Assessment & treatment of patients with suspected/confirmed deep vein thrombosis (DVT) in an ambulatory setting

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<tr>
<th>Approved By:</th>
<th>Emergency &amp; Specialist Medicine CMG</th>
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<td>Date Approved:</td>
<td>20th August 2014</td>
</tr>
<tr>
<td>Trust Reference:</td>
<td>C36/2014</td>
</tr>
<tr>
<td>Version:</td>
<td>V6July 2013</td>
</tr>
<tr>
<td>Supersedes:</td>
<td>V5 May 2010</td>
</tr>
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<td>Sept 2016</td>
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</table>
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction</td>
<td>3</td>
</tr>
<tr>
<td>2. Policy Aims/Statement of Intent</td>
<td>3</td>
</tr>
<tr>
<td>3. Policy Scope</td>
<td>3</td>
</tr>
<tr>
<td>4. Definitions</td>
<td>3</td>
</tr>
<tr>
<td>5. Roles and Responsibilities</td>
<td>3, 4</td>
</tr>
<tr>
<td>6. Policy Statements and Procedures</td>
<td>5-15</td>
</tr>
<tr>
<td>7. References</td>
<td>16</td>
</tr>
<tr>
<td>8. Appendix 1 – nurse led discharge</td>
<td>17</td>
</tr>
<tr>
<td>9. Appendix 2 – outpatient treatment</td>
<td>18</td>
</tr>
<tr>
<td>10. Appendix 3 – anticoagulation (warfarin and heparin)</td>
<td>19-24</td>
</tr>
<tr>
<td>11. Appendix 4 – anticoagulation (rivaroxaban)</td>
<td>25-26</td>
</tr>
<tr>
<td>12. Appendix 5 – malignancy screening questions</td>
<td>27</td>
</tr>
<tr>
<td>13. Appendix 6 - thrombophlebitis</td>
<td>28, 29</td>
</tr>
<tr>
<td>14. Appendix 7 – free floating thrombus</td>
<td>29</td>
</tr>
<tr>
<td>15. Appendix 8 – calf muscle vein thrombosis</td>
<td>30</td>
</tr>
<tr>
<td>16. Appendix 9 - UHL Initiation Pack for Rivaroxaban in the Treatment of first Deep Vein Thrombosis (DVT) and the prevention of recurrent DVT and PE.</td>
<td>31</td>
</tr>
</tbody>
</table>
1 Introduction

1.1 This document sets out the University Hospitals of Leicester (UHL) NHS Trusts Policy and Procedures for the investigation and treatment of suspected or confirmed deep vein thrombosis (DVT) in an ambulatory (outpatient) setting.

2 Policy Aims / Statement of Intent

2.1 The aim of this document is to:

a) Define the inclusion/exclusion criteria for the investigation and treatment of deep vein thrombosis as an outpatient.

b) Outline the assessments and investigations to be undertaken for suspected deep vein thrombosis.

c) Describe the treatment and follow up for patients with confirmed deep vein thrombosis, managed in an ambulatory setting.

3 Policy Scope

3.1 This policy applies to adult patients with suspected or confirmed DVT who meet the criteria to be investigated/treated in an outpatient setting. It does not include patients who are pregnant or less than 8 days postpartum, who should be managed by the obstetric team. It does not apply to patients on renal replacement therapy or those with eGFR<20.

4 Definitions

Ambulatory care – care delivered in an outpatient setting.

5 Roles and Responsibilities

All clinical staff within UHL that are involved in the management of the Ambulatory DVT clinic need to be aware of this policy and ensure the guidelines are followed.

5.1 Responsibilities within the organisation

Ambulatory treatment of DVT is initially the responsibility of the ambulatory DVT service which is in the Emergency and Specialist Medicine CMG. Responsibilities of the team whilst the patient is undergoing treatment include the following:

- Administration of outpatient care programme
- Commencement and control of anticoagulant therapy
- Liaison with community agencies (appendix 3 p.19-23)
- Patient information and education including advice and phone numbers if worsening symptoms
- Referral for thrombophilia testing where appropriate: see UHL Thrombosis and Haemophilia guideline DMS No 17261

Prescription of LMWH and oral anticoagulants is the responsibility of the medical team on AMU or bed bureau clinic, or the Specialist ambulatory DVT nurse prescriber at the time of diagnosis.

The clinical lead of the ambulatory DVT service is Dr Jane Strong, consultant haematologist. She will retain overall clinical responsibility for the patients who have been diagnosed as having a deep vein thrombosis.
Urgent clinical problems in Dr Strong’s absence are the responsibility of the on call medical team. The Haemostasis and thrombosis team will deal with specific haematological queries.

Haemostasis & thrombosis referrals:

- All patients requiring thrombophilia screens or with known thrombophilic defects – see Haematology - Thrombosis and Haemophilia Investigation Guidelines DMS No 17261

All other DVT patients (i.e. those not requiring thrombophilia screens or specialist haemostasis and thrombosis advice) will attend the deep vein thrombosis follow up clinic.

All patients with negative tests will be referred back to their GP unless they require admission.

Nurses who undertake the role of ambulatory deep vein thrombosis nurse specialists must:

- Be level 1 Registered Nurse
- Be registered with NMC
- To have completed the education and training programme and hold a valid statement of competence
- Be assessed as competent and hold a Statement of Competence to assess patients and adjust warfarin treatments as defined in this policy.
- Be familiar with the following documents:
  i) NMC Code of Professional Conduct – NMC 2002
  ii) The Scope of Professional Practice – UKCC 1992

The UHL Trust will accept vicarious liability for the action of the ambulatory deep vein thrombosis Nurse Specialists. The ambulatory deep vein thrombosis Nurse Specialist will adhere to the guidelines and policies identified.

5.2 Responsibilities of and communication with stakeholders

All patients discharged from the ambulatory DVT clinic should have a preliminary discharge letter sent to their GP stating diagnosis and any change in management.

All patients started on anticoagulation should be referred to the anticoagulation clinic through the online referral system (INSITE).
6 Policy Statements and Procedures

6.1 Introduction

Outpatient treatment of venous thromboembolism (VTE) with low molecular weight heparin (LMWH) is safe, effective and feasible for most patients. It is associated with a high degree of patient satisfaction and frees hospital beds for other admissions. LMWH is the anticoagulant currently used for the initial treatment of venous thromboembolism. It has improved bioavailability and a more predictable anticoagulant response compared with unfractionated heparin.

Ambulatory DVT care is clearly of benefit for a substantial percentage of patients. There will however, be a number of medical conditions and social situations which preclude outpatient therapy in some cases. The advent of ambulatory DVT therapy involves collaboration between a number of health care agencies including Emergency Departments and the medical admissions units, haematologists, anticoagulant and haemostasis specialist nurses, radiology departments, general practitioners and district nurses. This policy sets out the outpatient management of patients with deep vein thrombosis as they progress from diagnosis to outpatient treatment and follow up.

The incidence of VTE i.e. deep vein thrombosis (DVT) and pulmonary embolism (PE) is 0.1%. The risk of VTE increases exponentially with advancing age. It increases 1.9 fold per decade rising from an annual incidence of approximately 30:100,000 at 40 years to 90:100,000 at 60 years and 260:100,000 at 80 years.

VTE is a potentially fatal disease. The aims of treatment are to decrease the incidence of recurrent VTE, post thrombotic syndrome, venous leg ulcers and chronic thromboembolic pulmonary hypertension.

