Birmingham Women's NHS
NHS Foundation Trust

Prevention and Treatment of Venous Thromboembolic Disease Guideline

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Name/Designation of Lead Officer:	Dr Will Lester – Consultant Haematologist
Name/Designation of author:	Dr Will Lester – Consultant Haematologist Pam Jordan – Specialist Midwife Dr Tracey Johnston – Consultant Obstetrician Mr Bill Martin - Consultant Obstetrician Mr Matthew Parsons – Consultant Gynaecologist
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Version Control

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1. Introduction

Deep vein thrombosis (DVT) is commonly without symptoms, however, the condition can lead to sudden death due to pulmonary embolism (PE) or cause long-term effects on health due to venous ulceration and development of residual pain and/or swelling in the limb (post-phlebitic limb syndrome). Post-mortem studies suggest that PE following lower limb deep vein thrombosis is the cause of death in 10% of patients who die in hospital (Lindblad 1991). The risk of venous thrombo-embolism (VTE) is increased tenfold during pregnancy (Rodger et al, 2003) and the puerperium and is the leading cause of maternal death in the UK (Lewis 2004).

In 2005, a House of Commons Health Committee report on the prevention of venous thromboembolism in hospitalised patient (2005) and the subsequent Government response serve to highlight that there are currently far too many preventable deaths from venous thromboembolism (VTE) in hospitalised patients (an estimated 25,000 deaths a year in England due to VTE). This is more than the combined total of deaths from breast cancer, AIDS and traffic accidents, and more than twenty-five times the number who die from MRSA

In April 2007, NICE produced guidelines on thromboprophylaxis for high risk surgical patients and the CMO authorised guidelines produced by an expert committee on thromboprophylaxis for hospitalised patients, including medical patients. In September 2008, a template for risk assessment was published by the Department of Health. This was updated and re-issued in March 2010.

The most recent guidance has been published by NICE (2010) and it addresses the need to reduce the risk of VTE in patients admitted to hospital, including pregnancy related admissions. NICE have also produced a set of quality standards relating to VTE prevention (June 2010)

The Trust guidelines have been based on advice from both the NICE (2010) guidelines and the RCOG Green Top guidelines (2009)

2. Objectives

To provide a comprehensive guideline for the prevention and treatment of venous thromboembolic disease for all women treated at Birmingham Women's NHS Foundation Trust.

3. Policy Scope

This guideline applies to all women treated by staff from Birmingham Women's NHS Foundation Trust, including both gynaecology and maternity.

4. Document Definitions

4.1 Clexane

Proprietary name for enoxaparin (low molecular weight heparin)

4.2 GECS

Graduated Elastic Compression Socks also commonly referred to as 'TEDS' which can be fitted either below or above knee

4.3 LMWH
Low molecular weight heparin

4.4 Thromboprophylaxis
A term for interventions to reduce the risk of developing VTE. This includes mechanical and pharmacological interventions

4.5 VTE
Venous Thromboembolism (includes deep vein thrombosis and pulmonary embolism)

5. Duties and Responsibilities

5.1 Nursing and Midwifery Staff

- Provide nursing and midwifery care to all women treated at Birmingham Women's NHS Foundation Trust.
- Ensure risk assessments are carried out and if any risk factors are detected, women are referred to medical staff.
- Ensure appropriate documentation is completed.

5.2 Medical Staff (Obstetric & Gynaecology)

- Receive referrals from nursing/midwifery staff and review women.
- Ensure individual management plans are completed and documented in the medical notes, seeking senior and specialist medical help as appropriate.
- Prescribe drugs as required.
- Ensure follow up on transfer home.

5.3 Specialist Haematology Team

- Provide expert advice and support to the hospital staff, both medical, nursing and midwifery.
- Provide advice and guidance on the formation of individual management plans for women, including investigations and treatment.

6. Procedures

6.1 Risk Assessment and Thromboprophylaxis for Gynaecology Patients

STEP 1

Review risk factors for VTE on the Gynaecology risk assessment sheet (Appendix D) on admission and at pre-op assessment clinic.

STEP 2

Complete the electronic VTE risk assessment form on Lorenzo Care Plan

STEP 3

Check there are no contraindications to intervention (graduated compression stockings and/or clexane). See table 1 for details.

STEP 4

Refer to Gynaecologist to prescribe appropriate treatment (if indicated by risk assessment score):

- All patients, including day cases, should be risk assessed on admission and re-assessed within 24 hours and if the clinical situation changes.
- All patients should be offered verbal and written information on VTE prevention on admission and also on discharge, along with information about signs and symptoms of VTE. Women should be advised to keep as mobile and well-hydrated as possible. Trust patient information leaflet "Preventing Deep Vein Thrombosis and Pulmonary Emobolism" contains all the relevant information and should be given to patients at pre-op assessment clinic and / or discharge.

All patients should be risk assessed on admission to hospital. Patients should be reassessed within 24 hours of admission and whenever the clinical situation changes.

(Based on Department of Health national risk assessment tool)

6.1.1 Assessment of Risk Procedure

STEP ONE

Assess all patients admitted to hospital for level of mobility (tick one box). All surgical patients, and all medical patients with significantly reduced mobility, should be considered for further risk assessment.

STEP TWO

Review the patient-related factors shown on the assessment form against thrombosis risk, ticking each box that applies (more than one box can be ticked).
Any tick for thrombosis risk should prompt thromboprophylaxis based on Trust guidelines.

The risk factors identified are not exhaustive. Clinicians may consider additional risks in individual patients and offer thromboprophylaxis as appropriate.

STEP THREE

Review the patient-related factors shown against bleeding risk and tick each box that applies (more than one box can be ticked).

STEP FOUR

Prescribe appropriate treatment.

