calder ⁵	0.6-1%	43,281
Griffiths ⁶	0.42%	2,564
Shibuya ⁷	0.49%	75,664

Conclusion: The rate of VTE after foot and ankle surgery/trauma is low and we do not feel that the risks of TP outweigh the risks of VTE in the vast majority of patients.

Review of the scientific evidence regarding the effectiveness of TP

Level 1 evidence (randomized controlled trials):

Author	year	Patient numbers	agent	Outcome measure	Quality of study	Recommendation
Van Adrichmen ⁸	2017	1,435	LMWH*	CIVTE [#]	excellent	No TP
Selby ³	2015	280	LMWH	CIVTE	excellent	No TP
Goel ⁹	2009	238	LMWH	CIVTE + venography	good	No TP
Lapidus ¹⁰	2007	272	LMWH	venography	good	No TP
Lassen ¹¹	2002	371		venography	good	LMWH
Jorgensen ¹²	2002	300	LMWH	venography	intermediate	No TP
Kock ¹³	1995	339	LMWH	venography	poor	LMWH
Kujath ¹⁴	1993	252	LMWH	venography	poor	LMWH

*LMWH- low molecular weight heparin

[#]CIVTE- clinically important VTE, ie symptomatic VTE or pe/DVT popliteal or above

Level 2 evidence (meta-analysis):

Author	year	Papers analysed	Patient numbers	recommendation	
Calder ⁵	2016	cdefgh+	43,381	No TP	
Patterson ¹⁵	2017	bcdef	1,181	No TP	
ACCP ¹⁶	2010	defgh	1,490	No TP	
Ettema ¹⁷	2008	defgh	1,456	LMWH	
Testroote ¹⁸	2008	defgh	1,490	LMWH	

Conclusion: There is no evidence that the incidence of clinically important VTE (CIVTE) events can be reduced with the use of TP.

There is no evidence that PE or death from VTE can be reduced with TP.¹⁹

A further observational study involving 1,540 patients who had had ankle fracture surgery and post-operative plaster immobilisation showed no difference in the VTE rate either with or without VTE TP.²⁰

Whilst there is evidence that the incidence of DVT in screened populations (either venography or ultrasound) is higher than CIVTE evidence from extensive research in VTE following total hip or knee replacement has shown that the majority of these VTE events are not clinically important and do not appear to lead to significant consequences. There are concerns amongst Orthopaedic surgeons that there is overtreatment of patients leading to increased side effects from potent anticoagulants.^{21,22}

Review of the evidence of harm from TP

Increased mortality:

A study in 2009 looking involving 25,000 patients showed that since the increased use of potent anticoagulants (LMWH) all-cause mortality following total joint replacement has increased in the US^{21,23} however there has been no further reduction in the rate of PE or fatal PE. This trend has also been seen in the UK.²⁴

Bleeding risk of LMWH TP:

Record 1-4 trials in **6,000** hip replacement patients using LMWH TP:²⁵

Major bleeding risk:	0.21%
Major bleeding including surgical site with LMWH:	1.37%
Clinically relevant non major bleeding:	2.34%
Any bleeding:	6.20%

RENOVATE Trials, LMWH in THR **1154** patients:²⁶

Major bleeding:	1.6%
Clinically relevant non-major bleeding:	3.5%
Minor bleeding:	6.4%

NICE analysis (major bleeding):¹⁹ 1.6-1.9% Orthopaedic surgery
0.4% medical patients

Other large studies in Orthopaedic patients: 2% adverse effect rate
(**219,602** patients)²¹

Heparin induced thrombocytopenia with LMWH TP:

Orthopaedic patients: 0.5% (NICE cg92)¹⁹
0.11-0.16%²¹

Mortality associated with HIT: 10-20%^{19,21}
Mortality rate from HIT: 0.02-0.04%

Conclusion 1: All-cause mortality is higher with the use of LMWH

Conclusion 2: Risk of major bleeding event with LMWH is approximately 1.5%

Conclusion 3: Mortality risk HIT is at least (if not greater than) the risk of death from VTE

Review of data from our own department

In 2012 we analysed the data of 2155 patients who had received a lower limb plaster cast and found that the incidence of DVT was 0.65% and PE was 0.28%, additionally 42% of these patients had no identifiable risk factor suggesting that even in patients with risk factors present there was little increased risk compared to those with no risk factors.²

Conclusion: The use of routine extended TP does not appear to be warranted when taking the risks of TP into account.

