Southern Health and Social Care Trust

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Venous Thromboembolism (VTE) Prophylaxis Procedure

December 2012

1.0 Introduction

The purpose of this document is to set out the organisational arrangements for implementing the Regional VTE risk assessment tool and best practice in relation to prevention of venous thromboembolism, within the Acute Directorate of the SHSCT.

1.1 Background

Venous thrombosis is a condition in which a blood clot (thrombus) forms in a vein. A deep vein thrombosis (DVT) can form in any part of the venous system but most commonly occurs in the deep vein of the legs. In the majority of cases the DVT is asymptomatic however by reducing blood flow through the affected vein, the clot can cause acute swelling and pain. By damaging the valves and permanently narrowing the channel within the vein, the DVT can cause long term pain and swelling and skin changes; these are symptoms of venous incompetence. An embolism is created if a part or all of the blood clot in the deep vein breaks free and travels through the venous system until it lodges in a smaller vein usually in the lung when it is known as a pulmonary embolism (PE). This is most likely to result from a proximal DVT and occur either before the DVT is diagnosed or within 4 weeks of diagnosis. With many DVT's being asymptomatic the first indication of thrombosis can be chest pain, shortness of breath or collapse as a result of the pulmonary embolus. Pulmonary embolism can be life threatening. DVTs and PEs are known collectively as venous thromboembolism (VTE).

VTE is a common disease that is likely to become more prevalent due to the ageing population. Patients admitted to hospital are at increased risk of developing VTE; this will manifest as DVT on average at 1 week after discharge or PE at 3 weeks after discharge. Hospital associated VTE is defined as VTE occurring within 3 months of a hospital admission. VTE undetected and/or untreated can be fatal; in 2005 it was calculated that 25000 patients in the UK would die as a result of hospital associated VTE. It is known that risk assessment and administration of appropriate thromboprophylaxis is safe and effective in reducing the risk of VTE.

Whilst it is accepted that admission to hospital increases a patient's risk of developing VTE, there are other 'patient specific' and 'admission specific' factors that influence the VTE and bleeding risks and must be taken into consideration. This challenge of adequately identifying and assessing patients at risk of VTE was recognised by the Health & Social Care Safety Forum, who duly established a VTE Advisory Group.

In July 2011, the Chief Medical Officer for Northern Ireland recommended to all Trusts the risk assessment of all inpatients using a regional risk assessment tool prepared by the DHSC Safety Forum VTE Advisory Group. Thus would ensure that every adult inpatient has a documented VTE risk assessment on admission to hospital, and that the risk assessment is conducted in accordance with the clinical risk assessment criteria that reflects NICE clinical guideline CG92 (*"Venous Thromboembolism: reducing the risk of venous thromboembolism" January 2010)*.

2.0 Scope

This guidance applies to adult inpatients aged 18 years and over within the Acute Directorate.

Please note this guidance does not apply to patients who are pregnant or less than 6 weeks post-partum – for patients who fall within this category please refer to the obstetric risk assessments held within the patient's maternity notes.

3.0 VTE Risk Assessment Tool

This section provides guidance around completion of the VTE risk assessment tool and recommended actions following completion of the assessment. The steps needed to complete the form are summarised in Appendix A.

3.1 VTE Risk Assessment Tool: Where to find it & who should complete it

All adult inpatients must be VTE risk assessed on admission:

- Medical Inpatients: must be risk assessed using the Regional VTE risk assessment tool which is incorporated into the Medical Admission Booklet (see Appendix A)

- Surgical Inpatients (including ENT & Urology): must be risk assessed using the SHSCT amended version of the Regional VTE risk assessment tool. For emergency admissions the risk assessment tool is incorporated into the Surgical Emergency Admission Booklet on page 7. For elective admissions the risk assessment tool is on the reverse of the Elective Surgical Checklist. (see Appendix B).
- Gynaecology Inpatients (elective & emergency admissions): must be risk assessed using the Regional VTE risk assessment tool which is incorporated into the gynaecology admission pack.
- Trauma & Orthopaedic Inpatients: must be risk assessed using the risk assessment tool held within the admission pack.

In general the responsibility for completing the VTE risk assessment and prescribing thromboprophylaxis lies with the admitting Doctor. In Trauma and Orthopaedics the nurse admitting the patient is responsible for completing the risk assessment tool and for arranging for the doctor to prescribe appropriate thromboprophylaxis. Overall responsibility remains with the Consultant in charge of the patient.