6.1.2 Notes for Prescribing Thromboprophylaxis

- For surgical patients with risk factors and no contraindications, please prescribe either above or below knee TEDS, whichever is more appropriate for the patient. In high risk patients, intermittent pneumatic compression may be used as an alternative or in addition to graduated compression/anti-embolism stockings in theatre and during recovery on the ward if appropriate, especially if Enoxaparin (Clexane) is contraindicated.
- For all inpatients, if risk factors identified and no contra-indication, Enoxaparin 40mg* once daily is recommended, usually prescribed in the evening at 5pm. The usual timing for a post-operative Enoxaparin dose is 4-12 hrs after surgery unless there is excessive bleeding so may need to be delayed till 10pm if surgery is on the afternoon list.
  It should usually be continued until the patient is fully mobile. High risk patients (e.g. previous VTE) should receive a minimum of 5-7 days after major surgery
  *20mg recommended if:
  Creatinine >150umol/L
  Weight <50kg
  When given <12 hours pre-operatively
  *40mg bd to be considered if morbidly obese (e.g. > 140 kg) or weight > 100kg and history of VTE.

- **Do not give within 12 hours before and 4 hours after regional anaesthesia (e.g. epidural)**
- Extended thromboprophylaxis (up to 30 days) should be considered in patients with a history of VTE and is recommended after pelvic surgery for cancer
- Most day case admissions will not require enoxaparin prophylaxis, as the majority of day case procedures are classed as low risk for VTE e.g. :
  Hysteroscopic procedures
  Laparoscopic surgery*
  Cystoscopy
  Bladder neck installations*
  Vulval surgery*
  Change of coil (IUCD)
  Surgical TOP / evac*

  Patients with risk factors on assessment who are undergoing above procedures will usually require TED stockings only

  * Very high risk patients (e.g. previous DVT / PE, or multiple risk factors on risk assessment) may require enoxaparin for these procedures. Please ask for advice from Haematologist / Consultant Gynaecologist

Advise patients to consider stopping combined oral contraceptives 4 weeks before elective surgery – ensure they are advised re alternative contraception

TABLE 1: **CONTRAINDICATIONS TO MECHANICAL AND PHARMACOLOGICAL THROMBOPROPHYLAXIS**

CONTRAINDICATIONS TO GRADUATED ELASTIC COMPRESSION STOCKINGS (GECS)

- Suspected or proven peripheral arterial disease
- Peripheral neuropathy/significant sensory impairment
- Skin fragility ("tissue paper" skin, cellulitus, dermatitis, gangrene or recent skin graft) or venous ulceration
- Known allergy to material of manufacture
- Congestive heart failure/pulmonary oedema
- Severe leg oedema
- Unusual leg size or shape/ limb deformity preventing correct fit

CONTRAINDICATIONS TO CLEXANE

- Haemophilia, profound thrombocytopenia or other bleeding disorder
- Acute thrombotic stroke or history of haemorrhagic stroke
- Acute or end stage renal failure
- Severe liver disease
- Active GI bleed or acute antenatal bleed (review daily)
- Ectopic pregnancy
- Severe hypertension
- Oesophageal varices, leaking aortic aneurysm or pericarditis
- Recent eye surgery
- Non operatively managed hepatic and splenic injuries
- Undergoing a thyroidectomy or tonsillectomy
- Acute bacterial endocarditis or meningitis or sepsis with DIC
- Heparin allergy, including heparin induced thrombocytopenia (HIT)
- On oral anticoagulants with therapeutic INR

TABLE 2: SIGNS AND SYMPTOMS OF DVT AND PE

DVT	PE*
<u>SYMPTOMS</u> Swelling of calf or leg Pain or stiffness of affected limb	Difficulty breathing (may be sudden onset) Pleuritic chest pain (sharp pain worse on inspiration) Haemoptysis (coughing up blood Syncope (partial or complete loss of consciousness)
<u>SIGNS</u> Pitting oedema / calf swelling Increased skin temperature Erythema / skin discolouration Tenderness Mild fever	Tachypnoea (> 20 breaths per min) Tachycardia Hypotension and elevated venous pressure Pleural rub Mild fever

***NB signs may be absent. Suspect massive PE if severe dyspnoea, dull central chest pain, elevated venous pressure, hypotension and right heart failure**
In the presence of known risk factors, symptoms and signs become increasingly significant.

6.1.3 Management of Venous Thromboembolism in Non-pregnant Women

Before starting anticoagulants:

- Take blood for FBC, PT, PTT, renal and liver function. D Dimers are not helpful during pregnancy, post-partum or post-surgery
- Initiation of anticoagulation need not await scanning (see table 2 for symptoms and signs of VTE)
- Confirm diagnosis by Doppler ultrasound for DVT and VQ or CTPA scan for PE
- Once all results are available review patient's management
- Clexane (Enoxaparin) should be given sub-cutaneously 1.5mg per kg body weight once daily. See table 3. If active haemorrhage or patient immediately post surgery or if renal impairment, consult Haematologist for advice
- Use prefilled syringe nearest to patient's weight. Reduce doses in the elderly, in renal and hepatic failure
- It is recommended that a platelet count is performed every 2-4 days from day 4-14 after starting Clexane in non pregnant women. A platelet fall of >50% from baseline pre-surgery may indicate heparin induced thrombocytopenia

TABLE 3: CLEXANE DOSE FOR VTE IN NON PREGNANT WOMEN

Patient's weight in (kg)	Syringe Colour	Clexane dose in (mg)	Injection volume in (ml)
100mg/ml Clexane Syringe			
40	Orange 60	60 once daily	0.60
45	Brown 80	68 o.d.	0.70
50	Brown 80	75 o.d.	0.75
55	Black 100	83 o.d.	0.85
60	Black 100	90 o.d.	0.90
65	Black 100	98 o.d.	1.00
150mg /ml Clexane Syringe			
70	Mauve 120	105 o.d.	0.70
75	Mauve 120	113 o.d.	0.75
80	Mauve 120	120 o.d.	0.80
85	Blue 150	128 o.d.	0.85
90	Blue 150	135 o.d.	0.90
95	Blue 150	143 o.d.	0.95
100	Blue 150	150 o.d.	1.00

When warfarin is not contra-indicated start it when proven venous thrombosis (see table 4 for dosing algorithm). Use lower starting doses (eg. 5mg) in the elderly.

