**Trust Standard Operating Procedure**

Plymouth Hospitals NHS
NHS Trust

# Investigation and Management of Venous Thromboembolism (VTE)
# Standard Operating Procedure

| Date | Version |
|---|---|
| **January 2016** | **Draft v 2.0** |

## Purpose

This procedural document sets out the Trust's approach to investigating suspected VTE events and the treatment of confirmed events

There are Trust guidelines for the investigation of both deep vein thrombosis (DVT) and pulmonary embolism (PE). There are also policies for the treatment of VTE events, using oral anticoagulation (Vitamin K antagonists and direct oral anticoagulants (DOAC)) and the procedure for discharging the patient to primary care for onward management.

This document sets out the requirement for any suspected VTE event.

## Who should read this document?

Trust Clinical Directors because they are required to understand the Trust process of managing patients with suspected VTE and treating patients who develop VTE either as a hospital inpatient or admitted for management of such.

Senior clinicians, because they are responsible for the investigation and subsequent treatment of VTE events in patients under their care.

All clinical staff, because they may be involved in the care of patients suspected of VTE and in treating PE and DVT. They may also be involved in the education of other clinical staff and patients who develop VTE.

## Key messages

All patients with suspected VTE should follow a pathway for management, including appropriate radiological investigation as required.

Appropriate treatment should be commenced in all patients with suspected and subsequently confirmed positive VTE events, following Trust procedures.

For commencing LMWH and oral anticoagulation with warfarin, the Trust prescription chart contains the protocols to be followed. For the novel anticoagulant (rivaroxaban) a separate locality guidance document exists.

## Accountabilities

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| **Production** | Tim Nokes, Consultant Haematologist and Chair of Thrombosis Committee |
| **Review and approval** | Thrombosis Committee |
| **Ratification** | Medical Director |

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| **Dissemination** | Head of Clinical Governance Systems |
| **Compliance** | VTE Prevention Team and Thrombosis Committee |

| **Links to other policies and procedures** |
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| VTE Prevention SOP<br>Patient Group Directive for: supply and administration of ENOXAPARIN for use in the Nurse Led DVT clinic<br>Patient Group Directive for: supply and administration of WARFARIN for use in the Nurse Led DVT clinic<br>Patient Group Directive for: supply and administration of RIVAROXABAN for use in the Nurse Led DVT clinic<br>Guidelines for the Prescribing of Low Molecular Weight Heparin (LMWH) in Secondary Care |

| **Version History** | | |
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| **v1.0** | July 2012 | First version, compiled in accordance with NHSLA minimum expectations |
| | Current version = v 2.0 | Compiled with information about use of novel anticoagulants |

| **Last Approval** | **Due for Review** |
|---|---|
| Jan 2016 | Jan 2019 |

*PHNT is committed to creating a fully inclusive and accessible service.*

*Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff.*

*We will treat people with dignity and respect, actively promote equality and diversity, and eliminate all forms of discrimination regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/ maternity.*

**An electronic version of this document is available on the Trust Documents Network Share Folder (G:\TrustDocuments). Larger text, Braille and Audio versions can be made available upon request.**

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

# Investigation and Management of Venous Thromboembolism (VTE)

# Standard Operating Procedure

## 1 Purpose and Scope

The purpose of this SOP is to enable healthcare practitioners to follow a common pathway for all VTE management (apart from those presenting to the DVT clinic, where there is already a designated PGD in place) and those treated by the Acute GP Service where a slightly different pathway is used for outpatient management.

### Definitions

- **Venous thromboembolism (VTE)** - A condition in which a blood clot (thrombus) forms in a vein. It most commonly occurs in the deep veins of the legs; this is called deep vein thrombosis (DVT). The thrombus may dislodge from its site of origin to travel in the blood – a phenomenon called embolism. Usually the embolism occurs in the lung, called pulmonary embolism (PE) (NICE, 2010).

