Weston Area Health
NHS Trust

Protocol for DVT Management
V1

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Brief summary of contents	Diagnosis, management and investigation of patients with possible DVT
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Title and date of committee/forum/group consulted during development :	DT committee, Medical Consultants, Haematology Consultants in BHOC
Signature of Executive Director giving approval	Medical Director
Intranet location:	Yes
Links to key external standards	See references
Related Documents:	DVT protocol in BRI, DVT protocol Oxford
Training Need Identified?	No

Version Control Table

Date	V	Summary of changes	Author
11/09/2017	1	Stop date for Anticoagulation in provoked DVT	W Al-Sakkaf
		Removal of Fondaparinaux from SVT letter	

Document Amendment Form – minor amendments

No.	Date	Page no	Amendment	Authorised by
1				
2				
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10				

Ten or less minor amendments can be made before the document is revised.

Major changes must result in immediate review of the document

If printed, copied or otherwise transferred from the Trust intranet, procedural documents will be considered uncontrolled copies. Staff must always consult the most up to date version – located on the intranet.

Table of Contents

1. Introduction and purpose

This is the first guidance of DVT management in WGH aimed at giving some guidance to medics dealing suspected lower limb DVT

2. Scope

Can be used in ED, Ambulatory care and inpatient wards by staff to diagnose and manage lower limb DVT

3. Explanation of terms

DVT: Deep vein thrombosis
DOACs: Direct oral anticoagulants
COCP: Combined oral contraceptive pills

4. Roles and Responsibilities

Medical staff in Ambulatory care/MAU/ED review patients with suspected DVT
Organise the necessary investigations
Initiate treatment
Advise GP of further management/referrals needed

5. Policy details

DIAGNOSTIC ALGORITHM FOR SUSPECTED DVT

Pre-test probability assessment

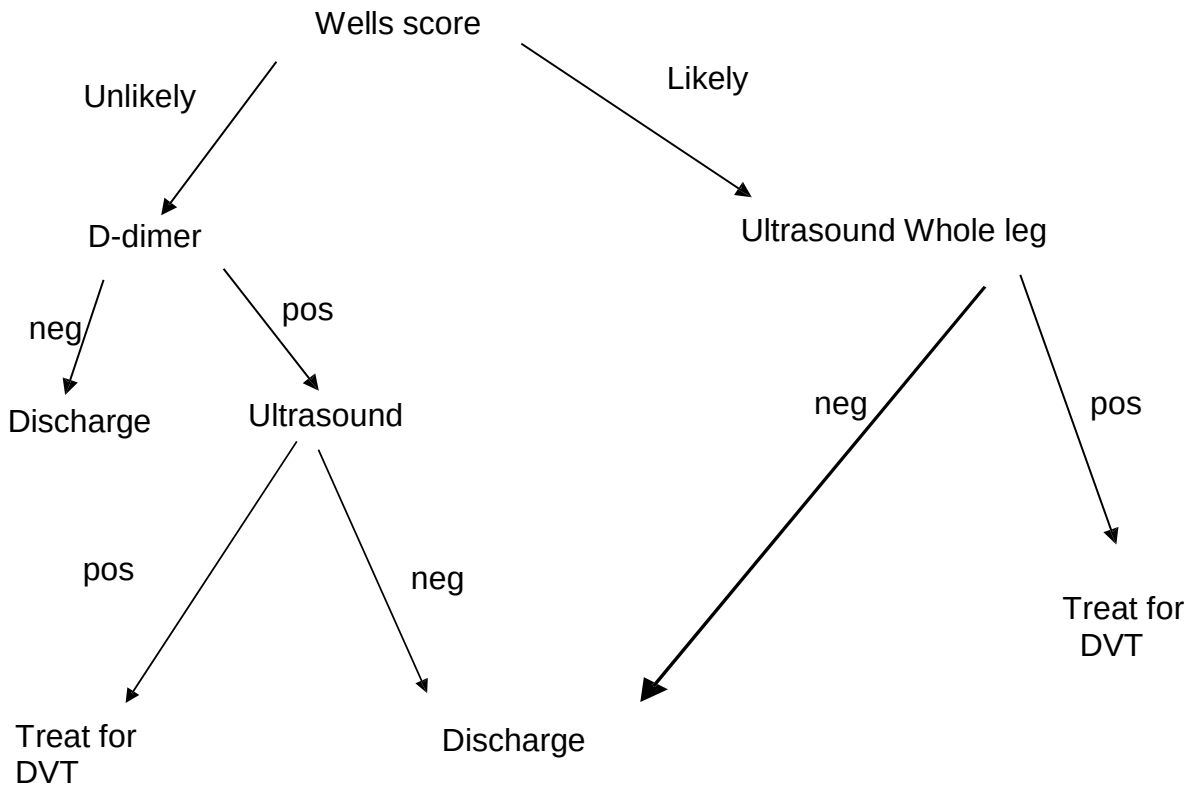
Patients will initially have a pre-test probability assessment (Wells Score) (Keeling*, et al* 2004, Wells*, et al* 1997, Wells*, et al* 2003, Wells*, et al* 1995) and be classified as unlikely or likely to have a DVT (see table below). They will then follow the algorithm in the figure overleaf.