When the VTE risk assessment has not been completed, Nursing and Pharmacy staff should bring this to the attention of the medical team looking after the patient and request that assessment be completed. Any request(s) of this nature should be documented in the appropriate medical and/or nursing notes. If following request the risk assessment still remains uncompleted Nursing and Pharmacy Staff should follow the appropriate lines of escalation/inform the Consultant in charge of the patient.

3.2 VTE Risk Assessment Tool: Step 1 - Assessing the Level of Mobility

All adult inpatients should have their level of mobility assessed on admission. The level of the patient's mobility must be documented by completing step one of the VTE risk assessment tool (see below).

Step 1: Assess for level of mobility – All Patients					
	Tick		Tick		Tick
Surgical patient		Medical patient expected to have ongoing reduced mobility relative to normal state		Medical patient NOT expected to have significantly reduced mobility relative to normal state	
Assess for thrombosis and bleeding risk below (Complete steps 2 – 5)				Risk assessment complete (Go to step 5)	

Any surgical inpatient or medical inpatient with significantly reduced mobility must be further risk assessed by completing steps 2 through to 5 on the risk assessment tool.

3.3 VTE Risk Assessment Tool: Step 2 - Assessing the Risk of VTE

On the risk assessment tools, the thrombotic risk factors are listed in 'patient related' and 'admission related' categories (see below).

Step 2: Review thrombosis risk Any tick for thrombosis risk factors should prompt consideration for thromboprophylaxis			
Patient related	**Tick**	**Admission related**	**Tick**
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age >60		Hip or knee replacement	
Dehydration		Hip fracture	
Known thrombophilias		Total anaesthetic + surgery time > 90 minutes	
Personal history / first degree relative with history of VTE		Surgery involving pelvis or lower limb with anaesthetic + surgery time > 60 minutes	
One or more significant medical comorbidities (eg heart disease; metabolic, endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)		Acute surgical admission with inflammatory or intra-abdominal condition	
Obesity (BMI>30kg/m^2)		Critical care admission	
Use of hormone replacement therapy		Surgery with significant reduction in mobility	
Use of oestrogen-containing oral contraceptive therapy		**The above risk factors are not exhaustive, additional risks may be considered. Other:**	
Varicose veins with phlebitis			
Pregnancy or < 6 weeks post partum (see obstetric risk assessment for VTE)			

The risk factors noted on the VTE risk assessment tool are neither exhaustive nor absolute, additional risk factors may include:

Additional Thrombotic Risk Factors Not on the VTE Risk Assessment Tool	
Acute Medical Illness	Bechet's Disease
Heart of Respiratory Failure	> 3 hours continuous travel within 4 weeks
Infection	Central Venous Catheter
Paroxysmal Nocturnal Haemoglobinuria	Medicines e.g. tamoxifen, thalidomide, raloxifene
Active Collagen Vascular Disorder	Critical Care Admission
Hyperviscosity	Lower Limb paralysis (excluding acute stroke)
Nephrotic Syndrome	

In Step 2 any risk factor should be identified by a tick and additional thrombotic risk factors should be documented in the space provided.

- The presence of one or more risk factor for VTE identifies the patient at high risk for VTE and requires the Doctor to consider the need for pharmacological thromboprophylaxis.
- If no boxes are ticked and no additional risk factors have been identified then the patient is deemed to be at low risk of VTE.

3.4 VTE Risk Assessment: Step 3 - Assessing the Bleeding Risk

The bleeding risk factors are listed in 'patient related' and 'admission related' categories.

Step 3: Review bleeding risk
Any tick should prompt staff to consider if bleeding risk is sufficient to preclude pharmacological intervention

Patient related	Tick	Admission related	Tick
Active bleeding		Neurosurgery, spinal surgery or eye surgery	
Acquired bleeding disorder (such as acute liver failure)		Lumbar puncture / epidural / spinal anaesthesia expected in the next 12 hours	
Concurrent use of anticoagulants known to increase risk of bleeding (such as warfarin with INR >2)		Lumbar puncture / epidural / spinal anaesthesia within the previous 4 hours	
Acute stroke		Other procedure with high bleeding risk	
Thrombocytopaenia (Platelets <75x10^{9}/l)		**The above risk factors are not exhaustive, additional risks may be considered. Other:**	
Uncontrolled systolic hypertension (>230/120)			
Untreated inherited bleeding disorder (such as haemophilia and von Willebrand's disease)			

The bleeding risk factors noted on the VTE risk assessment tools are neither exhaustive nor absolute. Additional bleeding risk factors may be identified and should be documented in the space provided in step 3 on the risk assessment tool.