6.2 Criteria for outpatient management

6.2.1 Patient characteristics

- Be able to understand the treatment instructions or have home support or carer to understand instructions and carry them out (must have access to telephone)
- Appreciate the importance of full compliance with treatment
- Have the ability to attend hospital for treatment
- Not perceived as having a bleeding risk e.g. liver disease, active peptic ulcer disease
- Have no contra-indications to warfarin or LMWH
- Haemodynamically stable (pulse <110, systolic BP >100)
- Not hypoxic (O₂ sats >92% on air, RR<30)
- Not requiring iv analgesia
- No intercurrent illness requiring admission
- Adult (18 years and above). Not pregnant
- No other diagnosis likely
- No clinically obvious PE
- Must be able to weight bear and transfer to couch

6.2.2 Thrombotic indications for admission

- Extension of venous thrombosis despite therapeutic anticoagulation
- Signs and symptoms of pulmonary embolism. If the patient fulfills the criteria for the ambulatory PE clinic refer to (PE policy and referral process)
- Phlegmasia cerulea dolens – very painful blue leg due to extensive venous occlusion
- Phlegmasia alba dolens ie very painful white leg due to arterial spasm secondary to the DVT
• Heparin induced thrombocytopenia

6.2.3 **Bleeding indications for admission**

• Patients with active bleeding
• Patients at significant risk of bleeding
  o Active peptic ulceration
  o Liver disease (PT>2s beyond normal range)
  o Uncontrolled hypertension (diastolic >110mmHg, Systolic >200mmHg)
  o Angiodysplasia
  o Recent eye or CNS surgery or recent haemorrhagic stroke (within 1 month)
  o Thrombocytopenia (platelet count below 80 x 10^9 /l)
  o Renal Failure on haemodialysis or eGFR <20 ml/min/1.73 m²

6.3 **Aims of the service**

• To investigate and treat suspected DVT patients safely as an outpatient and prevent these patients being admitted to hospital enabling them to lead a normal lifestyle.
• Free admission beds for more acutely ill patients.
• To accelerate assessment, imaging, diagnosis and commencement of treatment.
• To educate patients/carers in ongoing treatment and future preventative care.
• To provide telephone support and advice to patients/carers.
• To improve the investigation and management of suspected DVT and improve adherence to UHL guidelines.
• To act as a resource for other wards, staff, junior doctors and GP’s.
• To refer patients back to primary care providers of anticoagulation, UHL anticoagulation service and GPs.
## 6.4 Ambulatory DVT service working timetable

<table>
<thead>
<tr>
<th></th>
<th>Weekdays</th>
<th>Weekends</th>
<th>Bank Holidays</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Base</strong></td>
<td>Balmoral level 1 (opposite Balmoral WRVS)</td>
<td>Balmoral level 1 (opposite Balmoral WRVS)</td>
<td>Balmoral level 1 (opposite Balmoral WRVS)</td>
</tr>
<tr>
<td><strong>Hours</strong></td>
<td>08:00-19:00</td>
<td>Saturdays 08:00-12:00</td>
<td>PLEASE CHECK</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sundays currently no service</td>
<td>Either 08:00-12:00hr or 08:00-16:00hr pending service requirements</td>
</tr>
<tr>
<td><strong>Consultant</strong></td>
<td>Consultant on call for the acute medical clinic</td>
<td>On call acute medical care consultants</td>
<td>On call acute medical care consultants</td>
</tr>
<tr>
<td><strong>Junior doctors</strong></td>
<td>Acute medical clinic juniors</td>
<td>On call AMU team</td>
<td>On call AMU team</td>
</tr>
<tr>
<td><strong>Nursing staff</strong></td>
<td><strong>DVT Nurse Specialists:</strong> Jo Eggleston Victoria Frimpong Tamyka Stewart Deb Thornton Helen Briggs</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Healthcare assistants</strong></td>
<td>Karen Coults Rachel Clarke-Drury</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Radiographers</strong></td>
<td>Michael Warren Sandy Jordan Claire Towers Claudius Maskure Julie Broughton</td>
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## 6.5 Patient Care Pathway

Procedures for the outpatient management of patients with deep vein thrombosis involves two separate processes – ASSESSMENT/DIAGNOSIS and TREATMENT.

### 6.5.1 Assessment & Diagnosis

Assessment and diagnosis falls under the responsibility of the ambulatory DVT service which is in the Emergency and Specialist Medicine CMG.
The diagnostic process is facilitated by validated clinical probability scores and second generation D-dimer assays. This may allow the discharge of a subgroup of patients without further radiological investigation i.e. low clinical probability of DVT and normal D-dimers.

Assessment of patients with possible venous thromboembolism either de novo presentation or possible recurrence involves the following:

**Clinical probability** in all patients

**D-dimers** in selected patients dependent on the clinical probability

**Radiology** in selected patients dependent on the clinical probability alone if ‘DVT likely’ (greater than or equal to 2 points) and dependent on clinical probability in conjunction with raised D-dimers if the clinical probability is ‘DVT unlikely’ (less than or equal to 1 point).

Other responsibilities of the team whilst the patient is undergoing assessment and diagnosis include the following:

- Provision of appropriate analgesia
- Assessment of patients with confirmed DVT for outpatient care
- Assessment of patients with confirmed DVT for associated pathology using malignancy proforma (appendix 4, page 24)
- Follow up arrangements for patients with a confirmed DVT
- Liaison with general practitioners regarding outcomes (appendix 1 p.17)

### 6.5.2 DVT assessment protocol

- All patients presenting with signs or symptoms of deep vein thrombosis (DVT), must have an assessment and a physical examination to exclude other causes.
- If DVT is suspected, use the two-level DVT Wells score (see table below) to estimate the clinical probability of PE.
- Routine bloods will be performed to include:
  - INR
  - D-Dimer
  - FBC, U&E, LFT, glucose

**Wells clinical probability score unlikely and D-Dimer <0.5 µg/ml FEU**
Seek alternative diagnosis/ Refer back to GP

**Wells clinical probability score likely or unlikely clinical probability but raised D Dimers:**
Start weight based treatment doses of Low Molecular Weight Heparin (LMWH) as per protocol and arrange compression venous ultrasonography
### 6.5.3 Two-level DVT Wells Score\(^{5,10}\)

<table>
<thead>
<tr>
<th>Clinical feature</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undergoing active or palliative cancer treatment in the last 6/12</td>
<td>1</td>
</tr>
<tr>
<td>Paralysis, paresis or plaster immobilisation of the lower extremities within the last 12/52</td>
<td>1</td>
</tr>
<tr>
<td>Bedridden &gt;3days, or surgery under general or regional anaesthesia in last 12/52</td>
<td>1</td>
</tr>
<tr>
<td>Localised tenderness along deep venous system distribution</td>
<td>1</td>
</tr>
<tr>
<td>Entire leg swollen</td>
<td>1</td>
</tr>
<tr>
<td>Affected calf larger than the other side by 3cm or more</td>
<td>1</td>
</tr>
<tr>
<td>Pitting oedema (NB only if found in the symptomatic leg)</td>
<td>1</td>
</tr>
<tr>
<td>Collateral (non-varicose) superficial veins</td>
<td>1</td>
</tr>
<tr>
<td>Previously documented DVT</td>
<td>1</td>
</tr>
<tr>
<td>Alternative diagnosis at least as likely as DVT</td>
<td>-2</td>
</tr>
</tbody>
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**Clinical probability simplified score**

| DVT likely                          | 2 points or more |
| DVT unlikely                        | 1 point or less  |
6.5.4 Flow chart for clinical assessment of suspected DVT

1. Patients with a suspected deep vein thrombosis are given an interim therapeutic dose of anticoagulant therapy (weight based treatment dose of low molecular weight heparin or treatment dose of rivaroxaban) if diagnostic investigations are expected to take longer than 4 hours from the time of first clinical suspicion.

2. If proximal leg scan has been carried out and is negative anticoagulants are withheld until the repeat scan result is known. Patients are warned to contact the DVT clinic or A&E out of hours if they experience any worsening symptoms.

PLEASE NOTE – inconclusive scans should be discussed with radiology on an individual basis regarding others forms of imaging
6.5.5D-Dimers

This measures cross-linked fibrin broken down by plasmin. **D-dimer levels are usually elevated with DVT and/or PE**

- Normal levels can help to exclude VTE but
- Elevated D-dimer levels are non-specific and have low positive predictive value.