Lower limb trauma/immobilisation in POP	+1	Pitting oedema confined to symptomatic leg	+1
Bedridden>3 days/surgery in last 4 weeks	+1	Entire limb swollen	+1
Tenderness along lines of femoral/popliteal veins	+1	Dilated superficial collateral veins	+1
Malignancy (treatment ongoing or within previous 6 months or palliative)	+1	Previous DVT/PE/thrombophilia (diagnostic D-Dimer)	+1
Difference in calf circumference 3cms or more	+1	**Alternative diagnosis as/more likely than DVT**	**-2**
		Total Wells Score	

In cases in which it is unclear as to whether there is an alternative diagnosis the assumption of no alternative diagnosis will ensure the highest level of safety.

Score	Probability
≤1	Unlikely
≥2	Likely

Diagnostic Algorithm



If Ultrasound is normal, consider looking for other causes of leg swelling and investigate or advice GP accordingly. In patients who have already had an anticoagulant, D-dimers cannot be used as part of the diagnostic algorithm.

Patients on anticoagulation with a suspected recurrence will all get an initial ultrasound scan and a D-dimer. A doctor will use both of these plus clinical assessment to decide if a new clot has occurred.

Ultrasound

Patients in whom a DVT cannot be ruled out by clinical examination and D-dimers will be given Apixaban, Rivaroxaban or LMWH if scanning is delayed by 4 hours or more. The scan should take place within 24 hours.

Patients with high clinical suspicion, a grossly swollen leg, but a negative scan

If a patient has a grossly swollen leg but a negative scan consider a CT venogram to look for iliac or pelvic vein thrombosis or pelvic pathology causing external compression of pelvic veins.

Patients who have a DVT excluded

The patient will be referred back to their GP with the exception of patients found to have SVT adjacent to (within 3 cm of) the sapheno-femoral junction (SFJ).

Patients who have a DVT diagnosed – these patients will be treated as out-patients and have a medical assessment by a doctor on the unit. Patients will be ambulant but we suggest to avoid vigorous exercise and air travel within two weeks of DVT.

Investigations

All should have:

FBC
UE/LFT
PT/INR and APTT

Pregnancy test for women of child bearing potential.

Investigation for cancer in patients with unprovoked DVT (as per NICE guidance)

All patients should have a full history and examination. Patients with any concerning symptoms or signs should have targeted further investigations to investigate for an underlying cancer.

Offer all patients diagnosed with unprovoked DVT or PE who are not already known to have cancer the following investigations for cancer:

- a physical examination (guided by the patient's full history) **and**
- a chest X-ray **and**
- blood tests (full blood count, serum calcium and liver function tests) **and**
- urinalysis.

Consider further investigations for cancer with an abdomino-pelvic CT scan (and a mammogram for women, PSA in men) in all patients aged over 40 years with a first unprovoked DVT or PE who do not have signs or symptoms of cancer based on initial investigation.

OUT-PATIENT TREATMENT OF DVT

This can be either with A) apixaban, B) rivaroxaban or C) LMWH and warfarin

A) Treatment with apixaban

Apixaban, a direct inhibitor of factor Xa, is given orally for the treatment of DVT and PE and for the secondary prevention of recurrent DVT and PE (Agnelli*, et al* 2013a, Agnelli*, et al* 2013b). Apixaban does not require therapeutic monitoring (nor concurrent initial treatment with heparin).

It should not be used in those less than 18 years of age.

Dose
10 mg twice daily for 7 days, then 5 mg twice daily.
On the first day the second dose can be taken later that evening even if the first dose is given in the afternoon.
The licenced dose for prevention of recurrent DVT and/or PE following completion of 6 months of treatment for DVT or PE is 2.5 mg twice a day.

Renal impairment – no dose adjustment is necessary in patients with mild or moderate renal impairment. In patients with severe renal impairment (eGFR 15-29 mL/min) apixaban is to be used with caution. We will not routinely use apixaban if eGFR < 30 mL/minute but in selected patients it can be considered for use if the eGFR is 15-30 ml/min.