In step 3 any bleeding risk factors should be ticked and additional risks documented in the space provided

- Any tick or additionally documented bleeding risk factor requires the Doctor to consider if the bleeding risk is sufficient to preclude pharmacological intervention.

3.5 VTE Risk Assessment: Step 4 - Choosing the Appropriate Risk Category

Before offering VTE prophylaxis, balance the risks of thrombosis and bleeding by taking into account the risks identified in steps 1, 2 and 3.

Step 4 requires the Doctor to identify which risk category the patient is in. There are three potential risk categories:

1. High risk of VTE with low risk of bleeding
2. High risk of VTE with significant risk of bleeding
3. Low risk of VTE

Reassessment of the bleeding and thrombotic risks is essential when the clinical condition changes.

4.0 Recommended Action following Risk Category Identification

Upon identification of the appropriate risk category the SHSCT Specialty Specific VTE Prevention Guidelines should be followed, please see:

- Appendix C for Medical Inpatients including stroke & palliative care
- Appendix D for Emergency Surgical Inpatients
- Appendix E for Elective Surgical Inpatients
- Appendix F for Elective Orthopaedic Inpatients
- Appendix G for Trauma Inpatients

4.1 Pharmacological Thromboprophylaxis

If the risk of VTE outweighs the risk of bleeding (i.e. high risk of VTE with low risk of bleeding) the administration of low molecular weight heparin (LMWH) should be considered. In the SHSCT, Enoxaparin is the LMWH of choice.

Fondaparinux is the drug of choice for patients with a documented history of allergic reaction to enoxaparin, including heparin induced thrombocytopenic thrombosis (HITT) and for patients who refuse to receive enoxaparin because it is manufactured from porcine analogues.

The dose of Fondaparinux is 2.5mg sc daily or if eGFR is <30ml/min, consider 50% dose reduction.

4.1.1 Novel Oral Anticoagulants

NICE has approved the novel oral anticoagulants, rivaroxaban, dabigatran and apixaban for the prevention of VTE in patients having elective hip or knee replacement surgery. NICE Clinical Guideline 92 recommends combined VTE prophylaxis with mechanical and pharmacological methods. For pharmacological prophylaxis NICE recommends, if there is no contraindication, a choice of any one of LMWH, Fondaparinux, dabigatran, rivaroxaban and unfractionated heparin. The Department of Health for Northern Ireland had approved the HSC Board's commissioning plan for Apixaban.

Rivaroxaban has been approved for use in the Southern Trust since 2009 but use has been minimal because of reports of higher rates of wound complications and clinically relevant bleeding (Jameson et al 2012, Gomez-outes et al 2012).

Similarly, dabigatran has not been used because post marketing safety data shows an increased rate of wound complications (Aquilina et al 2012, Gill et al 2011,).

The Advance 2 and Advance 3 trial data shows that apixaban 2.5mg daily is more effective than enoxaparin 40mg once daily without increased bleeding (Raskob et al 2012, Gomez-Outes et al 2012). However given concerns with the bleeding risks associated with anticoagulant prophylaxis in this group of patients, it is agreed that at present apixaban will not be incorporated in the trust guideline for VTE prevention; post marketing data will be assessed and this decision will be reviewed after one year. Use of apixaban would be considered if LMWH was not suitable for an individual patient undergoing hip or knee replacement surgery.

In August 2012 aspirin was replaced by enoxaparin as the drug of choice for VTE prevention in elective hip and knee surgery; the effectiveness and safety of LMWH over aspirin remains a concern. Surgical and VTE outcomes are being audited (Jameson et al Jan 2012, Jameson et al Feb 2012).

4.1.2 Prophylactic Dose & Precautions

The standard prophylactic dose of enoxaparin is 40mg once daily by subcutaneous injection; if eGFR is <30ml/min the dose is 20mg once daily.

If the patient is morbidly obese adjust the dose of enoxaparin:

- weight 100kg to 149kg, give enoxaparin 40mg bd; if eGFR<30, give 40mg od.
- weight above 150mg, give enoxaparin 60mg bd; if eGFR<30 give 60mg od.

Prophylactic enoxaparin and regional anaesthesia.

Please note precautions must be taken if regional anaesthesia is to be used. Placement of the catheter should be delayed for at least 12 hours after the administration of a prophylactic dose of enoxaparin.