Continue Clexane until INR >2.0 and both Clexane and Warfarin have been given for at least five days then continue with Warfarin for the optimum duration (usually 3 to 6 months). Always inform Haematologist or deputy before discharge and send a written referral form to Haematology laboratory. Supply the patient with yellow anticoagulant booklet and sufficient tablets until follow up clinic date.

TABLE 4: WARFARIN INITIATION ALGORITHM AND EMERGENCY REVERSAL

Day	INR	Warfarin dose in mg
1	<1.4	10
2	<1.8	10
	1.8	1.0
	>1.8	0.5
3	<2.0	10
	2.0-2.1	5.0
	2.2-2.3	4.5
	2.4-2.5	4.0
3	2.6-2.7	3.5
3	2.8-2.9	3.0
3	3.0-3.1	2.5
3	3.2-3.3	2.0
3	3.4	1.5
3	3.5	1.0
3	3.6-4.0	0.5
3	>4.0	NIL
Day	**INR**	**Maintenance dose***
4	<1.4	>8.0
	1.4	8.0
	1.5	7.5
	1.6-1.7	7.0
4	1.8	6.5
	1.9	6.0
	2.0-2.1	5.5
	2.2-2.3	5.0
	2.4-2.6	4.5
4	2.7-3.0	4.0
	3.1-3.5	3.5
	3.6-4.0	3.0
	4.1-4.5	miss one day then 2mg
	>4.5	miss 2 days then 1 mg

Target INR:

Single episode of DVT or PE	2.5
Recurrent DVT or PE when not on Warfarin	2.5
Atrial fibrillation	2.5
Recurrent DVT or PE while on Warfarin	3.5
Mechanical heart valve replacement	3.5
Arterial disease	3.5

Reversal of Warfarin

1 Patients with serious bleeding:
Stop Warfarin
Vitamin K 5mg IV stat
FFP or prothrombin complex concentrate (Beriplex 30u/kg) & consult haematologist

2 Patients without significant bleeding:
INR < 8.0 omit Warfarin until INR <5.0
INR >8.0 Vitamin K 1-2 mg po
INR >10 Vitamin K 1-2 mg IV stat
Repeat INR following day

Duration of anticoagulation:

DVT	3-6 months
PE	3-6 months
Atrial fibrillation	long term
Mechanical heart valve	long term
Recurrent DVT PE while on Warfarin	long term

6.1.4 Management of Anticoagulants and Anti-platelet Agents in Gynaecological Surgery

Discontinuation of antiplatelet or anticoagulant therapy carries a risk of thrombosis. For many patients a short period without treatment (or reduction in INR in the case of warfarin) carries only a small risk but in others the chance of thrombosis is significant.

Anticoagulants in the Peri-operative Period

Patients receiving Warfarin for DVT, PE & Atrial fibrillation (INR 2-3)

All non-urgent surgery should be delayed until at least 3 months after VTE.

1. Minor surgery (INR before surgery approx 2.0 or less): Omit Warfarin 2 days before and resume same dose on day of surgery.

Patients who have other risk factors such as obesity, immobility etc. should receive Clexane 40 mg daily post surgey until INR reaches 2.0

2. Major surgery: Omit Warfarin 4 days. INR on day of surgery must be <1.5. Resume the previous dose of Warfarin on the day of surgery. Commence Clexane 40mg daily on the evening before surgery and then at least 4 hours after surgery if haemostasis secured. Use TEDS and consider use of intermittent pneumatic compression device (eg. FLOTRON boots)

3. For women at high risk of thrombosis eg. recent venous thrombosis when the surgery cannot be delayed or antiphospholipid syndrome, more intensive heparin bridging therapy may be required. Please discuss with consultant haematologist.

Patients receiving Warfarin for Prosthetic Heart Valves

1. Minor surgery: (INR before surgery approx 2.0 or less): Omit Warfarin 2- 3 days prior to surgery. Use Clexane up to 1.5mg/kg daily If INR <2.0 (last dose more than 24 hours before surgery). Resume the previous dose of Warfarin on the same day of surgery. For modern prosthetic aortic valves in women in sinus rhythm with good ventricular function, Clexane 1mg/kg once daily post surgery until INR >2.5. For high risk prosthetic valves, consider IV unfractionated heparin APPT ratio 1.5 - 2.5 or Clexane 40mg 4 hours post surgery then 1mg/kg bd from 16 hours post surgery if no bleeding.

2. Major surgery: proceed as for minor surgery but omit warfarin 4-5 days. Each patient must be assessed individually and discussed with haematologist and/or cardiologist

Antiplatelet Agents in the Peri-operative Period

General principles:

- Aspirin and Clopidogrel are irreversible inhibitors of platelet function. They should be stopped for 7 days when necessary to allow platelet recovery. NSAID's cause a milder reversible inhibition of platelet function
- Aspirin increases post-op bleeding in cardiac surgery. The effect in non-cardiac surgery is more variable in published studies
- It is reasonable practice, if the surgery has significant potential for bleeding complications which would impair the outcome, to stop aspirin for 7 days before surgery in most patients
- For patients having many types of surgery when the aspirin is for secondary prophylaxis (after MI or CVA) then it's reasonable to continue aspirin rather than postpone surgery
- Aspirin is not a contraindication to spinal anaesthetic
- Clopidogrel appears to be more potent than aspirin and probably causes more peri-operative bleeding. Patients on clopidogrel are often at the highest risk of arterial thrombosis when it's stopped.
- If a patient is on clopidogrel and surgery cannot be delayed, the half life of clopidogrel is approximately 8 hours - if it is more than 24 hours after the last dose, platelet transfusion may be effective

High Risk Patients

Please note. In patients who received a coronary artery stent, the risk of discontinuation of anti-platelet therapy is acute stent thrombosis. This is manifest as acute myocardial infarction and carries a mortality of almost 50%. It is strongly advised that in all patients considered high risk that the treating cardiologist is consulted prior to an interruption in therapy.