Hepatic impairment – avoid in liver disease with coagulopathy.

Pregnancy or breast feeding – avoid.

Missed doses - If a dose is missed the patient should take the missed dose immediately and take the next dose on time (if the next dose is due a double dose can be taken).

Interaction with other medicinal products
The use of factor Xa inhibitors is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (such as ritonavir). These active substances are strong inhibitors of both CYP3A4 and P-gp and therefore may increase rivaroxaban and apixaban plasma concentrations to a clinically relevant degree. Co-administration of factor Xa inhibitors with strong CYP3A4 inducers e.g. rifampicin, phenytoin, carbamazepine, phenobarbital or St. John's Wort, may lead to reduced rivaroxaban and apixaban plasma concentrations. We therefore recommend that strong CYP3A4 inducers should not be co-administered with factor Xa inhibitors when treating acute venous thromboembolism. Macrolide antibiotics, such as clarithromycin and erythromycin, may inhibit metabolism of factor Xa inhibitors and therefore caution should be applied if co-prescribed.

Prescription
Initially three weeks treatment should be prescribed and the GP should then continue.

B) Treatment with rivaroxaban

Rivaroxaban, a direct inhibitor of factor Xa, is given orally for the treatment of DVT and PE and for the secondary prevention of recurrent DVT and PE (Bauersachs*, et al* 2010). Rivaroxaban does not require therapeutic monitoring (nor concurrent initial treatment with heparin).

It should not be used in those less than 18 years of age.

Dose
15 mg twice daily with food for 21 days, then 20 mg once daily with food.

Renal impairment – if eGFR 15–49 mL/minute initially 15 mg twice daily for 21 days, thereafter, the recommended dose is the standard 20 mg once daily but a reduction of the dose from 20 mg once daily to 15 mg once daily should be considered if the patient's assessed risk for bleeding outweighs the risk for recurrent DVT and PE. The SPC says use with caution if eGFR 15-29 mL/minute and avoid if eGFR less than 15 mL/minute.

We will not routinely use rivaroxaban if eGFR < 30 mL/minute.

Hepatic impairment – avoid in liver disease with coagulopathy.

Pregnancy or breast feeding – avoid.

Missed doses - If a dose is missed during the 15 mg twice daily treatment phase (day 1 - 21), the patient should take the missed dose immediately and take the next dose on time (if the next dose is due two 15 mg tablets can be taken together). The patient should then continue with 15 mg twice daily.

If a dose is missed during the once daily treatment phase (day 22 and onwards), the patient should take the missed dose immediately, and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.

Interaction with other medicinal products
The use of factor Xa inhibitors is not recommended in patients receiving concomitant systemic treatment with azole-antimycotics (such as ketoconazole, itraconazole, voriconazole and posaconazole) or HIV protease inhibitors (such as ritonavir). These active substances are strong inhibitors of both CYP3A4 and P-gp and therefore may increase rivaroxaban and apixaban plasma concentrations to a clinically relevant degree. Co-administration of factor Xa inhibitors with strong CYP3A4 inducers e.g. rifampicin, phenytoin, carbamazepine, phenobarbital or St. John's Wort, may lead to reduced rivaroxaban and apixaban plasma concentrations. We therefore recommend that strong CYP3A4 inducers should not be co-administered with factor Xa inhibitors when treating acute venous thromboembolism. Macrolide antibiotics, such as clarithromycin and erythromycin, may inhibit metabolism of factor Xa inhibitors and

therefore caution should be applied if co-prescribed. Co-administration of rivaroxaban with dronedarone should be avoided given limited clinical data.

Prescription
Initially three weeks treatment should be prescribed and the GP should then continue.

C) Treatment with low molecular weight heparin and warfarin

Warfarin will be used if eGFR < 30 ml/min or if there is liver dysfunction.

Tinzaparin 175 units/kg once daily
Tinzaparin should be continued until the INR has been ≥ 2 for at least two consecutive days or for five days – whichever is the longer.

Monitoring the platelet count for heparin induced thrombocytopenia is not necessary.

Warfarin

The recommended target INR is 2.5 (target range 2.0 – 3.0)

Follow hospital green warfarin chart for dosing

Continuing LMWH in patients with cancer

Patients with an underlying malignancy will be considered for continuing LMWH rather than oral anticoagulation. However, in those who do not want to inject, an oral Xa inhibitor (that is apixaban or rivaroxaban) is a reasonable alternative. If continuing LMWH the patient will need to be able to administer their own LMWH or have a carer do it. Compared to warfarin, LMWH carries a similar risk of bleeding but halves recurrences in patients with cancer (Lee*, et al* 2003). Give a prescription for the first 4 weeks supply of Tinzaparin, and after that time the GP should prescribe it.