Removal of the catheter should take place at least 6 hours after a prophylactic dose of enoxaparin.

After removal of a catheter the next dose of prophylactic enoxaparin should be given more than 6 hours later.

For further cautions and contraindications for the use of LMWH, please refer to the British National Formulary (BNF) and summary of product characteristics.

4.1.3 Commencement of Thromboprophylaxis with Enoxaparin

In general thromboprophylaxis with enoxaparin should start as outlined in the table below. For more detailed guidance please refer to the specialty specific VTE Prevention Guidelines in Appendices C to G.

Type of Patient	Time Enoxaparin should commence
Medical Inpatients	At 2200hrs on night of admission
Emergency Surgical Inpatients	At 2200hrs on night of admission or on the first night the patient is haemostatically fit for LMWH
Elective Surgical Inpatients	6 to 9 hours post-op or at 22 00hr on the night of admission

4.1.4 Administration & Duration of Thromboprophylaxis with Enoxaparin

Enoxaparin should be administered subcutaneously once daily and until the patient is no longer at risk of VTE, or according to the patient's clinical situation. Extended thromboprophylaxis with enoxaparin is recommended for:

- Elective hip replacement
- Elective knee replacement
- Fracture of neck of femur
- Major abdominal / pelvic cancer surgery

For specialty specific guidance re: duration of pharmacological thromboprophylaxis please refer to the VTE Prevention Guidelines in Appendices C to J.

4.1.5 Self-Administration & Patients Discharged on Prophylactic Enoxaparin

Due to the VTE risk and the recommended duration of pharmacological thromboprophylaxis some patients will be discharged on enoxaparin. Where clinically possible these patients should be taught to self-administer. Ideally self-administration teaching should commence with the initial dose of enoxaparin. Where patients are unable/unwilling to self-administer, family members or carers should be asked and encouraged to take part in the administration of enoxaparin.

If a patient is discharged on enoxaparin, it is the responsibility of the medical team and the ward staff to ensure that:

- Any remaining doses of enoxaparin and the accompanying sharps bin are prescribed and dispensed by the hospital prior to discharge.
- The patient and/or their carer is competent in self-administration of the enoxaparin; the patient/carer should be given the information leaflet "How to inject yourself with CLEXANE" (see Appendix K).
- The patient and/or their carer are to be given the patient Information leaflet entitled *"Things to look out for when injecting Clexane®"* and the information should be explained by the staff nurse. (see Appendix L).
- Patients should be asked to contact their GP immediately the signs or symptoms described in the leaflet occur and to not administer any further doses of Clexane until medically assessed.

- The shared care guideline is implemented: refer to this to ensure best practise.

4.1.6 Extended Enoxaparin Regime & Monitoring Requirements

Monitoring the platelet count:

Only patients who have received unfractionated heparin, have been admitted to ICU, or have undergone cardiothoracic surgery within 3 weeks require platelet monitoring for Heparin induced thrombocytopenic thrombosis (HITT). This recommendation is based on a review of HITT testing carried out on SHSCT patients since February 2008, a review of the evidence and guidance published in February 2012 by the American College of Chest Physicians and the recommendations of the British Committee for Standards in Haematology 2102.

All patients should be alert to the symptoms of HITT and the need to report these symptoms urgently to their doctor so that a blood count can be checked before the next dose of LMWH is given. The symptoms are described in the Patient leaflet "Things to look out for when injecting Clexane".

It platelet monitoring for HITT is indicated:

- Check platelet count before first dose of unfractionated heparin and within 24hours if previous exposure within 100days.
- Check platelet count on day 4 and while the patient is in hospital continue to check counts every 2 to 4 days until day 15 of therapy
- If the platelet count falls by 50% between day 5 and 21 without other obvious cause and/or the patient develops thrombosis (arterial or venous) or skin necrosis at injection site, HITT should be considered and the HITT score calculated using the tool on the intranet. If indicated, the assay for 'HITT' should be arranged by contacting the haematology registrar covering haemostasis at BCH. In addition discuss with local haematologist.

- If the patient requires monitoring after discharge use the Shared care guideline. After discharge then it is reasonable to check the count once between days 5 and 7 and once between days 10 to 14 day of therapy. In accordance with the Enoxaparin Shared Care Guideline, a member of the medical team should contact the patient's GP prior to discharge to establish whether they will accept shared cared and carry out the required monitoring. Enoxaparin is an amber drug so the patient's GP is not obliged to accept the shared care. When a GP is not willing to accept shared care, monitoring arrangements should be put in place by ward staff e.g. arrange for district nurse to take the blood samples with completed forms being given to the patient. A designated member of the medical or nursing team must follow up the results and the patient should know to contact this person regarding the results.