A number of studies have shown the value of D-dimers for the exclusion of venous thromboembolism. When a clot is formed, fibrin monomers are cross-linked to each other in the region of the D domains of the molecules. After lysis the D domains remain cross-linked giving rise to D-dimers, which can be detected by commercial assay. They are, therefore, sensitive to clot formation. At present the UHL acute ambulatory DVT service is using a quantitative point of care (POC) d-dimer assay (Cardiac d-dimer, Roche) using the Cobas h232 POC instrument.

The normal range is <0.5 µg/ml FEU. Negative D-dimer results, in the presence of a low clinical probability score can exclude a PE in 99.8% of cases.

However, there are many causes for a raised D-Dimer other than VTE and therefore the test cannot be used to support the diagnosis but only to exclude the diagnosis in patients with a low clinical probability score.

Specificity of D-dimers decreases with age and with co-morbid illnesses such as cancer, infection, inflammation, vasculitis, pregnancy, trauma, haemorrhage and post surgical states. All of these can cause a positive D-dimer test. Consequently D-dimer testing may have limited value as a diagnostic test for VTE in hospitalized patients (more false positive results) and is unhelpful in the early postoperative period.

Normal D-dimers in a patient on vitamin K antagonist treatment such as warfarin must be interpreted with caution as the anticoagulant therapy may normalise this despite acute thrombus being present. These patients should be discussed on an individual basis.

6.5.6 Radiological Investigation

For the outpatient therapy programme to be effective it is important that there should be no undue delay in the diagnosis of the patient. There are currently 80 dedicated compression venous ultrasonography slots each working week for the diagnosis of patients with suspected DVT who might then be suitable for outpatient care.

Those outpatients who are considered on clinical assessment as being at risk of DVT should be treated with rivaroxaban or therapeutic doses of LMWH pending confirmation of the diagnosis. It is not considered good medical practice for patients to be treated on this presumptive basis for more than 24 hours as for many patients this would involve unnecessary treatment and a bleeding risk.

**Negative whole leg Imaging**

- Patients who have negative imaging are referred back to GP with letter.
- Copy of letter filed in patients notes.
- DVT Nurse Specialist only to discharge patients following Discharge Protocol. (Appendix 3, p19-23)

**Only proximal leg scan carried out**

- Repeat proximal venous leg ultrasound in 6-8 days

**Inconclusive imaging**
• inconclusive scans should be discussed with radiology on an individual basis regarding repeat imaging or others forms of imaging

Positive Imaging

- Patients who are diagnosed with DVT have to fit criteria for home/outpatient treatment as per protocol.
- Doctor in department or independent prescriber or DVT specialist nurse using a patient group directive (PGD) to prescribe rivaroxaban, LMWH and warfarin on drug prescription chart.
- TTO's to be prescribed by doctor or independent prescriber
- Yellow anticoagulation booklet supplied and explained
- DVT information booklet supplied
- Educate re: warfarin, heparin, lifestyle etc.
- Arrange transport if required.
- Supply contact numbers
- Letter to GP
- Complete pre malignancy screen (appendix 4,p24)
- Following initiation of warfarin patients can be referred to UHL anticoagulation clinic to continue monitoring of their INRs
- All information to be documented in patients notes:
  - Signed
  - Dated
  - Timed
  - Legible signature

6.5.7 Screening for malignancy

For all patients aged over 40 years with a first unprovoked DVT a limited cancer screening strategy consisting of history, physical examination, urinalysis, basic laboratory tests and chest X-ray is sufficient. Any signs or symptoms of cancer based on initial investigation should be followed by appropriate further investigation eg an abdomino-pelvic USS or CT scan,a mammogram or GI endoscopy. NICE CG144 suggests consideration of extensive screening without symptoms but the evidence suggests that this is not currently warranted.

6.5.8 Treatment

Ambulatory treatment of DVT is initially the responsibility of the ambulatory DVT service which is in the Emergency and Specialist Medicine CMG. Responsibilities of the team whilst the patient is undergoing treatment include the following:

- Administration of outpatient care programme
- Commencement and control of anticoagulant therapy
- Liaison with community agencies
- Patient information and education including advice and phone numbers if worsening symptoms
- Referral for thrombophilia testing where appropriate: see UHL Thrombosis and Haemophilia guideline, DMS No 17261

6.5.9 Prescription of medication

Prescription of LMWH and oral anticoagulants is the responsibility of the medical team on AMU or bed bureau clinic, or the ambulatory specialist DVT nurse (either nurse prescriber or DVT specialist nurse using LMWH or rivaroxaban patient group directive PGD) at the time of diagnosis. Patients on renal replacement therapy or with eGFR <20 should be discussed with the renal team before anticoagulation is commenced (see page 24).
6.5.10 Drug Interactions

The patient is educated about the side effects of warfarin and possible drug and food interactions. This is done prior to starting warfarin - see UHL guidance on Warfarin Drug Interactions and Contraindications, DMS No 33165

6.5.11 Anticoagulation

Suspected or confirmed 1st DVT – all these patients should be offered rivaroxaban as a treatment option. Patients should be fully counselled before therapy is initiated. Exclusions to rivaroxaban therapy include:

- Rivaroxaban contraindicated
- Renal function (Creatinine clearance/Cockcroft Gault calculation) less than or equal to 30ml/min (local guidance)
- Patients who would prefer warfarin
- Patients with recurrent DVT

All newly diagnosed patients excluded or declining rivaroxaban treatment to start LMWH for at least 5 days until INR greater than (>2.0 for 2 consecutive days as recommended by supplier.

Patients to have slow induction of Warfarin - Tait and Sefcick protocol, DMS No 37425

Warfarin dosed as per INR to keep within range as per anticoagulation protocol.

Those on slow induction (Tait and Sefcick) to attend the ambulatory clinic for INRs on days 1 and 5. Administration of LMWH to be undertaken by patient or, if patient unwilling or unable, the ambulatory nurse specialist to arrange administration by district nurse/ community nurse.

6.5.12 Patient Information

Patients having anticoagulation treatment will be given verbal and written information about:

- how to use anticoagulants
- duration of anticoagulation treatment
- possible side effects of anticoagulant treatment and what to do if these occur
- the effects of other medications, foods and alcohol on oral anticoagulation treatment
- monitoring their anticoagulant treatment
- how anticoagulants may affect their dental treatment
- taking anticoagulants if they are planning pregnancy or become pregnant
- how anticoagulants may affect activities such as sports and travel
- when and how to seek medical help

6.5.13 Duration of Anticoagulation

- Offer LMWH to patients with active cancer and confirmed proximal DVT, and continue the LMWH for 6 months. At 6 months, assess the risks and benefits of continuing anticoagulation.

- Offer oral anticoagulants to patients with confirmed DVT within 24 hours of diagnosis and continue the oral anticoagulants for a minimum of 3 months. At 3 months, assess the risks and benefits of continuing warfarin treatment.
• Offer warfarin for 6 months to patients with a proximal DVT, taking into account the patient’s risk of VTE recurrence and whether they are at increased risk of bleeding. Discuss with the patient the benefits and risks of extending their warfarin treatment.

• Consider extending the warfarin beyond 6 months for patients with unprovoked DVT if their risk of VTE recurrence is high and there is no additional risk of major bleeding. Discuss with the patient the benefits and risks of extending their warfarin treatment.

6.5.14 Transfer of care for anticoagulation monitoring

All patients are initially followed up by the UHL anticoagulant service and then transferred to the most appropriate monitoring service depending on GP practice. Patients can be referred from initiation (INR does not have to be within therapeutic range).

Duration of warfarin treatment must be clearly documented in the notes, on anticoagulation prescription and in front of the yellow booklet as per national consensus.