- **Venous thromboembolism risk assessment** – Is a tool to identify patients at risk of developing a VTE. This assessment is based on a combination of the condition of the patient and the procedure for which the patient is admitted and on any predisposing risk. It is combined with an assessment of the risk of bleeding. In England, it is mandated to use the DH risk assessment tool for hospital inpatients

- **Post Thrombotic Syndrome (PTS)** - DVT can be life threatening when it occurs in an unusual site (e.g. intra-abdominal), but can also predispose to chronic changes in the legs, causing permanent swelling, varicose veins, poor skin condition (often with discoloration) and eventually chronic ulceration. This is known as post thrombotic syndrome, occurring in approximately one third of patients and caused predominantly by damage to valves in leg veins from the DVT. It may be prevented in 50% of cases by the application of appropriate compression hosiery. It is often impractical to apply compression hosiery in hospital, as the affected leg is usually too swollen and inflamed to tolerate the stockings.

- **D-Dimer** – This is a fibrin degradation product, which is a component of blood produced after a blood clot is broken down, by a process called fibrinolysis. It is called D-Dimer as it contains two cross-linked D fragments of the fibrinogen protein.

- **Patient Group Directive (PGD)** – These are legal frameworks allowing certain health care professionals to supply and administer medicines to groups of patients that fit the criteria laid out in the PGD. It is signed by a senior doctor and agreed by a pharmacist and allows a nurse to supply and/or administer prescription-only medicine using their own assessment

of patient need without referring back to a doctor for an individual prescription

- **INR** – International normalised ratio is a measurement of the extrinsic pathway of coagulation and derived from the Prothrombin Time (PT). It measures the time for blood to clot and compares this to a control standardised against an international standard, used to monitor the effectiveness of anticoagulants. The higher the INR the longer it takes blood to clot
- **FBC** – Full blood count is a blood test that measures the number of red cells, white cells and platelets in patient's blood. It is used to determine general health status and for safety of VTE treatment in relation to the baseline platelet count.
- **Renal Function** – essential for those patients being started on Enoxaparin, rivaroxaban or any other direct oral anticoagulant
- **Clinical Probability Score** – Is a scoring system (e.g. Modified Wells) for assessing the probability of a DVT or PE based upon validated criteria such as previous VTE, active cancer, leg swelling or whether alternative diagnosis is as likely. It is usually used in parallel with D-Dimer to assess the likelihood of a VTE event

## Regulatory background

The 2012/13 NHS Litigation Authority Risk Management Standards for NHS Trusts providing acute services historically set expectations for the prevention and management of the risk of VTE. NICE clinical guidance 92 also states the need for VTE risk assessment.

## Key Duties

### Medical Director

As the executive lead for managing VTE risk across the Trust, the Medical Director is responsible for ensuring that appropriate arrangements are established for the prevention and management of VTE. This will include ensuring the establishment and maintenance of the Thrombosis Committee and the appointment of an appropriate clinician as the lead for thrombosis within the Trust.

### Thrombosis Committee and Trust Lead Clinician for thrombosis

The Thrombosis Committee and Lead Clinician are responsible for:

- Ensuring that the procedures set out in this SOP are followed across the Trust, for all relevant patients.
- Seeking assurance from clinical areas that clinically correct VTE treatment decisions are implemented.
- Receiving monitoring reports from the VTE prevention team on these standards and also including VTE outcomes.

- Overseeing the education of patients and staff on matters concerning VTE prevention.

**Clinicians**

Clinicians are responsible for ensuring that:

- The procedure for suspected VTE is followed as detailed in Section 2 of the SOP
- Positive VTE events are treated according to appropriate treatment schedule within this SOP.

**Trust VTE Prevention Team**

Trust VTE prevention team are responsible for:

- Acting as a resource for the investigation and treatment of VTE events diagnosed within the Trust
- To audit the appropriateness of VTE treatment by spot check audit of five sets of notes in each clinical area monthly
- Reporting the results of this monitoring to the Thrombosis Committee.