National practice

A survey carried out in 2012 looking at current UK hospital practice regarding extended (out of hospital) TP concluded that 84% of hospitals did not offer routine TP to patients with lower limb immobilisation. Our policy therefore was in accordance with the vast majority of hospitals in the UK.²⁷

Conclusion: Routine practice in the UK is not to offer extended TP to patients with lower limb immobilisation.

National and international guidance

British Orthopaedic Foot and Ankle Society: Guidelines for Venous Thromboembolism Prophylaxis. Scientific Committee British Orthopaedic Foot & Ankle Surgery Society

“Prolonged immobilisation: There is little evidence to show that prolonged immobilisation, in a below knee plaster or splint, in the absence of patient related risk factors merits the use of chemoprophylaxis.”

NICE Guidelines. Venous thromboembolism: reducing the risk CG 92 2010:

1.6.3 “Consider* offering pharmacological VTE prophylaxis to patients with lower limb plaster casts after evaluating the risks and benefits based on clinical discussion with the patient. Offer LMWH (or UFH for patients with severe renal impairment or established renal failure) until lower limb plaster cast removal.”

* NICE uses 'consider' to reflect a recommendation for which the evidence of benefit is less certain.

“We cannot say definitively that the benefits outweigh the harms since the mortality rate is too low to make a conclusion about all-cause mortality. The data on pulmonary embolism and major bleeding were very sparse.”

Scottish Intercollegiate Guidelines Network. Prevention and management of venous thromboembolism: A national clinical guideline²⁷

“The evidence for, and efficacy of, pharmacological thromboprophylaxis for more minor orthopaedic procedures is weak. A small, placebo-controlled, randomised trial revealed a high incidence of, mainly distal, DVT detected by screening after surgery and immobilisation for Achilles tendon rupture, with no reduction in DVT events with prophylactic LMWH for six weeks. A similar result was found in a study of surgery for ankle fracture.”

American College of Foot and Ankle Surgeons' clinical consensus statement: risk, prevention, and diagnosis of venous thromboembolism disease in foot and ankle surgery and injuries requiring immobilization.²⁸

“A panel composed of all authors of this document reviewed the published evidence and, through a series of meetings, reached consensus regarding the viewpoints contained herein. We conclude that routine chemical prophylaxis is not warranted; rather, patients should be stratified and have a prevention plan tailored to their individual risk level.”

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Prevention of VTE in Orthopedic Surgery Patients.¹⁶

3.0. We suggest no prophylaxis rather than pharmacologic thromboprophylaxis in patients with isolated lower-leg injuries requiring leg immobilization(Grade 2C)

Conclusion: The majority of guidance for extended TP in patients with lower limb immobilisation from recognised expert bodies both nationally and internationally does not support the routine use of extended TP in these patients.

Overall conclusions and review of evidence and guidelines:

We feel that there is insufficient evidence to support the routine use of extended TP in the majority of patients with lower limb immobilisation. Furthermore the available evidence suggests that there is a risk of a significant side effect from TP that is as large as, if not larger than, the risks from VTE. On the balance of probabilities and weighing up the risks vs benefits we do not recommend the use of extended TP. This position is supported by a number of national and international bodies.

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12 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

This document will be uploaded onto SharePoint and available for access by Staff through INsite. It will be stored and archived through this system.

POLICY MONITORING TABLE

The top row of the table provides information and descriptors and is to be removed in the final version of the document

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Lead(s) for acting on recommendations	Change in practice and lessons to be shared
Unit VTE rates	A. Best	RCA process Regular review of VTE rates following THR/TKR	RCA routinely carried out by thrombosis nurse Yearly review of THR/TKR VTE rates(Usually April)	Thrombosis committee (RCA process) Thrombosis nurse Individual consultants (part of RCA process) Unit leads	MSK consultant body	No proposed change in practice- updating of guidelines