Antiplatelet medication

For patients with stable coronary artery disease patients (> 12 months from ACS, NSTEMI, STEMI, CABG or stent) antiplatelet therapy can be stopped when anticoagulated unless there is a high risk of future coronary events (prior stenting of the left main, proximal LAD, proximal bifurcation, recurrent MIs), in which case cardiology advice should be sought. Patients with more recent coronary artery disease should have their antiplatelet and anticoagulant regimen discussed with the relevant interventional cardiologist.

Duration of treatment and follow up

Patients with proximal DVT should be treated for at least 3 months (Boutitie*, et al* 2011)

Isolated calf DVT: Treat for 3 months (Kearon*, et al* 2012). No need for further investigations. If risk of bleeding, consider withholding treatment and repeat scan in 1-2 weeks' time to check for progression.

For a **first proximal DVT with transient risk factors** treatment will stop at three months. Prescribing Doctor should Inform patient of the stope date and write it on discharge letter to GP.

Transient risk factors (TRF):

surgery (the various studies used within 6 weeks/8 weeks/3 months)
significant trauma e.g. fracture, plaster cast
COC/HRT
pregnancy/puerperium

Long–term treatment will be *considered* for

recurrent thrombosis
patients with an on-going risk factor such as cancer
a first unprovoked proximal DVT.

Follow-up

Patients who may require long-term anticoagulation should be reviewed at three months to decide whether to stop or whether to continue indefinitely. Advise GP to refer to Haematology.

Patients who are definitely stopping at three months do not need follow-up.

3 months	**3 months then consider for long-term**
1st proximal DVT with TRF 1st isolated calf vein DVT	Recurrent thrombosis Proximal DVT with on-going risk factors 1st unprovoked proximal DVT

TESTING FOR THROMBOPHILIA

Do not offer routine thrombophilia testing.

Compression stockings

.
Stockings should no longer be prescribed routinely but only used selectively in patients to treat symptoms (Kahn*, et al* 2013)

Absolute contra-indications are: advanced peripheral arterial occlusive disease, decompensated heart failure, septic phlebitis, and phlegmasia caerulea dolens (DVT leading to severe swelling of the whole leg). Relative contra-indications are suppurative dermatoses, intolerance of compression stocking fabric, advanced neuropathy, and chronic arthritis.

Superficial Thrombophlebitis / Superficial Vein Thrombosis (SVT)

The most commonly affected superficial veins are the long (great) and short saphenous veins of the leg. Referral for investigation should not normally be necessary for a short segment of below knee SVT unless concomitant DVT is suspected. Patients who are referred with suspected concomitant DVT are assessed for DVT. If during this investigation it is found that SVT is adjacent to (within 3 cm of) the sapheno-femoral junction (SFJ) we will treat with therapeutic anticoagulation for three months (as for DVT) as there is a high risk of progression to DVT (Tait, et al 2012). A three month review is not required.

Otherwise SVT has been considered to be a benign and self-limiting condition and in the past was treated exclusively with non-steroidal anti-inflammatory drugs (NSAIDs). Although this is reasonable for mild cases it has become recognised that more severe cases have a better symptomatic response to anticoagulation.

"SVT letter" to GPs says:

Your patient has Superficial Vein Thrombosis (SVT). Patients with mild SVT (eg less than 5 cm in length) can be treated with NSAIDs but patients with more severe disease (eg more than 5 cm in length) may be better treated with an intermediate dose of LMWH for six weeks (Cosmi*, et al* 2012, Scott*, et al* 2015) as this has been shown to provide better symptomatic relief. If you wish to do this we would suggest: Tinzaparin at approximately 100 units/kg od.

Incidentally discovered asymptomatic DVTs

In patients who are unexpectedly found to have asymptomatic DVT the ACCP recommend the same initial and long-term anticoagulation as for comparable patients with symptomatic VTE (Kearon*, et al* 2012).

Upper limb DVT

These patients are not normally seen for diagnosis as pre-test probability assessment and D-dimers are not used but rather all suspected cases have an ultrasound examination.
Recurrence rates for upper limb DVT after treatment for three to six months are low and it is likely that prolonged anticoagulation is not required for most patients.