**Monitoring and assurance**

Compliance with this SOP will be monitored by the VTE CNS as detailed above.

The results of the monitoring undertaken, including any recommendations and actions to address issues arising, will be reported by the Clinical Lead and VTE CNS to the Thrombosis Committee at each meeting, generally every two months. Ongoing review and implementation of recommendations and actions will be overseen by the Committee and will be managed in accordance with the severity and priority of the issue arising.

## 2 Procedure to Follow

**Procedure to be followed if VTE is suspected**

The procedure for managing patients with suspected VTE depends on where the patients are presenting.

1. **Community patients with suspected DVT:** Present to the DVT clinic (or Emergency department (ED), acute medical unit (AMU) or acute GP unit (AGPU) if out of hours). In the nurse-led DVT clinic, these patients are managed according to a patient group directive (PGD). Out of hours, patients should be assessed according to the criteria from the DVT clinic and if high risk for DVT, treated accordingly with enoxaparin or a novel anticoagulant ( usually rivaroxaban or apixaban) and referred to the DVT clinic for ongoing investigation and management at the earliest possible time.

2. **Community patients with suspected PE:** Present to AGPU, ED or AMU and are assessed and managed according to Trust guidelines on the Trust intranet. A proportion of low risk patients will be managed as outpatients and others as inpatients, according to a risk assessment score, also present within the Outpatient PE guidelines on Trust intranet.

3. **Patients presenting with suspected DVT or PE as inpatients:** Should be prescribed a treatment dose of enoxaparin if there is any delay in obtaining a radiological scan. Such patients are at high risk for VTE and should be scanned without further assessment (Clinical probability score or D-Dimer), acknowledging their high-risk status.

**Summary of investigation and management of suspected VTE**

- Suspicion of VTE episode should immediately flag an assessment of risk, whether that be according to distinct scoring systems (DVT clinic, AGPU and ED) or be automatic (inpatients). Diagnosis and subsequent management of VTE will depend on the circumstances around its presentation. Guidelines exist for diagnostic pathways for DVT and PE, which differ, depending on whether the patient presents within hospital or from the community. Generally, suspected DVTs presenting in the community are diagnosed and managed by the nurse-led DVT clinic. Acute suspected PE in the same patients are generally managed in the acute GP unit, Medical Assessment Unit or Emergency Department. In-hospital presentation of suspected VTE does not require a D-Dimer or clinical risk algorithm (unlike the presentations from out of hospital), acknowledging that such patients are already at high risk. The team responsible for their care manages these patients as hospital inpatients. The further purpose of this SOP is to ensure a common pathway for all VTE treatment.
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- D-Dimers will be used to further assess likelihood of VTE in DVT clinic, AGPU and ED). These should not be used for hospital inpatients.

- An appropriate scan must be organised as soon as possible – within 24 hours at latest if feasible.

- If radiology scan cannot be obtained within four hours, commence treatment dose of LMWH (currently enoxaparin), as long as there is not a significant bleeding risk as assessed on the bleeding risk assessment within the Trust prescription chart.

**Management of patients with acute VTE. Initiating anticoagulation following VTE diagnosis**

Following VTE diagnosis the goal of effective anticoagulation is principally to prevent thrombus propagation and embolisation.

The initiation of treatment should be with a rapid-acting anticoagulant, which may be a low molecular weight heparin (LMWH), but may also be unfractionated heparin (UFH), fondaparinux (very rarely) or one of the direct oral anticoagulants (DOAC). The first three of these agents are given parenterally.