CHECKLIST FOR THE REVIEW AND APPROVAL OF P&G DOCUMENTS

Title of P&G Document Being Reviewed:		No	Comments
Checklist for the Review and Approval of P&G Documents			
1.	Title and Format		
	Is the title clear and unambiguous?	Yes	
	Is type of document clear (e.g. policy, guideline, procedure)	Yes	
	Does the document follow UHL template format? <i>If no document will be returned to author</i>	Yes	
3.	Development Process		
	Are the reasons for developing described (usually as part of introduction)	Yes	Existing guideline. Now updated to correct format
4.	P&G Content		
	Does the P&G have an introduction and aims?	Yes	
	Is the P&G scope clear?	Yes	
	Does the P&G set out clear roles and responsibilities?	Yes	
	Are P&G Statements/Standards clear and easy to follow?	Yes	
5.	Associated policies and supporting references		
	Are associated policies listed and key references clearly cited?	Yes	
6.	Consultation and Endorsement		
	Has there been appropriate consultation? (see the consultation proforma)	Yes	
	Does the Document identify which who has endorsed it?	Yes	
7.	Dissemination and Implementation		
	Has the dissemination plan been completed? (see Admin Proforma)	yes	
	Have all implementation issues been addressed?	yes	None required
8.	Equality and Benefits Realisation		
	Has an Equality Impact Assessment Screening Tool been completed?	yes	
	Have potential costs / benefits been considered or anticipated outcomes described?	yes	
9.	Process to Monitor Compliance		
	Are there measurable outcomes / key indicators to support the monitoring of compliance?	yes	
	Is there a plan to audit compliance with the document?	yes	Irregular departmental audits and yearly UHL wide audit RCA process UHL VTE assessment rates reported monthly
	Have audit timescales and audit lead been identified?	yes	
10.	Document Control, Archiving and Review		
	Have details regarding document control and archiving been provided?	yes	
	Is the review date and reviewer identified?	yes	
	If reviewed document, are changes identified or is there a statement that no changes required and 'fit for purpose'?	yes	
11.	Overall Responsibility for the Document	MSS Board	
	Is it clear who is responsible for co-ordinating the dissemination, implementation?		

INITIAL EQUALITY IMPACT ASSESSMENT TOOL

Pro-forma for the Initial Assessment

Name of Policy / guidance Document : Guidelines for Venous Thromboprophylaxis for patients attending the Orthopaedic Trauma and Elective service

.....

To be completed and attached to any procedural document (e.g., policies, guidance notes, etc) when submitted to the appropriate committee for consideration and approval.

An Equality Impact Assessment must always be carried out when there is a proposal to develop or change a function, e.g., Service Development within the Organisation.

		Comments	
1.	What is the purpose of the proposal/ Policy	Protection of patients from blood clots	
2.	Could the proposal be of public concern?	Indirectly, it relates to providing optimum patient care	
3.	Who is intended to benefit from the proposal and in what way?	Patients- prevention of Blood Clots	
4.	What outcomes are wanted for the proposal?	Clear guidance to clinical staff	
		Yes/No	Comments
5.	Is there a possibility that the outcomes may affect one group less or more favourably than another on the basis of:		
	• Race	no	
	• Ethnic origins (including gypsies and travellers)	no	
	• Nationality	no	
	• Gender	no	
	• Culture	no	
	• Religion or belief	no	
	• Sexual orientation including lesbian, gay and transsexual people	no	
	• Age	no	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	no	
6.	Is there any evidence that some groups are affected differently?	no	Policy is individualised according to recognised risk factors but does not discriminate
7.	If you have identified that some groups may be	no	Nice Guidance available

		Comments	
	affected differently is the impact justified E.g. by Legislation: National guidelines that require the Trust to have a policy, or to change its practice.		
8.	Is the impact of the proposal / policy likely to be negative?	no	
9.	If so can the impact be avoided?	N/A	
10.	What alternatives are there to achieving the proposal/ policy without the impact?	N/A	
11.	Can we reduce the impact by taking different action?	N/A	

If you have identified a potential discriminatory impact; please ensure that you do a Full Impact Assessment.

Initial Assessment completed by:

Name:	A. Best
Signed:	
Date:	01/6/2024
Contact number:	0116 2584721

If you require further advice please contact Service Equality Manager on 0116 2584382.