- Patients who have undergone coronary artery stenting within 6 weeks. Almost invariably these patients will be on dual anti-platelet therapy (clopidogrel and aspirin). This treatment should only be stopped in the presence of life threatening bleeding. Defer all surgery if possible.
- Patients who have been treated with a drug eluting stent (DES) within 12 months. If possible defer any procedure. If a biopsy or surgery must be undertaken, defer as long as possible, a minimum of 3 months. Stop clopidogrel but continue aspirin. Restart clopidogrel as soon as possible.
- In patients treated with a DES there is a small but continuing risk of very late stent thrombosis, even after 12 months. This can be precipitated by discontinuation of anti-platelet therapy. Never stop both agents, continue aspirin in all cases.

6.2 Risk Assessment for Venous Thromboembolism (VTE) in Pregnancy and Puerperium

Pregnancy is associated with an increased risk of VTE (deep vein thrombosis or pulmonary embolism). There are many other factors which can increase the risk of VTE. Women should have a risk assessment done for VTE at the following times in pregnancy:

- Booking visit or early pregnancy
- Antenatal admission (except early labour / induction)
- Following delivery prior to transfer to postnatal ward.

(NB: Risk may need to be re-assessed at any stage if there is a change in the mother's condition)

- All patients, including day cases, should be risk assessed on admission and re-assessed within 24 hours and if the clinical situation changes.
- All patient should be offered verbal and written information on VTE prevention on admission and also on discharge, along with information about signs and symptoms of VTE. Women should be advised to keep as mobile and well-hydrated as possible.
- For the signs and symptoms of VTE see table 2.

6.2.1 Risk Assessment Procedure

Step 1: Review risk factors for VTE on assessment sheet (Appendix E)
- at taking of booking history
- on antenatal admission (except early labour / induction)
- following delivery (before transfer to ward).

Step 2: Document the score on the individual risk assessment sheet. This will be completed electronically following delivery.

Step 3: Check no bleeding risks
Check there are no contraindications to intervention (graduated compression stockings and/or clexane). See table 1 for details

Step 4: If risk of VTE has been identified following the Risk Assessment refer to an obstetrician to consider / prescribe Clexane.
If further input is needed, the obstetrician can refer to or request advice from (Consultant Haematologist)

Antenatally, the individualised management plan will be documented in the maternity records. As a minimum, this plan will include; dose and duration of treatment.

Postnatally the individualised management plan will be as per the Individual Risk Assessment for VTE screen on the electronic computer system. The management plan will inculde one, or a combination of; none required, early mobilisation, hydration, anti-embolic stackings, flowtron boots and LWMH prescribed

6.2.2 Thromboprophylaxis in Pregnancy

This Trust generally uses Clexane (enoxaparin) which is a low molecular weight Heparin (LMWH) for prophylaxis and treatment of DVT and PE

Guidance on prophylactic Clexane dose	
Booking weight < 50kg	20mg OD
Booking weight 50-90kg	40mg OD
Booking weight > 90kg	40mg BD (or 60mg OD)*
Booking weight > 130kg	40mg BD (or 80mg OD)*
Renal impairment with creatinine > 150	20mg OD

* If patient unable or reluctant to manage BD injections

Additional Notes on Thromboprophylaxis during Pregnancy

Always check obstetric records in case higher doses of Clexane have been recommended and for any management plan from the Obstetric Haematology Clinic

Where risk assessment at booking suggests possible need for antenatal Clexane treatment (as outpatient), the woman can be referred to the antenatal Haematology clinic for more detailed risk assessment. A thrombophilia screen may occasionally be helpful but should be interpreted with caution.

Most women on long term Warfarin or with Antithrombin deficiency are at a high risk of thrombosis. They should be given Clexane 1 mg per kg early pregnancy weight S.C.12 hourly. Aim for Anti-Xa range 0.6 -1.0 units/ml.

Women with antiphospholipid syndrome (the presence of a lupus anticoagulant and/or anticardiolipin antibodies with an appropriate pregnancy history) should receive 40 mg of Clexane S.C. daily and Aspirin 75 mg daily from early pregnancy and usually postpartum Clexane prophylaxis for 6 weeks. Women with antiphospholipid syndrome and previous thrombosis usually require higher doses of Clexane.

Some women with equivocal results on an antiphospholipid laboratory screen (eg.

isolated IgM ACA <20 MPL U/ml) may be offered Aspirin 75 mg daily without Clexane from the start of pregnancy.

Women with recurrent fetal loss who have thrombophilia other than antithrombin deficiency are sometimes offered Clexane 40 mg S.C. once daily as soon as the pregnancy is confirmed and continue postpartum Clexane prophylaxis for 6 weeks.

6.2.3 Care during Labour for Women on Thromboprophylaxis

Women should be advised to discontinue Clexane as soon as they believe they are in labour **or** should have the last dose at least 24 hours before a planned surgical delivery **or** at least 12 hours before commencing induction of labour.

If delivery occurs within 24 hours of the last Clexane dose, there is a higher risk of secondary delayed haemorrhage/haematoma. Close attention should be given to repair of tears following vaginal delivery and regular inspection for occult pelvic bleeding following caesarean section.