6.5.15 Additional Information

Additional guidance documents can be found in the Anticoagulation, Thrombosis and Thromboprophylaxis Policy DMS No B24/2006

Criteria and guidance for treatment with LMWH alone – Appendix 3, p19

Treatment with rivaroxaban – appendix 4, p25

Guidelines on the management of warfarin overdose DMS No 33167

Prothrombin Complex Concentrate administration guide DMS No 33168

Thrombophlebitis appendix 5

Floating thrombus appendix 6

Calf muscle vein thrombosis(gastrocnemius and soleal veins) appendix 7

6.5.16 TTOs

3 boxes of 1mg tablets x 28 tablets per box

Patients informed to get further supplies from GP

LMWH – weight based dosage in pre filled syringes is administered on site for the first injection. Subsequent doses are self administered or given by the District Nurse. LMWH for self or district nurse administration is supplied along with a sharps box.

Compression hosiery

Patients are discharged with a pair of below knee anti embolism stockings but instructions are given to the patient verbally and in writing and to the GP in the preliminary discharge letter that these need replacing within 1-2 weeks or when the swelling is reduced sufficiently (provided there are no contraindications) with class 2 below knee graduated elasticated compression hosiery.

Patients are advised to continue wearing the stockings for at least 2 years and ensure that the stockings are replaced two or three times per year or according to the
manufacturers' instructions.

6.5.17 Dosing of Warfarin

Patients have their INRs tested using the Coaguchek near patient testing device. The INR is documented and warfarin dosage instructions are given verbally and in writing in the patient’s yellow anticoagulant monitoring book.

6.5.18 Out of hours, bank holidays and weekends

In the absence of the ambulatory DVT Nurse Specialist, patients become the responsibility of the doctors on AMU/bed bureau clinic.

If these patients with suspected DVT based on clinical probability and raised Ddimers are suitable for outpatient management LMWH should be started and referral made to the ambulatory DVT clinic for imaging. If the patient has a low clinical probability and normal D-dimers (<0.5µg/ml FEU) there is a low probability of venous thromboembolism and an alternative diagnosis should be sought and discharge back to the GP should be considered.

NOTE all patients should have had baseline U&Es, LFTs, FBC and INR.

6.5.19 Audit and evaluation

Yearly audits:
a) Nurse competencies/appraisal
b) Patient process and adherence to policy
c) Time to scan audit
REFERENCES


10. **NICE clinical guidelines** – CG144 Venous thromboembolic diseases; the management of venous thromboembolic diseases and the role of thrombophilia testing *Issued June 2012*


APPENDIX 1:

NURSE LED DISCHARGE FOR PATIENTS REFERRRED TO AMBULATORY DVT CLINIC WITH SUSPECTED DVT

It has been agreed by the ambulatory DVT team that if the criteria listed below has been achieved then the patient can be referred back to their GP:

- All patients have been assessed using the clinical probability score.
- All patients have had routine bloods taken (FBC, U&E, LFTs, INR, D-dimer unless high clinical probability)
- If patients have a 'DVT unlikely' probability and D-Dimers are <0.5µg/ml FEU.
- If whole leg imaging has been performed it is negative for DVT.
- If no other diagnosis requiring admission has been identified by imaging.
- Patients have been advised what to do if their condition worsens or they have new symptoms.
- They have no other conditions that require admission.
- A letter has been sent to the GP.
- Events have been clearly documented in the patients’ notes.
- A copy of the GP letter is filed into the notes.
- If patients have a DVT they are referred to clinic to be seen by either DVT follow up clinic or the H/T Team.

Undertaken only by ambulatory DVT Nurse Specialist
APPENDIX 2

OUTPATIENT TREATMENT

FOR PATIENTS DEEMED SUITABLE FOR OUT-PATIENT TREATMENT

Continue LMWH as per protocol.

Start anticoagulation (warfarin or equivalent) therapy.

Patient’s INR to be obtained prior to outpatient treatment.

Nurse specialist to continue care of anticoagulation stabilisation or alternative arrangements to be made.

Refer to UHL anticoagulant clinic for reinforcement of education and triage to the most appropriate long term monitoring service:
- GP
- UHL community Anticoagulation Monitoring Service
- Hospital based anticoagulant Clinic

NOT SUITABLE FOR OUT PATIENT TREATMENT

Admit patient

Continue LMWH as per local protocol

Stabilise patient on anticoagulation therapy (warfarin or equivalent) prior to discharge

Anticoagulation maintenance by GP, Community Anticoagulation Service or hospital anticoagulation clinic.
APPENDIX 3: ANTICOAGULATION.
INITIATION CHECKLIST, INITIATION SCHEDULES AND
REFERRALS FOR MONITORING

ANTICOAGULATION THERAPY CHECK LIST FOR NEW POSITIVE PATIENTS UHL

| Diagnosis: ........................................ |
| Seen by: .......................................... |
| Date: .............................................. |

Please tick each point once the patient has been informed of the following:

1. Clinical need for anticoagulation
2. How heparin works (if applicable)
3. How warfarin works
4. Need for regular INR monitoring.
5. Using a calendar to remember dose adjustments / appointments
6. Obtaining supply of medication from:
   • Hospital initially
   • Repeat prescriptions from GP
7. Discuss current drug therapy and the need to inform clinic of change of medication.
8. Discuss over the counter medication and herbal remedies.
9. To ask their local pharmacist for advice on medications and possible interactions
10. Advice on alcohol consumption
    • Need for moderation (no more than 2 units per day)
    • Not to ‘binge’
    • Effects of warfarin combined with alcohol
11. Aware of possible side effects of therapy eg bleeding, bruising.
12. For women only, contraception, periods, pregnancy and HRT.
13. Dietary advice given, especially regarding avoidance of crash diets.
15. Lifestyle issues discussed, smoking, exercise, weight control and work
16. Contact numbers given.

FOR PATIENTS WITH DVT
17. Need for leg care, wearing compression stockings, rest and moderate exercise.
18. What to do if experiencing worsening pain, leg swelling or discolouration or dyspnoea.
Pre Treatment INR <1.3 and not on Amiodarone  
Warfarin 5mg days 1-4  
Check INR day 5, 8 & 12

<table>
<thead>
<tr>
<th>INR Day 5</th>
<th>Warfarin Dose From Day 5</th>
<th>INR Day 8</th>
<th>Warfarin Dose From Day 8</th>
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</thead>
<tbody>
<tr>
<td>&lt;1.7</td>
<td>5mg</td>
<td>&lt;1.7</td>
<td>6mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.8-2.4</td>
<td>5mg</td>
</tr>
<tr>
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<td></td>
<td>2.5-3.0</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;3.0</td>
<td>3mg for 4 days</td>
</tr>
<tr>
<td>1.8-2.2</td>
<td>4mg</td>
<td>&lt;1.7</td>
<td>5mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.8-2.4</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.5-3.0</td>
<td>3.5mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.1-3.5</td>
<td>3mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;3.5</td>
<td>2.5mg for 4 days</td>
</tr>
<tr>
<td>2.3-2.7</td>
<td>3mg</td>
<td>&lt;1.7</td>
<td>4mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.8-2.4</td>
<td>2.5mg</td>
</tr>
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<td></td>
<td>2.5-3.0</td>
<td>2mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.1-3.5</td>
<td>1.5mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;3.5</td>
<td>1mg for 4 days</td>
</tr>
<tr>
<td>2.8-3.2</td>
<td>2mg</td>
<td>&lt;1.7</td>
<td>3mg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.8-2.4</td>
<td>2.5mg</td>
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<td>2mg</td>
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<td>1.5mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;3.5</td>
<td>1mg for 4 days</td>
</tr>
<tr>
<td>3.3-3.7</td>
<td>1mg</td>
<td>&lt;1.7</td>
<td>2mg</td>
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<td></td>
<td>1.8-2.4</td>
<td>1.5mg</td>
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<tr>
<td></td>
<td></td>
<td>2.5-3.0</td>
<td>1mg</td>
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<td></td>
<td>3.1-3.5</td>
<td>0.5mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;3.5</td>
<td>omit for 4 days</td>
</tr>
<tr>
<td>&gt;3.7</td>
<td>0mg</td>
<td>&lt;2.0</td>
<td>1.5mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2.0-2.9</td>
<td>1mg for 4 days</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3.0-3.5</td>
<td>0.5mg for 4 days</td>
</tr>
</tbody>
</table>