POLICY AND GUIDANCE CONSULTATION PROFORMA

(To be completed and attached to Policy and Guidance documents when submitted to the UHL Policy & Guidelines Committee)

Elements of the Policy or Guidance Document to be considered (this could be at either directorate or corporate level or both)	Implications (Yes/No)	Local or Corporate	Consulted (Yes/No)	Agree with P/G content (Yes/No)	Any Issues (Yes / No)	Comments / Plans to Address
Education (ie training implications)	yes	local			no	Available on Insite, already presented at each junior doctor induction
Corporate & Legal						
Clinical Risk	yes				no	Practice is based on NICE guidance and best available evidence
Health & Safety	no					
Manual Handling	no					
Legal Issues	yes				no	Practice is based on NICE guidance and best available evidence. Ratified by Thrombosis Committee
IM&T (ie IT requirements)	no					
Infection Prevention and Control	no					
Human Resources	no					
Operations (ie operational implications)	yes				no	Already embedded as routine practice
Facilities (ie environmental implications)	no					
Finance (ie cost implications)	no					
Staff Side (where applicable)	no					
Patients/Carers (where appropriate)	yes				no	Already embedded as routine practice
Relevant CBUs or Divisions:						
MSK	yes				no	Already embedded as routine practice
Committee or Group (ie Directorate Board) that has formally reviewed the Policy or Guidance document			Date reviewed		Outcome / Decision	
MSS board NOF MDT Group			Dec 2024 Nov 2024		New guidelines ratified and implemented	
Lead Officer(s) (Name and Job Title)			Contact Details			
Nichols, J, Consultant			0116 2585353			
Reviewer			Contact Details		Review Date	
J Nichols, Orthopaedic Consultant, NOF Lead			As above		Nov 2024	
Please advise of other policies or guidelines that cover the same topic area:						
Title of Policy or Guideline:						
Existing policy in use since October 2012 but in wrong format. This document puts the policy in the correct format						

POLICY AND GUIDANCE ADMIN PROFORMA

(To be completed and attached to Policy and Guidance documents when submitted to the UHL Policy & Guidelines Committee)

Title of Policy / Guideline:	Guidelines for Venous Thromboprophylaxis for patients attending the Orthopaedic Trauma and Elective service
Policy / Guideline Lead:	A Best
Date for P&G Review:	Nov 2027


IMPLEMENTATION	
Please advise how any implications around implementation have been addressed:	
Financial	Policy already in place- no implications
Training	Policy already in place- no implications
Benefits realisation	Compliance with NICE guidance. Reduction in costs of detecting and treating Venous thromboembolism









REVIEW OF PREVIOUS P&G DOCUMENT	
Previous P&G already being used? Yes	Trust Ref No: C10/2013
If yes, Title: Guidelines for Venous Thromboprophylaxis for patients attending the Orthopaedic Trauma and Elective service	SharePoint No:
Changes made to P&G? Yes- highlighted	If yes, are these explicit Yes If no, is P&G still 'fit for purpose?' Yes
Supporting Evidence Reviewed? Yes	Supporting Evidence still current? Yes

VERSION CONTROL AND ARCHIVING
Where will previous versions be archived? UHL harddrive
Proposed action to retrieve expired paper copies of P&G: not required

DISSEMINATION PLAN			
Date Finalised:	Dec 2024		
To be disseminated to:	MSS board then PAGL	Paper or Electronic?	Electronic

CATEGORY 'C' POLICIES OR GUIDELINES ONLY	
Divisional/CBU Approval Process:	
Approving Group / Committee:	
Any comments?	
Date of Approval:	

<p>University Hospitals of Leicester  NHS Trust</p> <p>To be used in conjunction with the VTE risk assessment pathway</p>	<h2 style="text-align: center;">Thromboprophylaxis ADMINISTRATION GUIDE Enoxaparin (Inhixa®)</h2>
<p>Some of the doses below are off label and differ from the SPC. As this is the recommendation from UHL, prescribers will be protected by UHL vicarious liability</p>	<p>Enoxaparin dosage for Adult, non-pregnant, non-orthopaedic (see specific guidelines) patients deemed to be at risk of thrombosis (medical/surgical)</p>

	Renal Function	
Bodyweight	CrCl ≥30ml/min	CrCl <30ml/min
<50kg	20mg OD 	20mg OD 
50-100kg	40mg OD 	20mg OD 
>100-150	40mg BD 	40mg OD 
>150kg	60mg BD 	40mg OD 
CrCl <15ml/min Monitor heparin assay on Day 4 and every 4 days to ensure there is no accumulation. Aim for peak levels <0.3iu/ml		