Epidural or spinal block should not be given until 12 hours have elapsed since the last dose of prophylactic Clexane and 24 hours after therapeutic Clexane administration (more than 40 mg once daily). An Epidural catheter should not be removed until 12 hours have elapsed since a dose of prophylactic Clexane and it should not be given within 4 hours of removal (6 hours if traumatic)*

*There is virtually no evidence/guidance specific for spinal anaesthetic. It is common practice to delay clexane by at least 2 hours after spinal anaesthetic. Current CMO guidance on thromboprophylaxis for hospital patients (which excludes obstetrics) recommends a 4 hour delay for both spinal and epidural anaesthesia

Consider IVC filter if labour expected within 2 weeks of VTE. Discuss with Haematology consultant.

6.2.4 Care Postnatally for Women on Thromboprophylaxis

Prophylactic doses of Clexane can be restarted 2 to 4 hours after delivery if there is no excessive bleeding. A full bd dose can usually be restarted 16 hours post partum if there is no excessive bleeding.

Most women receiving antenatal Clexane automatically continue until 6 weeks post-partum.

Inform consultant Haematologist or deputy when a woman is on full dose Clexane has been transferred to a post-natal ward.

Always check obstetric records in case higher doses of Clexane have been recommended and for the management plan from the Obstetric Haematology Clinic

It is usual practice to delay starting warfarin until at least 4 days post partum. When changing to Warfarin, use dosing algorithm in table 5. Continue with Clexane until INR is >2.0 for >24hours and both Warfarin and Clexane have been administered together for at least 5 days. Warfarin is usually continued for 3 to 6 months post partum at a target INR of 2.5. Always inform the Haematology Consultant or deputy when a woman restarts warfarin.

A referral should be made jointly to the Haematology and Fetal Medicine clinic for follow up after discharge, at an interval dependent on their individual management plan, following discussion with consultant Haematologist

Breast feeding should still be encouraged in women on Clexane or warfarin as there are no known adverse effects on the baby
Graduated elastic compression stockings (GECS) recommended after **all** caesarean deliveries and if the postnatal risk assessment score is ≥ 3

- GECS optional following non-surgical delivery (may be included in birth plan)
- For women receiving 7 days of post-partum Clexane only, a discharge pack is available on the wards containing written information, a sharps box and Clexane syringes. This will be given by the woman once she is trained to self-medicate or by the community midwife, following discharge.

TABLE 5: POST PARTUM WARFARIN INDUCTION ALGORITHM

Changing to Warfarin following delivery

Day	INR	Warfarin dose in mg
First		7.0
Second		7.0
Third	<2.0	7.0
	2.0-2.1	5.0
	1.2-2.3	4.5
	2.4-2.5	4.0
	2.6-2.7	3.5
	2.8-2.9	3.0
	3.0-3.1	2.5
	3.2-3.3	2.0
	3.4	1.5
	3.5	1.0
	3.6-4.0	0.5
	>4.0	0.0
Fourth	<1.4	>8.0
	1.4	8.0
	1.5	7.5
	1.6-1.7	7.0
	1.8	6.5
	1.9	6.0
	2.0-2.1	5.5
	2.2-2.3	5.0
	2.4-2.6	4.5
	2.7-3.0	4.0
	3.1-3.5	3.5
Fourth	3.6-4.0	3.0
	4.1-4.5	Omit one day then give 2mg
	>4.5	Omit 2 days then give 1mg

6.2.5 Management of Venous Thromboembolism in Pregnant Women

- If DVT or PE is clinically suspected (see table 2) and there are no contraindications to anticoagulation (see table 1) then treatment should be started pending results of radiological imaging
- An individualised management plan will be documented in the health records of all women who require thromboprophylaxis or treatment for a diagnosis of VTE. This will include; dose and duration of treatment.
- Before commencement of anticoagulation, blood must be taken for FBC, coagulation screen, LFT's and U&E's. Measurement of D-dimer is not recommended
- These women will be cared for in the most appropriate place depending on their clinical condition.
- In pregnant women the radiation dose to the fetus is higher with VQ scanning than CTPA, however there is a radiation dose to the breast with CTPA which may increase the long-term risk of breast cancer. CTPA should be considered in preference to VQ during pregnancy if there is a history of asthma or abnormal baseline CXR. Consider using Doppler ultrasound – if DVT is identified, a lung scan is not necessary
- The initial dose of Enoxaparin (Clexane) for suspected VTE in pregnancy is 1mg/Kg S.C TWICE DAILY (use nearest dose syringe, table 6). Target therapeutic anti-Xa range 0.6-1.0 units/ml

TABLE 6: THERAPEUTIC CLEXANE DOSE

Early pregnancy weight	Syringe colour and strength	Initial dose of Enoxaparin (Clexane)
<50Kg	Yellow 40mg	40mg twice daily
50-69 Kg	Orange 60mg	60mg twice daily
70-89 Kg	Brown 80mg	80mg twice daily
>90Kg	Black 100mg	100mg twice daily

- For massive PE unfractionated Intravenous Heparin may be considered (bolus dose 80 units/kg, max 8000 units, followed by infusion of 18 units/kg/hr checking APTT at 6 hours aiming for APTT ratio of 1.5-2.5. Further dose advise can be given by the on call Haematologist. Surgical embolectomy can be organized through on call UHB cardiothoracic surgeons (for PE) or vascular surgeons (for DVT). An IVC filter can be arranged through UHB interventional radiology on call. Thrombolytic therapy should generally be avoided in pregnancy and the pueurperium (see BWH maternal collapse guideline for further information).
- Above knee GECS should be fitted to women with DVT
- Following diagnosis, refer to the Haematology clinic for further monitoring. Aim for anti-Xa level of 0.6-1.0 taken 3 to 4 hours post dose
- All women diagnosed with VTE in pregnancy or the postnatal period should be offered a postnatal appointment jointly to the Haematology and Fetal Medicine clinic for follow up after discharge

6.3 Training

Refer to the Trust Mandatory and Statutory Training Policy for details of mandatory training in relation to Venous Thromboembolic Disease.