Tait RO, Sefcick A 1998  
A warfarin induction regime for outpatient anticoagulation in patients with atrial fibrillation.
Record of Results For Attenders for Low molecular Weight Heparin and Warfarin

### Day 1

<table>
<thead>
<tr>
<th>Date</th>
<th>Day</th>
<th>LMWH dose</th>
<th>Time</th>
<th>Sig</th>
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<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Warfarin</th>
<th>INR</th>
<th>Dose</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments**

### Day 5

<table>
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<tr>
<th>Date</th>
<th>Day</th>
<th>LMWH dose</th>
<th>Time</th>
<th>Sig</th>
<th>Print</th>
</tr>
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<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Warfarin</th>
<th>INR</th>
<th>Dose</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Comments**

Check platelets: Y/N

Referral made to anticoagulation Date............................
Referral made by Print Name.................................
Signature .............................................
TREATMENT WITH LMWH

Start the LMWH presumptively if diagnostic imaging is not available within 4 hours of presentation. The dose is weight based and adjustments in dosage are required if there is an increased risk of bleeding or renal impairment (see algorithm below or UHL anticoagulation prescription chart). Weight and renal function must be documented. If progressing onto warfarin or equivalent anticoagulant continue the LMWH for at least 5 days or until the international normalised ratio (INR) is in the target range for at least 24 hours, whichever is longer.

**Indications for treatment with LMWH ALONE:** NB if dalteparin is required for more than 28 days a shared care request form is sent to the GP and management is in accordance with the LMSG guideline [http://www.lmsg.nhs.uk/SharedCare/default.asp](http://www.lmsg.nhs.uk/SharedCare/default.asp)


Previous problems with warfarin

Women who are pregnant or less than 8 days postpartum – these patients should be managed by the Obstetric department and NOT the ambulatory DVT service – see UHL anticoagulation policy – “Management of DVT and PE in pregnancy” INsite document 10836 [http://dms.xuhl-tr.nhs.uk/doc-info.asp?aid=10836&nav=0](http://dms.xuhl-tr.nhs.uk/doc-info.asp?aid=10836&nav=0)

Intravenous drug abusers with no venous access

Other groups with no venous access or with higher risk of bleeding

**Monitoring:**

1. **Baseline:** FBC, PT/INR, U&Es, LFTs
2. **First 2 weeks of LMWH:** FBC day 5-10 days to ensure no drop in platelet count and U&Es to ensure no hyperkalaemia (see LMSG shared care guideline link above)
3. **Anti Xa activity** (2 citrate green bottles) to assess potential accumulation or inadequate dosing 3-5 hours post-dose (peak level) after the 3rd dose for patients with
   - Significant renal impairment (eGFR<30)
   - Morbid obesity (>120kg) or underweight (<45kg)

1) **Prescribing of LMWH eGFR>29ml/min**

<table>
<thead>
<tr>
<th>kg</th>
<th>units</th>
<th>frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>5000</td>
<td>OD</td>
</tr>
<tr>
<td>40-45</td>
<td>7500</td>
<td>OD</td>
</tr>
<tr>
<td>46-56</td>
<td>10000</td>
<td>OD</td>
</tr>
<tr>
<td>57-68</td>
<td>12500</td>
<td>OD</td>
</tr>
<tr>
<td>69-82</td>
<td>15000</td>
<td>OD</td>
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<tr>
<td>83-99</td>
<td>18000</td>
<td>OD</td>
</tr>
<tr>
<td>100-124</td>
<td>18000 stat, then 12 hours later</td>
<td>10000</td>
</tr>
<tr>
<td>124-130</td>
<td>18000 stat, then 12 hours later</td>
<td>12500</td>
</tr>
<tr>
<td>&gt;130</td>
<td>18000 stat and seek specialist advice</td>
<td></td>
</tr>
</tbody>
</table>

In obesity with EGR >30ml/min a stat dose of 18,000 u sc should be given prior to starting split bd heparin doses.

If the weight is 130 kg or above further dalteparin dose escalation should be considered ie 100 u/kg bd 12 hours after an initial stat dose of 18,000 u sc on an individualised basis. Timed anti Xa levels should be taken after the 3rd dose.

Total dose should NOT exceed 18000 u sc bd
2) Prescribing of LMWH eGFR >29ml/min with increased bleeding risk*

*If the patient is actively bleeding seek specialist advice
*Ensure bleeding risk does not exclude from ambulatory pathway (section 6.2.3)

<table>
<thead>
<tr>
<th>kg</th>
<th>units</th>
<th>frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;40</td>
<td>3000 stat then 12-24 hours later start 2500</td>
<td>BD</td>
</tr>
<tr>
<td>40-45</td>
<td>7500 stat then 12-24 hours later start 5000</td>
<td>AM PM</td>
</tr>
<tr>
<td>46-56</td>
<td>10000 stat then 12-24 hours later start 5000</td>
<td>BD</td>
</tr>
<tr>
<td>57-68</td>
<td>12500 stat then 12-24 hours later start 7500</td>
<td>AM PM</td>
</tr>
<tr>
<td>69-82</td>
<td>15000 stat 7500</td>
<td>BD</td>
</tr>
<tr>
<td>81-99</td>
<td>18000 stat 10000 7500</td>
<td>AM PM</td>
</tr>
<tr>
<td>100-124</td>
<td>18000 stat, then 12 hours later 10000</td>
<td>BD</td>
</tr>
<tr>
<td>124-130</td>
<td>18000 stat, then 12 hours later 12500</td>
<td>BD</td>
</tr>
<tr>
<td>&gt;130</td>
<td>18000 stat and seek specialist advice</td>
<td></td>
</tr>
</tbody>
</table>

If there is an increased bleeding risk the dalteparin dose should be split into bd heparin doses after a single weight based stat dose
In obesity with EGR >30ml/min and an increased bleeding risk a stat dose of 18,000 u sc should be given prior to starting split bd heparin doses.
If the weight is 130kg or above further dalteparin dose escalation should be considered ite 100u/kg bd 12 hours after an initial stat dose of 18,000u sc on an individualised basis. Timed anti Xa levels should be taken after the 3rd dose.
Total dose should NOT exceed 18000u sc bd

3) Prescribing of LMWH eGFR greater than 20ml/min but less than 30ml/min

<table>
<thead>
<tr>
<th>kg</th>
<th>units</th>
<th>frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;46</td>
<td>5000 stat then 24 hours later start 2500</td>
<td>BD</td>
</tr>
<tr>
<td>46-62</td>
<td>7500 stat then 24 hours later start 5000</td>
<td>AM PM</td>
</tr>
<tr>
<td>63-80</td>
<td>7500 stat 2500</td>
<td>BD</td>
</tr>
<tr>
<td>81-98</td>
<td>10000 stat 7500</td>
<td>AM PM</td>
</tr>
<tr>
<td>98-116</td>
<td>10000 stat 7500</td>
<td>BD</td>
</tr>
<tr>
<td>117-134</td>
<td>12500 stat 7500</td>
<td>AM PM</td>
</tr>
<tr>
<td>&gt;134</td>
<td>Seek specialist advice if over 150kg 15000 stat, then 24 hours later start 10000</td>
<td>BD</td>
</tr>
</tbody>
</table>

In renal impairment the risk of bleeding may be increased – the above represents guidance on dose reduction.
Timed anti Xa levels should be taken 3-4 hours after the 3rd dose.
4) Prescribing of LMWH eGFR less than 20ml/min

- Calculate creatinine clearance (Cockcroft Gault) using UHL insite creatine clearance calculator

- If Cockcroft Gault creatinine clearance greater than 20 follow prescribing of LMWH eGFR greater than 20ml/min but less than 30ml/min (see 3 on p23)

- If Cockcroft Gault creatinine clearance LESS than 20 follow USE UNFRACTIONATED HEPARIN (UFH) IV
  - Give initial 5000ubolus over 5 minutes
  - Run infusion at 1400units/h
  - Check APTT ratio (APPTR) after 4-6 hours
  - Adjust infusion rate as per ‘UHL unfractionated heparin (UFH) adult infusion guidelines (Document ID 0668238651)

**Referral for Anticoagulant monitoring**

**Referral to hospital based A/C clinic for A/C monitoring**
Complete the on line referral below or type anticoagulation into INSITE

http://insite.xuhl-tr.nhs.uk/homepage/clinical/clinical-directorates/cancer--haematology/anticoagulation/making-a-referal
APPENDIX 4

TREATMENT WITH RIVAROXABAN

Rivaroxaban is an oral direct factor Xa inhibitor with 80-100% bioavailability. It is licensed and has NICE approval (technology appraisal 261) for the treatment of DVT and the prevention of recurrence of VTE in adults.