Monitoring potassium

LMWH is reported to cause hypoaldosterone which is rarely of clinical significance. Patients already at risk of hyperkalaemia should have potassium monitored eg renal impairment, ACE inhibitors, angiotensin II receptor blockers, potassium sparing diuretics.

4.2 Mechanical Thromboprophylaxis

Mechanical thromboprophylaxis is recommended primarily where the bleeding risk is high or as an adjunct to pharmacological measures in patients with high risk of VTE. Please see specialty specific VTE Prevention Guidelines in Appendices C to G for more details re: when to use foot impulse devices, intermittent pneumatic compression devices and thromboembolic deterrent stockings (TEDS).

4.2.1 Thromboembolic Deterrent Stockings

TEDS are available in full-length and knee-length stockings; to date the evidence available regarding the efficacy of one length over the other remains inconclusive. In the absence of conclusive evidence the SHSCT has decided that knee-length TEDS should be the stocking of choice. This decision was reached due to the following:

- Knee-length TEDS have been shown to be equally as effective as thigh-length TEDS
- Both patients and nursing staff report knee-length are easier to apply
- Both patients and nursing staff report knee-length TEDS appear to fit better
- Due to the two reasons above patients and nursing staff report greater compliance re: the use of knee-length TEDS for the duration of the required thromboprophylaxis
- Knee-length TEDS are most cost effective

The use of TEDS is contraindicated by severe peripheral vascular disease, severe dermatitis, significant leg oedema, leg deformity including gross obesity, peripheral neuropathy and recent skin graft.

Where knee-length TEDS are indicated they should be worn until the patient is no longer at risk of VTE, or according to the patient's clinical situation. TEDS should be removed daily for hygiene purposes and to inspect the skin condition.
For details on management of TEDS and contraindications see appendix J.

4.3 General Thromboprophylaxis including management of patients at low risk

Patients and/or their carers should be given verbal and written information on:

- The risks and possible consequences of VTE
- The importance of VTE prophylaxis and its possible side effects
- The correct use of VTE prophylaxis
- How patients can reduce their risk of VTE.

The Regional patient information *"Reducing the Risk of a Blood Clot"* (see Appendix I) should be offered to inpatients within the Acute Directorate and patients with lower limb plaster casts.

Hormone Replacement Therapy (HRT) and Oral Contraceptive Pill (OCP):
At Pre-Operative Assessment Clinics women being assessed for major surgery should be informed that HRT and the OCP can increase risk of VTE. If they decide to stop the OCP then effective alternative contraception must be arranged by the patient in consultation with her GP.

Women undergoing elective hip or knee replacement surgery must stop the OCP (oestrogen or progesterone) and arrange alternative contraception.

All patients including those at low risk for VTE should be mobilised as soon as possible and those patients unable to mobilise should be encouraged to do leg exercises. The medical and nursing staff should ensure that all patients are adequately hydrated.

Patients should be reassessed for VTE/bleeding risk within 24 hours of admission and whenever their clinical situation changes, this is to ensure that the prescribed thromboprophylaxis is appropriate, remains appropriate and to identify any adverse effects. Any changes to the prescribed thromboprophylaxis should be clearly documented in medical and nursing notes.

5.0 Monitoring Hospital Associated VTE and other adverse events

When a VTE occurs within 3 months of a hospital admission the Consultant in charge of the patient at the time of the preceding admission should carry out a root cause analysis and present this at the specialty M&M meeting. The event and RCA will be forwarded by the M&M administrator to clinical governance. The outcomes will be used to review the VTE prevention guidance.

The anticoagulant team will assist with the early screening and identification of patients with hospital associated VTE by reviewing the Doppler ultrasound and CT PA reports. Patient details will be forwarded to the M&M administrator who will send these to the Consultant with the RCA form.

In addition if a Consultant identifies a patient with hospital associated VTE the patients ID should be forwarded to the M&M Administrator. When the admission was to a hospital within another Trust the anticoagulant team will forward a letter and the RCA form to the consultant in charge.

Bleeding and other adverse events associated with the use of prophylaxis should be reported on an IRI form and be discussed at the specialty M&M to inform future guidance.

6.0 Evidence & References

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