7. Review, Monitoring, and Revision Arrangements

All Trust policies / guidelines will be monitored for compliance in one of three ways:

- **Review** is normally proactive and designed to evaluate the effectiveness of systems and processes;
- **Audit** is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria;
- **Continuous Audits** are repeated audit cycles to ensure new controls can be identified and tested as they arise.

Where deficiencies have been identified through any of the above, there must be evidence that recommendations and action plans have been developed and changes implemented.

The frequency and detail of the monitoring process is described in the table below:

Monitoring	Method	Frequency	Lead	Reporting to	Action Plan Review
For Maternity Directorate: • Appropriate and timely risk assessments. • The significance of signs and symptoms in light of known risk factors. • Were appropriate actions taken once the risk of VTE has been identified? • Individual management plan documented when women require thromboprophylaxis or treatment for a VTE. • Thromboprophylaxis during pregnancy. • Care in labour/delivery of women on thromboprophylaxis. • Thromboprophylaxis during PN period. • Management of PE in pregnancy. • PN appointment offered to all women diagnosed with VTE during pregnancy / PN period.	Audit	Annual	Specialist Midwife Antenatal Clinic	Maternity Clinical Improvement Group	Maternity Clinical Improvement Group

Actions resulting from deficiencies identified from any of the above.	Review	As specified when audit presented	Specialist Midwife Antenatal Clinic	Maternity Clinical Improvement Group	Maternity Clinical Improvement Group
For Gynaecology Directorate: • Appropriate and timely risk assessments. • prophylactic treatment regime for high risk patients • procedure to be followed if VTE is suspected • management of the patient once a positive diagnosis has been made	Audit	Annual	Head of Nursing for Gynaecology	Gynaecology Clinical Improvement Group	Gynaecology Clinical Improvement Group
Actions resulting from deficiencies identified from any of the above.	Review	As specified when audit presented	Head of Nursing for Gynaecology	Gynaecology Clinical Improvement Group	Gynaecology Clinical Improvement Group

7.1 Audit Proforma

Audit to be completed from case notes / electronic records:

Data to be collected following discharge from hospital postnatally (obstetric) or following surgery (gynaecology)

Obstetric

Patient hospital number:

Date of delivery:

Mode of Delivery: NVD Forceps Ventouse ElCS EmCS Breech

Antenatal	Yes	No
Was risk assessment carried out at booking?		
Was risk assessment carried out on admission to AN ward (except in early labour/ induction)?		
Were significance of signs or symptoms documented (on back of risk assessment sheet (in hand held records)		
If increased risk, was woman started on Clexane or referred to Consultant Haematologist for review?		
If no to previous question, was reason documented?		
Was the correct dose of Clexane prescribed?		
Was an individualised management plan documented in the maternity records. As a minimum, this plan will include; dose and duration of treatment.		

Labour	Yes	No
If epidural was used, was this > 12 hours after last dose of Clexane or > 24 hours if therapeutic dose of clexane?		
Was Clexane given at least 4 hours following removal of epidural/ spinal?		

Postnatal	Yes	No
Was risk assessment carried out following delivery, prior to transfer to ward?		
If risk assessment indicated need for Clexane, was Clexane recommended, prescribed and given?		
Was there an individualised management plan (as per the Risk Assessment for VTE screens on the electronic computer system) to include one, or a combination of; none required, early mobilisation, hydration, anti-embolic stackings, flowtron boots and LWMH prescribed		
If no to above question, was reason doumented?		
If patient was on clexane antenatally, was 6 week postnatal treatment recommended?		
Were GECS advised / fitted if appropriate (after C/S or score ≥ 3)		
If patient was diagnosed with VTE during pregnancy or postpartum		

period, was a follow up appt arranged with Obstetric Haematology clinic ?		

Diagnosis of VTE	Yes	No	N/A
Was a VTE diagnosed during pregnancy/postnatal period			
If diagnosis of VTE, was an individualised management plan documented in the maternity records. As a minimum, this plan will include; dose and duration of treatment			
If *life threatening PE* was diagnosed was the patient cared for in HDU/ CCU			
If a PE was diagnosis was the Consultant Haematologist informed?			

Gynaecology

	Yes	No
Was risk assessment carried out in pre-op assessment clinic (routine)		
Was risk assessment carried out on admission to ward (emergency)		
Were use of graduated elastic compression stockings (GECS) documented in records ?		
Was low molecular weight heparin (Clexane) recommended and prescribed ?		

VTE IN PREGNANCY / PUERPERIUM / GYNAE ADMISSION AUDIT DATA
GENERIC INFORMATION (all patients)

NAME	
HOSPITAL ID NO	
DOB	
DATE OF VTE DIAGNOSIS	
RISK FACTORS:	
PREVIOUS DVT / PE	
BMI	
SMOKING	
ACTIVE CANCER	
KNOWN THROMBOPHILIA	
OTHER RISK FACTORS	
RELEVANT MEDICAL HISTORY Y/N	
DETAILS	
FAMILY HISTORY Y / N	
DETAILS	
DIAGNOSTIC IMAGING	
DOPPLER / VQ / CTPA	
TREATMENT:	

LMWH DOSE PER KG	
WARFARIN (INPATIENT/OUTPATIENT)	
FOLLOW UP (HAEMATOLOGY/ CONSULTANT OBS/GYNAE)	

VTE DURING PREGNANCY / PUERPERIUM

PARITY	
ANTENATAL / POSTNATAL	
GESTATION (or)	
DAYS POST-DELIVERY	
PREGNANCY LOSS HISTORY	
RELEVANT PREGNANCY OR DELIVERY COMPLICATIONS Y / N	
Details :	

VTE DURING GYNAE ADMISSION

TYPE OF GYNAE SURGERY (PROCEDURE)	
LEVEL OF RISK AT ASSESSMENT	
LMWH PROPHYLAXIS - GIVEN AS PER RISK	
GECS/TEDS USED?	
COMPLICATIONS DURING ADMISSION (e.g. BLEEDING, INFECTION)	