It is given as a fixed dose and has less drug and food interactions than warfarin. It’s half life is 5-13 hours but anti Xa activity persists for 24 hours. This drug disrupts thrombin generation and clot development. The factor Xa inhibition is dose dependent. It is only 1/3 renally cleared.

There is no specific antidote for rivaroxaban (see link below for advice in management of bleeding patients) and the absence of monitoring makes non compliance more difficult to detect compared with warfarin.

Counselling and follow up is required to avoid a situation where recurrent VTE becomes the first sign of non compliance.

Rivaroxaban prescribing in DVT is currently restricted to Haematology or acute medical consultants and DVT nurse specialists.

Current prescribing eligibility

Criteria
1 Suspected or confirmed 1st DVT – all these patients should be offered rivaroxaban as a treatment option. Patients should be fully counselled before therapy is initiated. Exclusions to rivaroxaban therapy include:

- Rivaroxaban contraindicated
- Renal function (Creatinine clearance/Cockcroft Gault calculation) less than or equal to 30ml/min(local guidance)
- Patients who would prefer warfarin
- Patients with recurrent DVT

UHL Initiation Pack for Rivaroxaban in the treatment of first Deep vein thrombosis and the prevention of recurrent DVT and PE outlines the following:

- UHL process for the supply of rivaroxaban
- Pathway for initiating rivaroxaban
- Prescriber checklist
- Prescribing information
- Patient decision aid
- Patient information

UHL Initiation Pack for Rivaroxaban in the treatment of first Deep vein thrombosis and the prevention of recurrent DVT and PE is available Appendix 9
Further prescribing advice and management of patients that are bleeding is available on the links below:

LMSG website

INsite - New Oral Anticoagulants
### APPENDIX 5: SCREENING FOR UNDERLYING MALIGNANCY IN PATIENTS WITH A POSITIVE DIAGNOSIS OF DVT

#### Pretest Probability of Malignancy following Positive DVT

<table>
<thead>
<tr>
<th>Patient Ref No:</th>
<th>Compression venous ultrasound:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Result:</td>
</tr>
<tr>
<td>Address:</td>
<td></td>
</tr>
<tr>
<td>Tel No:</td>
<td>Prev Thrombotic History:</td>
</tr>
<tr>
<td>GP:</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weight loss &gt; 7lbs in 6 months</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recent abdominal pain</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Recent alteration in bowel habit</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Haematuria/malaena</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Bilateral DVT</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Unexplained PV bleeding</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Smoker or smoked within last 5 years</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Male &gt; 60 years</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Male &lt; 60 years with urinary problems</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

*Yes = abdominal imaging and/or upper or lower GI endoscopy*

*Yes = gynaecological screen*

*Yes = CXR*

*Yes = PSA*

History taken by:

Date:

Referral to haematology consultant: Yes Date: No
APPENDIX 6: Thrombophlebitis

Superficial thrombophlebitis usually presents with a gradual onset of localized tenderness followed by the appearance of an area of erythema along the path of a superficial vein. There may be a history of local trauma, previous similar episodes, varicose veins, prolonged travel or enforced stasis. On examination erythema is evident and a firm, thickened, tender thrombosed vein may be palpable. Every effort should be made to prevent superficial thrombophlebitis from progressing to involve the deep veins. The high risk groups with superficial thrombophlebitis require further evaluation for DVT:

- Those without coexisting venous varices and no other obvious aetiology
- Involvement of the greater saphenous vein above the knee especially if it extends to the saphenofemoral junction.

Classification and treatment of superficial thrombophlebitis (ST)

<table>
<thead>
<tr>
<th>Occluding thrombus in GSV and or SSV</th>
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</thead>
<tbody>
<tr>
<td>Less than or equal to 3cm from SFJ or SPJ</td>
</tr>
<tr>
<td>More than 3cm from the SFJ or SPJ PLUS More than 5cm in length, EXTENSIVE ST</td>
</tr>
<tr>
<td>More than 3cm from the SFJ or SPJ PLUS Less than 5cm in length, NON-EXTENSIVE ST</td>
</tr>
<tr>
<td>Treat as DVT with anticoagulants for 3-6 months, class 2 GCSs</td>
</tr>
<tr>
<td>Treat with doses dalteparin 5,000u sc od (duration 6 weeks), class 2 GCSs</td>
</tr>
<tr>
<td>NSAIDs (topical/oral) 8-10days/ resolution of symptoms Class 2 GCSs</td>
</tr>
</tbody>
</table>

GSV=great saphenous vein; SSV=short saphenous vein; SFJ=saphenofemoral junction; SPJ=saphenopopliteal junction; ST=superficial thrombophlebitis; DVT=deep vein thrombosis; GCSs=graduated compression stockings

The optimal agent, dose and duration of anticoagulant medication remain unclear. A high rate of recurrent superficial phlebitis has been reported following discontinuation of anticoagulation, further complicating decisions on how long such patients should be treated with anticoagulants. Recurrent superficial thrombophlebitis may require anticoagulation with warfarin but this should be discussed with a haematologist on an individual basis.
REFERENCE

C Lewis Managing Superficial thrombophlebitis in a nurse-led DVT service Thrombus, Sept2011,vol15 number2

Anand Lokare Superficial thrombophlebitis: a proposal for classification and management Sept 2013, vol17 number1


APPENDIX 7: FREE FLOATING THROMBUS

A free floating thrombus (FFT) is often perceived to be a risk factor for pulmonary embolism, despite adequate anticoagulation therapy in patients with proximal deep vein thrombosis. These patients are often excluded from ambulatory therapy. Evidence now exists that these patients are at no higher risk for pulmonary embolus and there is data to support the safety of ambulatory therapy in clinically stable patients. One series found that FFT occurred in 10% of cases of DVT and only 13% of these were associated with clinically significant pulmonary emboli, confirmed by ventilation perfusion scanning. Most FFT followed non invasively by duplex scanning do not embolize but instead become attached to the vein wall or resolve. These patients are informed of the signs and symptoms of pulmonary embolus and the need for urgent review should these occur.

REFERENCES


APPENDIX 8: CALF MUSCLE VEIN THROMBOSIS (SOLEAL and GASTROCNEMIUS DVT)

The natural history of isolated symptomatic thrombosis involving the deep veins draining the gastrocnemius and soleus muscles in the calf is unclear, and guidelines for the treatment of this condition do not exist. However, thrombosis confined to the muscular veins appears to have a lower risk of extension than true isolated distal DVT. Our local policy is to treat these DVTs for 6 weeks.

REFERENCE

Appendix 9

UHL Initiation Pack for Rivaroxaban in the Treatment of first Deep Vein Thrombosis (DVT) and the prevention of recurrent DVT and PE.