Warfarin is usually commenced at the same time as the parenteral anticoagulant (if VTE confirmed) and both are continued until the INR is therapeutic (usually 2-3) for 24 hours or the parenteral agent for at least 5 days.
Rivaroxaban is an oral anticoagulant with a short half-life; therefore treatment is started immediately following VTE diagnosis, with 15mg twice daily (switching to 20 mg daily after three weeks) for all patients with eGFR >30ml/min/1.73^2.
Apixaban is another oral anticoagulant, again with a short half-life to be started immediately post VTE diagnosis. The dose, for patients with eGFR >30ml/min/1.73^2, is 10mg twice daily for a week then switch to 5mg twice daily.
Dabigatran is another oral anticoagulant that differs from the previous medication as the treatment dose, with normal renal function eGFR > 30mls/min/1.73^2, is 150mg BD following 5 to 10 days of parenteral anticoagulation.
UFH or reduced doses of LMWH should be considered when renal function is significantly abnormal ( eGFR <30mls/min/1.73^2).

Enoxaparin by subcutaneous injection and warfarin tablets or Rivaroxaban, Apixaban and Dabigatran are the current default treatment for PE and DVT. Edoxaban has not yet received NICE approval for VTE treatment though this is likely to happen. Patients with active cancer should be treated with enoxaparin alone (see guidelines for use of LMWH).

Once the VTE event is confirmed, a risk assessment is important to assess the risk of bleeding. This is formally addressed in the PGD within the nurse-led DVT clinic; in other circumstances, physicians are required to assess the bleeding risk. Base-line blood tests should include: renal/liver function, FBC, clotting screen. One of the most important elements of treatment is to establish the patient's weight as the enoxaparin dose is based upon this. The weight must be accurately recorded on outpatient documents or the front page of the patient's drug chart for inpatients. This weight is then applied to work out the treatment dose. See enoxaparin dosing within the hospital prescription chart or the DVT clinic PGD. Enoxaparin should then be prescribed, initially for 5 days, but ensure this is reviewed for appropriateness, together with the INR. If a decision is made to anticoagulate with Rivaroxaban or Apixaban then no clexane is required. Rivaroxaban is initially prescribed at a higher dose (15mg bd) for the first 3 weeks, being switched to the maintenance dose (20 mg od) and Apixaban 10mg BD for the first week then 5mg after this. If using

Dabigatran, this is commenced after 5 days of Enoxaparin (1.5mg/kg) at the dose of 150mg bd.

If appropriate, warfarin should also be commenced on the same day using one of the two loading schedules in the inpatient drug chart. Daily INR checks should be requested for the first four days of warfarin loading to enable accurate prescribing, thereby ensuring a therapeutic level is reached safely and without delay. In the drug chart the target INR, indication for warfarin, duration of treatment and patient details should be recorded (similarly the PGD). The INR result and the warfarin dose given each day should also be detailed and when the INR > 2 for 1 days the enoxaparin injections should be stopped, or earlier if the INR rises above 3.0.

When treatment with Warfarin is initiated by either the DVT clinic or AGPS, with patients treated on an out patient basis, it is often not practical to request daily INR monitoring for the first four days. If possible early discharge to primary care should be organized for ongoing management after careful discussion with an appropriate GP. INR monitoring must be requested at least every 48 hours and it may be necessary to delay the start of warfarin if the weekend intervenes.

Patient discharge following initiation of VTE treatment will depend upon many factors. In all circumstances, consideration for discharge to the GP should not be undertaken until the INR is therapeutic and preferably stable, unless the GP is happy to take over initiation of treatment from an earlier stage.

All patients require a yellow oral anticoagulation therapy pack, which includes a therapy book and wallet-sized yellow card. All patients should be counselled about warfarin, focusing on safety in relation to dosing, concurrent medications, foodstuffs, pregnancy (including pregnancy testing where appropriate) and potential to cause bleeding. The use of a similar safety leaflet would also be indicated for patients starting any of the Direct Oral anticoagulants. Neither warfarin or any DOAC's are considered safe to use during pregnancy, so careful counseling and pregnancy testing of all fertile women should be carried out.

**Duration of Anticoagulation Treatment**

Guidance from NICE, Venous thromboembolic diseases: diagnosis, management and thrombophilia testing Clinical Guidance No CG 144, stresses the importance of determining whether the VTE was a provoked or unprovoked event. These are defined as;

Provoked DVT or PE in a patient with an antecedent (within 3 months) and transient major clinical risk factor for VTE for example surgery, trauma, significant immobility, pregnancy or having hormonal therapy (oral contraceptive or hormone replacement therapy).