For most patients with upper limb DVT in association with an indwelling central venous catheter, the catheter should not be removed if it is functional and there is an on-going need for the catheter. If the catheter is removed anticoagulant treatment should not be shortened to less than 3 months.
Elastic compression is not used routinely but is reserved for patients who have persistent oedema and pain.

Women on the combined oral contraceptive pill (COCP)

Standard advice is that once patients have been diagnosed with a blood clot they should immediately stop taking the combined oral contraceptive pill and switch to an alternative method of contraception. In the meantime it is advised to use barrier methods or abstain from sexual intercourse. However there is more recent evidence and doctors with expertise in managing patients with blood clots have recommended that as long as they are taking anticoagulation medication regularly as prescribed it may be possible to continue with the combined oral contraceptive, because the risk of developing further complications of a blood clot are low.

Discussion with patient can involve the following:

There are several things to think about:

- Getting pregnant is also a risk factor for VTE especially if you have had one before, therefore stopping contraception without a plan may not be suitable for you.
- There may be a delay in getting an appointment with your GP to switch to an alternative method.
- It is recommended that you avoid pregnancy whilst on oral anticoagulants (Warfarin, apixaban or rivaroxaban) and therefore you will need effective contraception whilst on these medications.
- Anticoagulants used to thin the blood can make your periods heavier.
- If this is your first blood clot it is likely that you will only be on anticoagulation short 3 months.
- If you stop taking anticoagulation and continue with the combined oral contraceptive pill then you are at risk of developing another blood clot.

Importantly when you stop taking the pill you are immediately not protected from getting pregnant but the risk of blood clots lasts for about 4 weeks whereas the blood thinning effects of anticoagulation only take a few days to wear off. Therefore you MUST stop the combined oral contraceptive pill at least 4 weeks before you stop the anticoagulant medication.

If the decision is not to follow the standard advice the GP must be informed what the agreed prescribing plan is for off license use of the combined oral contraceptive for this patient.

DVT patients who when reviewed are suspected to have concomitant symptomatic PE

These patients do not necessarily need to be investigated for PE as the treatment is the same. However, consider whether they should be referred to the medics for consideration of admission. They should if they have any of:

Age > 80 years
Pulse ≥ 110 bpm
Systolic bp < 100 mm Hg
Sat < 90% Cancer
Chronic cardiopulmonary disease

6 Dissemination

The guideline will be available on the intranet.

7. Implementation

Guidelines will be implemented from 01/10/2017

8. Monitoring Compliance and Effectiveness

Table 1. Mandatory Elements of Monitoring Compliance.

Element to be monitored	Diagnosis of lower leg DVT
Lead	Ambulatory care/Dr K.John/Dr W Al-Sakkaf
Tool	Has diagnostic algorithm been followed?
Frequency	When a lower leg DVT is missed
Reporting arrangements	DATIX incidents
Acting on recommendations and Lead(s)	Depends on the nature of the incident
Change in practice and lessons to be shared	Depends on the incidents investigations outcomes

9. Reference and bibliography

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thromboembolism on risk of recurrence after stopping treatment: analysis of individual participants' data from seven trials. *Bmj,* **342,** d3036.

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10. WAHT associated records

Outpatient lower limb DVT management Guidelines (Not PE)

11. Staff compliance statement

All staff must comply with the Trust-wide procedural document and failure to do so may be considered a disciplinary matter leading to action being taken under the Trust's Disciplinary Procedure. Actions which constitute breach of confidence, fraud, misuse of NHS resources or illegal activity will be treated as serious misconduct and may result in dismissal from employment and may in addition lead to other legal action against the individual concerned.

12 Equality and Diversity statement

The Trust aims to design and implement services, policies and measures that meet the diverse needs of users of our services, population and workforce, ensuring that none are placed at a disadvantage over others.

Equality Impact Assessment Screening Tool

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

		Yes/No	Rationale
1	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation	No	
	• Age	No	
	• Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
2	Is there any evidence that some groups are affected differently?	No	
3	If you have identified potential discrimination, are there any exceptions valid, legal and/or justifiable?	No	
4	Is the impact of the policy/guidance likely to be negative?	No	
5	If so can the impact be avoided?	No	
6	What alternatives are there to achieving the policy/guidance without the impact?	No	
7	Can we reduce the impact by taking different action?	No	
8	Actions identified following screening process	None	
9	Screening identified a full impact assessment.	No	

If you have identified a potential discriminatory impact of this policy/procedure, please refer it the appropriate Director in the first instance, together with suggested actions required to avoid/reduce this impact. For advice in respect of answering the above questions, please contact the H.R Department. For advice on completion of this form please contact the Governance Team.