8. Associated Documents

- Antenatal Care Guidelines
- Care of women during labour and birth
- Postnatal Care guidelines
- Maternal Collapse Guidelines
- Trust Mandatory and Statutory Training Policy

9. References

Green Top Guideline 28: Thromboembolic Disease in Pregnancy and the Puerperium: Acute Management (2007) (http://www.rcog.org.uk/files/rcog-corp/uploaded-files/GT28ThromboembolicDisease2007.pdf)

Green Top Guideline 37: Thrombosis and Embolism during Pregnancy and the Puerperium, Reducing the Risk (2009) (http://www.rcog.org.uk/resources/Public/pdf/Thromboprophylaxis_no037.pdf)

House of Commons Health Committee: The Prevention of Venous Thromboembolism in Hospitalised Patients Second Report of Session 2004–05 (http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/99/99.pdf) and Government Response to the House of Commons Health Committee Report on the Prevention of Venous Thromboembolism in Hospitalised Patients – Second Report of Session 2004–05 (http://www.official-documents.gov.uk/document/cm66/6635/6635.pdf)

Lewis G, editor. Why Mothers Die 2000–2002. Sixth Report of the Confidential Enquiries into Maternal Death. London: RCOG Press; 2004.

Lindblad B, Sternby NH, Bergqvist D. Incidence of venous thromboembolism verified by necropsy over 30 years. BMJ 1991;302:709-711,

NICE guideline CG46: Venous thromboembolism - Reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery) (http://guidance.nice.org.uk/CG46/niceguidance/pdf/English)

NICE guideline 92: Venous thromboembolism - Reducing the risk (2010) (http://guidance.nice.org.uk/CG92/niceguidance/pdf/English)

Report of the independent expert working group on the prevention of venous thromboembolism in hospitalised patients (http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_073957).

Risk assessment for venous thromboembolism (2008) (http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_088216.pdf)

Rodger MA, Walker M, Wells PS. Diagnosis and treatment of venous thromboembolism in pregnancy. Best Pract Res Clin Haematol 2003;16:279–296.

Appendix A – Plan for Dissemination of Procedural Documents

To be completed by the Head of Corporate Affairs and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Prevention and Treatment of Venous Thromboembolic Disease Guideline		
Date finalised:	August 2012	**Dissemination lead: Print name and contact details**	Diana Wylie
Previous document already being used?	**Yes**		
If yes, in what format and where?	Available on the intranet		
Proposed action to retrieve out-of-date copies of the document:	Archive out of date copy and replace with new version		

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
Trust Wide	Via Email	E	

Dissemination Record to be used once document is approved.

Date put on register / library of procedural documents	2nd October 2012	**Date due to be reviewed**	7th September 2015

Disseminated to: (either directly or via meetings, etc)	**Format (i.e. paper or electronic)**	**Date Disseminated**	**No. of Copies Sent**	**Contact Details / Comments**
Trust Wide	Electronic	2nd October 2012	0	Staff informed Policy has been updated and uploaded to the intranet

Appendix B – Equality Impact Assessment Tool

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

Policy/Function Details	
Name of Policy/Function[1], Service, Plan, SLA, Function, Contract or Framework:	Prevention and Treatment of Venous Thromboembolic Disease Guideline
Is this a new policy or function?	New ☐ Existing ☐ Updated ☒
Responsible Manager	Will Lester
Date Assessment Completed:	1st June 2012
Sources of Data	

Screening Assessment					
Equality Group	**Impact**		**Status of Impact**		**Brief Detail of impact**
	Yes	**No**	**Positive**	**Negative**	
Race, Ethnicity, Colour, Nationality or national origin (incl. Romany Travellers, refugees and asylum seekers)		X			
Gender or Marital Status of Men or Women		X			
Gender or Marital Status of Transsexual or Transgender people		X			
Religion or belief		X			
Physical or Sensory Impairment		X			
Mental Health Status		X			
Age or perceived age		X			
Sexual Orientation (Gay, Lesbian, Bisexual)		X			
Offending Past		X			
Other Grounds (i.e. poverty, homelessness, immigration status, language, social origin)		X			

[1] Policy/Function for the purpose of this document also includes Services, Plans, SLAs, Contracts, Care Pathways and Service or Care Frameworks.

Assessment Narrative
Are there any alternative service/policy provisions that may reduce or eradicate any negative impacts?
N/A
How have you consulted with stakeholders and equalities groups likely to be affected by the policy?
Clinical Governance Committee
What are your conclusions about the likely impact for minority equality groups of the introduction of this policy/service?
None
How will the policy/service details (including this Equality Impact Assessment) be published and publicised?
Intranet
How will the impact of the policy/service be monitored and reviewed?
Please see Section 8

Assessor Name:	Will Lester
Assessor Job Title:	Consultant
Date Completed:	1st June 2012

Appendix C – Policy Checklist

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Has all the information on the front page been completed?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Is the responsible policy leads name and title clearly printed?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	CGC
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Are the intended outcomes described?	Yes	
	Is the language used in the document clear, jargon free and spelt correctly?	Yes	
5.	**Format**		
	Does the policy conform to the prescribed policy format?	Yes	
6.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited using Harvard referencing?	Yes	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	
8.	**Document Control**		
	Has a version control sheet been placed at the front of document, and been filled out correctly?	Yes	
9.	**Process to Monitor Compliance and Effectiveness**		
	Is there a plan to review or audit compliance with the document?	Yes	
10	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11	**Equality Assessment**		
	Has an equality impact assessment been carried out?	Yes	

Individual Approval			
If you are happy to approve this document, please sign and date it below, and put the document onto the DMS for final approval			
Name / Designation	Will Lester, Consultant Haematologist	Date	1st June 2012
Signature			

Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name / Designation	Chair of Patient Outcome Committee Acting – Marianne Skelcher	Date	7th September 2012
Signature			

Appendix D – Risk Assessment for Venous Thromboembolism: Gynaecology Patients

NAME : DATE OF BIRTH : HOSPITAL NUMBER :	**PRE-OP ASSESSMENT**: Date ……Name of assessor…… **WARD ADMISSION**: Date ……Name of assessor…… **24 HOURS AFTER ADMISSION:** Date ……Name of assessor……

RISK ASSESSMENT FOR VENOUS THROMBOEMBOLISM (VTE) – GYNAECOLOGY

MOBILITY (all patients) Tick one box	Tick		Tick		Tick
Surgical patient ↓		Non- surgical patient : **expected** to have ongoing reduced mobility (relative to normal state) ↓		Non-surgical patient : **NOT expected** to have ongoing reduced mobility (relative to normal state) **RISK ASSESSMENT COMPLETE**	□
Assess for thrombosis and bleeding risk					

THROMBOSIS RISK FACTORS

Patient related	**Tick**	**Admission related**	**Tick**
Active cancer or cancer treatment		Significantly reduced mobility for 3 days or more	
Age > 60 years		Total anaesthetic and surgery time > 90 mins	
Dehydration		Surgery involving pelvis or lower limb with total anaesthetic and surgery time > 60 mins	
Known thrombophilia		Acute surgical admission with inflammatory or intra-abdominal condition	
Obesity : BMI ≥ 30 kg / m²		Surgery with significant reduction in mobility	
One or more significant medical comorbidites (eg.heart disease: metabolic, endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions)			
Personal history or 1st degree relative with history of VTE			
Use of hormone replacement therapy or oestrogen containing contraceptive			
Varicose veins with phlebitis			
Pregnancy or up to 6 weeks postpartum (Please use obstetric risk assessment tool)			

A tick against any thrombosis risk factor should prompt consideration of treatment with Clexane and TED stockings – refer to prescriber (see over for further information)

BLEEDING RISK **PATIENT RELATED**	**Tick**	**CONTRAINDICATION TO GRADUATED COMPRESSION STOCKINGS (USED FOR SURGICAL PATIENTS ONLY)**	**Tick**
Active bleeding		Suspected or proven peripheral arterial disease	
Acquired bleeding disorders (e.g. acute liver failure)		Peripheral neuropathy or significant sensory impairment	
Concurrent use of anticoagulants known to increase the risk of bleeding (such as warfarin with INR>2)		Skin fragility ("tissue paper" skin, cellulitus, dermatitis, gangrene or recent skin graft)	
Acute stroke		Cellulitis, dermatitis or venous ulceration	
Thrombocytopaenia (platelets < $75x10^9$/l)		Limb deformity	
Uncontrolled systolic hypertension (230/120mmHg or higher)		Congestive heart failure / pulmonary oedema / severe leg oedema	
Untreated inherited bleeding disorders (such as haemophilia and von Willebrand's disease)			
ADMISSION RELATED			
Surgical procedure with high bleeding risk			

All patients should be risk assessed on admission to hospital. Patients should be reassessed within 24 hours of admission and whenever the clinical situation changes.
(Based on Department of Health national risk assessment tool)

Appendix E – Risk Assessment of Venous thromboembolism in Pregnancy and Puerperium

OBSTETRIC VTE RISK ASSESSMENT

RISK FACTORS

Pre-existing risk factors :	Tick	Score
Previous recurrent VTE		3
Previous VTE - unprovoked or pregnancy / oral contraceptive pill related		3
Previous VTE – provoked (e.g. post trauma / surgery)		2
Family history of VTE (in parent / sibling or in 2 other family members)		1
Known thrombophilia * Antithrombin III deficiency		2 3
Medical conditions (e.g. SLE, inflammatory bowel disease, cardiac disease, nephrotic syndrome)		2
Age ≥ 35 years Age ≥ 40 years		0.5 1
Obesity : BMI > 30 BMI > 40		1 2
Parity ≥ 3 (previous pregnancies)		0.5
Smoker		0.5
Varicose veins with phlebitis		2
Obstetric risk factors :		
Pre-eclampsia		1
Dehydration / hyperemesis / ovarian hyperstimulation		1
Multiple pregnancy		1
Caesarean section in labour		2
Elective caesarean section		1
Mid-cavity or rotational forceps		1
Prolonged labour (> 24 hours)		1
PPH (> 1 litre or requiring transfusion)		1
Transient risk factors :		
Current systemic infection		1
Immobility		1
Surgical procedure in pregnancy or postpartum period		2

Thromboprophylaxis with LMWH (e.g Clexane) should be considered if :

- Antenatal (outpatient) score **3 or more** Refer to Obs Haematology clinic
- Antenatal (inpatient) score **1.5 or more** Refer to obstetrician to prescribe
- Post-delivery :
  Score 2, usually Clexane for 7 days
  Score 3 or more, or already on clexane antenatally, consider clexane for 6 weeks

GECS (TED stockings) should be given until fully mobile (unless contraindicated) after caesarean section or if score ≥ 3 following delivery

If any identified bleeding risk (see below), the balance of risks between bleeding and clotting may need to be discussed with Obstetrician or Haematologist.

Bleeding risks may include :
- Known bleeding disorder (e.g. Haemophilia / von Willebrands disease)
- Active antenatal or postnatal bleeding
- Women considered at risk of major haemorrhage (e.g. placenta praevia)
- Platelet count < 75
- Acute stroke in previous 4 weeks
- Severe renal disease (GFR < 30ml / min) or severe liver disease
- Uncontrolled hypertension (>200 mmHg systolic or > 120 diastolic)

* Thrombophilia : Factor V Leiden / PT20210A /
Protein C deficiency / Protein S deficiency
Antiphospholipid Syndrome