Unprovoked DVT or PE in a patient with no antecedent major clinical risk factor for VTE who is not having hormonal therapy or active cancer,

thrombophilia or a family history of VTE because these are underlying risks that remain constant with the patient.

In addition patients with active cancer should be offered LMWH and this continued for six months when the patient should be reviewed to assess the risks and benefits of continuing anticoagulation.

All patients should be treated, initially, with three months treatment within 24 hours of diagnosis and at three months an assessment of the risk and benefit of continuing anticoagulation should be made. For patients with unprovoked VTE consider offering treatment beyond three months taking into account benefits and risks associated with this.

Haematology will review any patients to look at whether to stop or continue anticoagulation particularly following an unprovoked event. Referral should be made via Red Top to Dr Tim Nokes secretary.

**Advice about compression hosiery to prevent post-thrombotic syndrome (PTS):**

Patients with new diagnosis of DVT (of the lower limbs) should be advised to wear below knee compression hosiery (UK grade 2 or 3) from as soon as possible following diagnosis (within a week of diagnosis if possible), in order to reduce the risk of PTS. Class 2 can be obtained from most large pharmacies, class 3 require a prescription from GP.

After clinical assessment of patient, consideration should be given to the risk of cancer, particularly in patients (usually >40 years) with unprovoked VTE events. Such consideration should include further radiological assessment, which is usually CT scanning and mammograms.

**Summary of treatment for VTE:**

- Patient weight written on drug chart or within PGD.
- Check renal function, liver function, FBC and clotting screen (& pregnancy test as necessary)
- Choice made following discussion with the patient of the medication to be used to treat the thrombosis
- Enoxaparin prescribed appropriate for weight (and renal function) if warfarin or dabigatran to be used.

- INR target duration and indication written on drug chart or PGD.
- Daily INR for first 4 days requested for patients on warfarin.
- The loading schedule followed to initiate warfarin therapy.
- The dose given and INR result recorded on drug chart.
- Enoxaparin stopped when INR > 2 for 1 day or INR > 3.0.
- Ensure patient aware of any dosing change for DOAC and when this will happen
- Ensure community anticoagulation information sheet is completed before patient discharged on warfarin or, for other treatments, that dosing, indication and duration or review date are clear on the discharge prescription.
- Ensure patient education is adequate for anticoagulation, symptoms of recurrent VTE and post thrombotic syndrome.
- Ensure yellow anticoagulation booklet (or equivalent for DOAC) is completed.

## 3 Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Thrombosis Committee and ratified by the Medical Director.

Non-significant amendments to this policy document may be made, under delegated authority from the Medical Director, by the nominated author. These must be ratified by the Medical Director and should be reported, retrospectively, to the Thrombosis Committee.

Significant reviews and revisions to this policy will include a consultation with senior clinicians in the Trust and Thrombosis Committee. All directors of the Trust will be invited to contribute to proposed revisions of the policy. For non-significant amendments, informal consultation will be restricted to directors and clinicians who are directly affected by the proposed changes.

**Dissemination and implementation**

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

## 4 Reference material

The following documents are referred to in this policy, or provide additional sources of reference material:

Guidance about compliance. Essential standards of quality and safety. **Care Quality Commission**, March 2010

NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and non-NHSProviders of NHS Care, 2012/13. **NHS Litigation Authority**, January 2012.

BCSH guidelines on oral anticoagulation with warfarin – fourth edition. 2011

National Patient Safety Agency. Patient Safety Alert 18. Actions that can make anticoagulation therapy safer. March 2007

In addition, the following references should be considered:

Bick RL, Proficient and cost-effective approaches for the prevention and treatment of venous thromboembolism (2000), *Drugs*, 60(3) 575-595