Page 2 Supply
Page 3 Pathway
Page 4 Prescriber checklist
Page 5 Prescribing Information
Page 6 Patient decision aid
Page 7 Patient Information

Dr Jane Strong. Consultant Haematologist
Dr Amit Mistri. Consultant Stroke Physician
Gill Stead. Principal Pharmacist Medicines Information
UHL Process for the Supply of Rivaroxaban for Treatment of confirmed and suspected first deep vein thrombosis (DVT) and prevention of recurrent DVT and PE in adult patients

1. Criteria

1.1 Patient groups
Ambulant Hospital Inpatients ready for discharge. 
Ambulant GP, community hospital referrals 
Ambulant A&E, outpatient referrals 
Inpatients should be referred to a Haematologist or acute physician

1.2 Confirmed and suspected DVT (identified by a physical examination, Wells score ≥2, or a Wells score <2 with +ve D-dimer test)

All patients should be offered rivaroxaban as a treatment option. Patients should be fully counselled before therapy is initiated. Exclusions to rivaroxaban therapy include:

a. Rivaroxaban contraindicated
b. Patients with active cancer *
c. Renal function ≤30ml/min (local guidance)
d. Patients who would prefer warfarin
e. Patients with recurrent DVT

*LMWH heparin remains the treatment of choice for patients with active cancer but rivaroxaban can be considered if this is the patient preference or for quality of life reasons.

2. Process

2.1 First visit

➢ For patients with suspected DVT who meet the criteria and cannot be scanned within 4 hours, a pre-pack of rivaroxaban 15mg bd for 3 days will be supplied from the DVT clinic to provide anticoagulation until scanning becomes available.

➢ Patients with confirmed DVT who meet the criteria will be supplied 21 days therapy of rivaroxaban 15mg bd from the DVT clinic.

Patients presenting before 12pm
Day 1 onwards: Take one dose immediately and a second dose approximately 12 hours later in the evening.

Patient presenting between 12-6pm
Day 1: Take one 15mg tablet immediately on Day 1 and a second tablet between 11-12pm.
Day 2 onwards: Take one tablet in the morning and one tablet approximately 12 hours later in the evening.

Patients presenting after 6pm
Day 1: Take one 15mg tablet immediately only on Day 1. Do not take a second tablet.
Day 2 onwards: Take one dose in the morning and one approximately 12 hours later in the evening.

➢ Therapy will be initiated by specialist nurse doctor or specialist nurses under a patient group directive. No prescription charge will be made for either of these supplies. Records of supply will be kept in the clinic.
2.2 Second visit
At 3 weeks after presentation, patients will be reviewed for drug tolerability during the standard working day by nurse prescribers in the Anticoagulant Clinic. A standard prescription will be issued for 70 Rivaroxaban tablets 20mg once daily or 70 Rivaroxaban tablets 15mg once daily for patients with moderate renal impairment. Prescriptions should be taken to LRI-Lloyds Pharmacy Balmoral. Eligible patients will be expected to pay one prescription charge. Anticoagulation nurses will liaise with a consultant if there are any problems.

Most patients will only require 3 months of treatment and no further supply is necessary. For patients requiring longer treatment, then the prescriber should request that the GP take over using the FULL Shared Care Agreement Form (for transfer of care to the GP) available on the LMSG website.

2.3 Follow up
All patients with a proximal DVT will be reviewed as a DVT outpatient. Patients requiring treatment longer than 6 months will be counselled regarding drugs choices and the current lack of long term safety data for rivaroxaban.
**Pathway for Initiating Rivaroxaban for First DVT**  
*(Confirmed and Suspected)*

- **Ambulant Hospital Inpatients**
- **A&E Attendees**
- **Outpatients**

---

**DVT – Not confirmed by scan**

- **No treatment required**

---

**Wells Score ≥ 2 or <2 with a positive D-dimer**

- **Refer to DVT clinic**

---

**DVT Confirmed by ultrasound scan (Target within 4 hours)**

- **Assessment and informed discussion between patient with DVT nurse specialist/prescriber**

---

**START** treatment in patients with suspected DVT where it is not possible to scan within 4 hours.

**RIVAROXABAN 15mg bd**

First line for up front treatment.  
*Supply 3 day pre-pack from clinic. OR*

**LMWH** for patients with recurrent DVT, active cancer*, contraindications to rivaroxaban or if creatinine clearance <30mL/min  
*Supply 5 day pre-pack from clinic*

---

**Initiate LMWH/warfarin if any of the following present:**

- Recurrent DVT
- Contraindications to rivaroxaban
- Creatinine clearance <30mL/min
- Patient prefers

---

**Initiate LMWH only**

- if warfarin contraindicated or not feasible.
- Active cancer*

---

**DVT – Not confirmed by scan**

- **No treatment required**

---

**Wells Score ≥ 2 or <2 with a positive D-dimer**

- **Refer to DVT clinic**

---

**DVT Confirmed by ultrasound scan (Target within 4 hours)**

- **Assessment and informed discussion between patient with DVT nurse specialist/prescriber**

---

**START** treatment in patients with suspected DVT where it is not possible to scan within 4 hours.

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---

**Initiate LMWH only**

- if warfarin contraindicated or not feasible.
- Active cancer*

---

**3 months treatment clinically indicated.**

Supply patient with a further 70 days rivaroxaban.  (Dose adjustment required)  
*(Supply from Lloyds Pharmacy UHL) Discharge back to GP.*

---

**>3 months treatment clinically indicated**

Supply patient with a further 70 days rivaroxaban.  (Dose adjustment required)  
*(Supply from Lloyds Pharmacy UHL)*  
Consultant/nurse prescriber to complete SCA request for GP to continue patient care as outlined in the SCA.

---

**Initiate rivaroxaban for first DVT**

- if preferred by patient, no contraindications, no active cancer* and creatinine clearance >30mL/min.  
*Supply:*
  - Pre-pack of Rivaroxaban (21 days) in clinic.
  - Anticoagulant Alert Card
  - Anticoagulant Booklet
  - Patient Leaflet.

---

7 day follow-up by Anticoagulation Clinic to check tolerability

---

**Problems Discuss with Haematologist**

- **No Problems**

---

Patients taking rivaroxaban reviewed by consultant/nurse prescriber at 3 weeks from presentation

---

**Rivaroxaban can be considered in patients with active cancer if this is preferred by the patient or for quality of life reasons.**
# Checklist of Rivaroxaban in the treatment of deep vein thrombosis and the prevention of recurrent DVT and PE.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td>Ensure the patient meets criteria <a href="#">See Pathway.</a></td>
</tr>
<tr>
<td><strong>Step 2</strong></td>
<td>Ensure the patient understands each of the following: <a href="#">See Patient decision aid</a></td>
</tr>
<tr>
<td></td>
<td>Clinical need for anticoagulation</td>
</tr>
<tr>
<td></td>
<td>How anticoagulants work.</td>
</tr>
<tr>
<td></td>
<td>Risks/benefits of anticoagulants (NOACs and warfarin)</td>
</tr>
<tr>
<td></td>
<td>Need for leg care, wearing compression stocking, rest and moderate exercise</td>
</tr>
<tr>
<td></td>
<td>What to do if experiencing pain, increased leg swelling or discolouration or dyspnoea</td>
</tr>
<tr>
<td></td>
<td>Lifestyle issues discussed, smoking, exercise, weight control and work</td>
</tr>
<tr>
<td></td>
<td>For women only, contraception, periods, pregnancy and HRT</td>
</tr>
<tr>
<td><strong>Step 3</strong></td>
<td>Check suitability <a href="#">See Prescribing information</a></td>
</tr>
<tr>
<td></td>
<td>Check there are no contraindications</td>
</tr>
<tr>
<td></td>
<td>Check if a dose adjustment is required <em>(Use rivaroxaban for DVT only if CrCl $\geq 30$ml/min)</em></td>
</tr>
<tr>
<td></td>
<td>Interactions with current drug therapy</td>
</tr>
<tr>
<td><strong>Step 4</strong></td>
<td>Safe use of NOACs</td>
</tr>
<tr>
<td></td>
<td>Possible side effects. Take with food.</td>
</tr>
<tr>
<td></td>
<td>Importance of compliance</td>
</tr>
<tr>
<td></td>
<td>Use of a calendar or mobile phone to remember doses</td>
</tr>
<tr>
<td></td>
<td>When to seek help urgently</td>
</tr>
<tr>
<td></td>
<td>What to do in an emergency</td>
</tr>
<tr>
<td><strong>Step 5</strong></td>
<td>Supply: Orange Anticoagulant booklet/ Alert card/ UHL Rivaroxaban Medicine Leaflet</td>
</tr>
<tr>
<td><strong>Step 6</strong></td>
<td>How to obtain supplies. <a href="#">See Pathway</a></td>
</tr>
<tr>
<td><strong>Step 7</strong></td>
<td>Refer to <a href="mailto:anticoagulation@uhl-tr.nhs.uk">anticoagulation@uhl-tr.nhs.uk</a> undertake 7 day follow up to check tolerability.</td>
</tr>
</tbody>
</table>

Attach patient addressograph here

Dose prescribed

Prescriber name

Signature

Must be a Haematologist, DVT specialist nurse prescriber or Acute Care Clinic AMU Consultant

Date

Print off this page and file in the patient notes when completed with the signed decision aid.
### Clinical Information: Initiating Rivaroxaban in the Treatment of First Deep Vein Thrombosis (DVT) and the prevention of recurrent DVT and PE

#### Section A: Contraindications to rivaroxaban.
- Hypersensitivity to the active substance or to any of the excipients.
- Active clinically significant bleeding
- Lesion or condition, if considered to be a significant risk for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities.
- Concomitant treatment with any other anticoagulants.
- Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C
- Concomitant treatment with any other anticoagulants
- Pregnancy and breast feeding

#### Section B: Dosing in renal impairment
Use the Cockcroft-Gault equation to estimate creatinine clearance. eGFR should not be used to estimate the dose as it will result in some patients being under or over dosed.

- **CrCl <15ml/min:** Contraindicated
- **CrCl 15-29 ml/min:** Rivaroxaban is not recommended unless under haematology supervision. Drug levels may need to be monitored. This is local guidance.

**Day 1-21**
- CrCl ≥ 30ml/min: Rivaroxaban 15mg bd

**Day 22 onwards**
- CrCl 30-49 ml/min: Rivaroxaban 15mg once daily
- CrCl ≥ 50ml/min: Rivaroxaban 20mg once daily

**Age**
- No adjustments based on age alone are required. Not recommended if < 18 years.

**Weight**
- No dose adjustment required for extreme body weight alone

#### Section C: Drug interactions
- Not recommended in patients receiving strong inhibitor of P-gp and CYP-3A4 eg tacrolimus, azoles (ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors eg ritonavir and macrolide antibiotics clarithromycin and telithromycin.
- Caution in strong inducers of P-gp and CYP-3A4 eg phenytoin, carbamazepine, phenobarbitone, St John's Wort and rifampicin.
- Caution with concomitant administration of antiplatelet agents, NSAIDs.

#### Section D: How to switch from warfarin to rivaroxaban
For patients treated for DVT, PE and prevention of recurrence, stop warfarin and initiate rivaroxaban therapy once the INR is ≤ 2.5.

#### How to switch to and from LMWH
Switching treatment from parenteral anticoagulants to rivaroxaban(and vice versa) can be done at the next scheduled dose.

#### How to switch from rivaroxaban to warfarin
- Start warfarin and continue rivaroxaban until the INR is ≥ 2.0. For the first two days of the conversion period, use standard initial dosing of warfarin and then adjust the dose as guided by INR testing.
- Whilst patients are on both rivaroxaban and warfarin the INR should not be tested earlier than 24 hours after the previous dose of rivaroxaban but prior to the next dose of rivaroxaban (ie trough level).
- For patients taking rivaroxaban twice daily, wait until the transfer to rivaroxaban once daily dosing before attempting to change to warfarin.

**Note:** Rivaroxaban can affect prothrombin levels although INR is not an appropriate reflection of the anticoagulant activity of rivaroxaban. Once rivaroxaban is discontinued INR testing may be done reliably at least 24 hours after the last dose.
The table below lists some of the differences between rivaroxaban and warfarin to help you decide the best option for you if you wish to have treatment.

<table>
<thead>
<tr>
<th></th>
<th>WARFARIN</th>
<th>RIVAROXABAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does this medicine reduce the risk of DVT/ PE</td>
<td>Once you have had DVT, warfarin reduces your risk of having another DVT. Without treatment, about 25 out of 100 people would have another DVT. With warfarin, about 3 out of every 100 people would have another DVT.</td>
<td>In clinical trials rivaroxaban was as effective as warfarin in reducing the risk of having another DVT or pulmonary embolism.</td>
</tr>
<tr>
<td>Risk of bleeding</td>
<td>The most common side effect of all anticoagulants is bleeding which can occur inside or outside the body. Bleeding into the brain (haemorrhagic stroke) or the stomach or bowels are the most serious side effects. The risk of serious bleeding is very small occurring in about 1 in 500 people in clinical trials.</td>
<td>The risk of bleeding with rivaroxaban was similar to warfarin in clinical trials.</td>
</tr>
<tr>
<td>Can the effects of the medicine be reversed?</td>
<td>An antidote (vitamin K) can be give to reverse the effects of warfarin.</td>
<td>There is no antidote for the rivaroxaban which is a major disadvantage. If you need urgent treatment, you can be given blood products whilst the anticoagulant effect wears off.</td>
</tr>
<tr>
<td>How much is known about the medicine?</td>
<td>Warfarin has been used for a long time in a lot of people and a great deal is known about its benefits and long term side effects.</td>
<td>Rivaroxaban has been used for only a few years in a relatively small group of people and less is known about its benefits and side effects. We do not know what the long term side effects are.</td>
</tr>
<tr>
<td>Do I need regular blood tests to monitor the dose?</td>
<td>Warfarin is taken once daily. At the beginning of therapy heparin injection is given subcutaneously (into the skin), as it can take a few days for warfarin to become effective. You will need blood tests regularly to monitor its effect on the blood. The dose may need to be adjusted.</td>
<td>Rivaroxaban is taken once or twice a day. There is no need to have heparin injections as it works very quickly. Rivaroxaban has a predictable effect on the body and so you will not need to have regular blood tests. (5) However you will need to have a blood test initially and after 12 months to check your kidney and liver function if you are still taking rivaroxaban</td>
</tr>
<tr>
<td>What are the risks if I forget to take medication?</td>
<td>If you regularly forget to take warfarin, you could lose the anticoagulant effect putting yourself at increased risk of stroke.</td>
<td>Taking the new anticoagulants as they have been prescribed is very important. If you regularly forget to take your medication, you could lose the anticoagulant effect more quickly than if you were taking warfarin.</td>
</tr>
<tr>
<td>Food, alcohol and other medicines.</td>
<td>Warfarin is affected by some foods, alcohol and many other medicines. You may need to alter your diet.</td>
<td>Rivaroxaban is not affected by food and alcohol. There are limited interactions with other drugs.</td>
</tr>
</tbody>
</table>

Agreed anticoagulant choice warfarin/ rivaroxaban (delete as appropriate)

Patient name---------------- Signature---------------------
------

Health care professional name----------------- Signature-------------------
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Appendix: Patient Information

The Anticoagulant Therapy Booklet provides the patient with important information about anticoagulant treatment. The booklet should be used by the prescriber to record contact details and patient specific information upon initiation and whenever renal and hepatic function tests have been undertaken. Patients should keep the book at home for easy reference but take it to show the pharmacist when they collect their prescription.

Order supplies from LRI.print@interservefm.com
Order Code LLR0053
Minimum order 50 booklets
A cost code will be required

An Anticoagulant Alert Card should be given to the patient at initiation. The card should be filled in and carried with the patient at all times in the event of an emergency.
Contact marie.harvey@uhl-tr.nhs.uk for supplies
A cost code will be required

UHL Medicine Leaflets describe in simple terms what the medicine is for, how to take it and side effects to look out for. Give one to each patient at initiation.

To print, click here and search on the A-Z browser for the correct leaflet.
Alternatively A5 colour copies can be ordered from medicines.info@uhl-tr.nhs.uk. See here for further information.