

REPORT TO THE PBC GOVERNANCE TO BE HELD ON 8th July 2009

Enclosure:					
Subject:	Seisdon management of suspected deep vein thrombosis				
Lead Director:	Geraint Griffiths				
Lead Officer:	Liz McCourt				
Recommendation:	For Approval	x	For Discussion		For Information

PURPOSE OF THE REPORT:

Proposal for a practice based system for suspected deep vein thrombosis (DVT). Practices will use system in conjunction with the Wells prediction tool and are required to produce an annual audit. The numbers are small, but still cheaper than a secondary care test and have the added advantage for the patient to receive a test whilst in the practice and save a hospital journey.

IMPLICATIONS:

Legal and/or Risk	Use of Wells prediction tool
Standards for Better Health	D2 (d) delivered by health care professionals who make clinical decisions based on evidence based practice
Financial	Initial set up funding from infrastructure. Long term this will be funded from acute contract.
Training	Educational event for practices to demonstrate system and how to use Wells prediction tool.
PBC	This is one of the areas in the Seisdon 9/10 PBC plan.
Patient Engagement & Safety	Seisdon Health survey 2008. People stated a preference for tests to be carried out in GP surgeries.

RECOMMENDATIONS / ACTION REQUIRED:

PBC Governance to consider and approve.

PEC views were sought on behalf of Seisdon PEC representative Claire Ward from Dr Ballard and Dr Shipman at the informal PEC in June. Both were supportive of proposal. The feedback was this did not need to go formally to PEC and could proceed to PBC governance.

Executive summary

The Seisdon Peninsula Locality Commissioning group met on the 1st April 2009 to discuss and consider the options of the management of suspected DVT in primary care (Appendix 1).

The options available were:

1. Service provided by intermediate care using one Cobas machine
2. Practice based service using Clearview system

The Locality felt due to their rural locations and distance to travel there would be no additional benefit to patients providing a service from the intermediate care team, who may not be able to respond quickly if there were other competing priorities. The GPs were in favour of a practice based service and supported a Clearview machine in each practice and branch surgery. This would be more convenient for the patient to save them from having to travel for a test.

The advantage of the Clearview system is there is no significant investment in set costs of machines.

One practice has already purchased a Cobas machine and for equity it was agreed they should be reimbursed for cost of the strips.

Each practice will sign up to follow the Wells prediction tool and produce an annual audit. To reimburse practices for nurse time etc it was agreed £250 per practice would be reimbursed, but only on the production of an audit after 12 months.

Costs	£
Clearview machines (8 incl. branch surgery)	455.20
Clearview strips (80 patients)	1,633.60
Cobas strips	80.60
Practice cost/audit	2,000.00
Total (estimated costs for 80 patients)	4,169.40
Average cost per patient	52.12

The cost in secondary care ranges from an A&E attendance to an emergency HRG cost of approximately £500.

PBC Governance are asked to consider introducing this scheme for 12 months on the condition practices follow the Wells prediction tool and produce an annual audit.

Appendix 1

Management of Suspected Deep Vein ThrombosisIntroduction

Currently, any patient in the Seisdon Peninsula with a suspected deep vein thrombosis (DVT) is referred to secondary care to prove or refute the diagnosis. Following discussions about near-patient D-Dimer testing at the meetings of the Seisdon Peninsula Locality Commissioning Group in March and April 2009, a suggestion was made to redesign the service for our patients with a suspected DVT. In the further development of this idea, a number of documents have been referenced and the issue discussed with Dr Paul Harrison, Consultant Haematologist and Medical Director of Russells Hall Hospital, Dudley.

Three questions have to be answered in any service redesign:
 Is the redesign clinically safe?
 Does the redesign improve the patient experience?
 Is the redesign cost-effective?

This paper sets out the proposal to redesign the pathway in the management of patients with a suspected DVT in the Seisdon Peninsula in the context of answering these questions and puts forward two options for further discussion.

Clinical Safety.

Deep vein thrombosis (DVT) is a common condition with an estimated annual incidence of 0.1% in white populations (1). Untreated DVT can result in pulmonary embolism, a potentially fatal outcome. Anticoagulant therapy reduces both morbidity and mortality from venous thromboembolism, and early diagnosis is therefore important. Accurate diagnosis of DVT minimizes the risk of thromboembolic complications and averts the exposure of patients without thrombosis to the risks of anticoagulant therapy.

Diagnostic strategies must correctly diagnose DVT when present and safely rule out DVT when absent. The desire not to miss a patient with DVT combined with the large number of non-specific signs and symptoms makes DVT part of the differential diagnosis in most patients presenting with leg pain or swelling and presents a diagnostic challenge to clinicians. Seventy five per cent of outpatients who present with signs and symptoms suggestive of DVT do not have the disease (2).

A clinical prediction rule is a scoring system that calculates the pretest probability of a disease (here, DVT) from a clinical assessment of risk factors and physical findings. The Wells prediction rule (Appendix A) has been the most frequently evaluated and analysis suggest modest discrimination between patients with DVT and without (3.) Using this model, less than 5% of outpatients classified as low clinical probability have a DVT (1).

D-Dimer is a degradation product of a cross-linked fibrin blood clot. Levels of D-Dimer are typically elevated in patients with acute venous thromboembolism. D-Dimer levels may also be increased by a variety of non thrombotic disorders, including recent major surgery, haemorrhage, trauma, pregnancy, cancer or acute arterial thrombosis. D-Dimer assays are, in general, sensitive but non specific markers so that a positive D-Dimer result is not useful to 'rule in' the diagnosis of DVT. Instead the value of the D-Dimer is with a negative result that works to lower the likelihood of the diagnosis.

There are a variety of D-Dimer assays available which vary in their sensitivity and specificity. The use of D-Dimer testing has improved the diagnostic process in suspected DVT but the D-Dimer result itself does not serve as the reference standard for the presence or absence of DVT (1).

Several studies have combined a clinical prediction rule with a D-Dimer assay. Using moderate-sensitivity D-Dimer assays, when combined with a negative D-Dimer result, diagnostic imaging and anticoagulant therapy can safely be withheld for those patients with a low clinical probability estimate (3,4). In such patients, the probability after testing for DVT is less than 1%. In other words, the use of a D-Dimer assay **with** a clinical prediction rule has a very high negative predictive value (1).

Wells et al state that the diagnosis of DVT can be excluded without the need for ultrasound by using a combination of low clinical probability estimate and a negative D-Dimer result, and that this strategy should apply to as much as 40% of patients referred with suspected DVT (1).

All patients with a high probability of DVT using the clinical prediction rule will require diagnostic imaging to rule out safely DVT.

A diagram illustrating the proposed redesigned pathway for the management of suspected DVT is shown in figure 1.

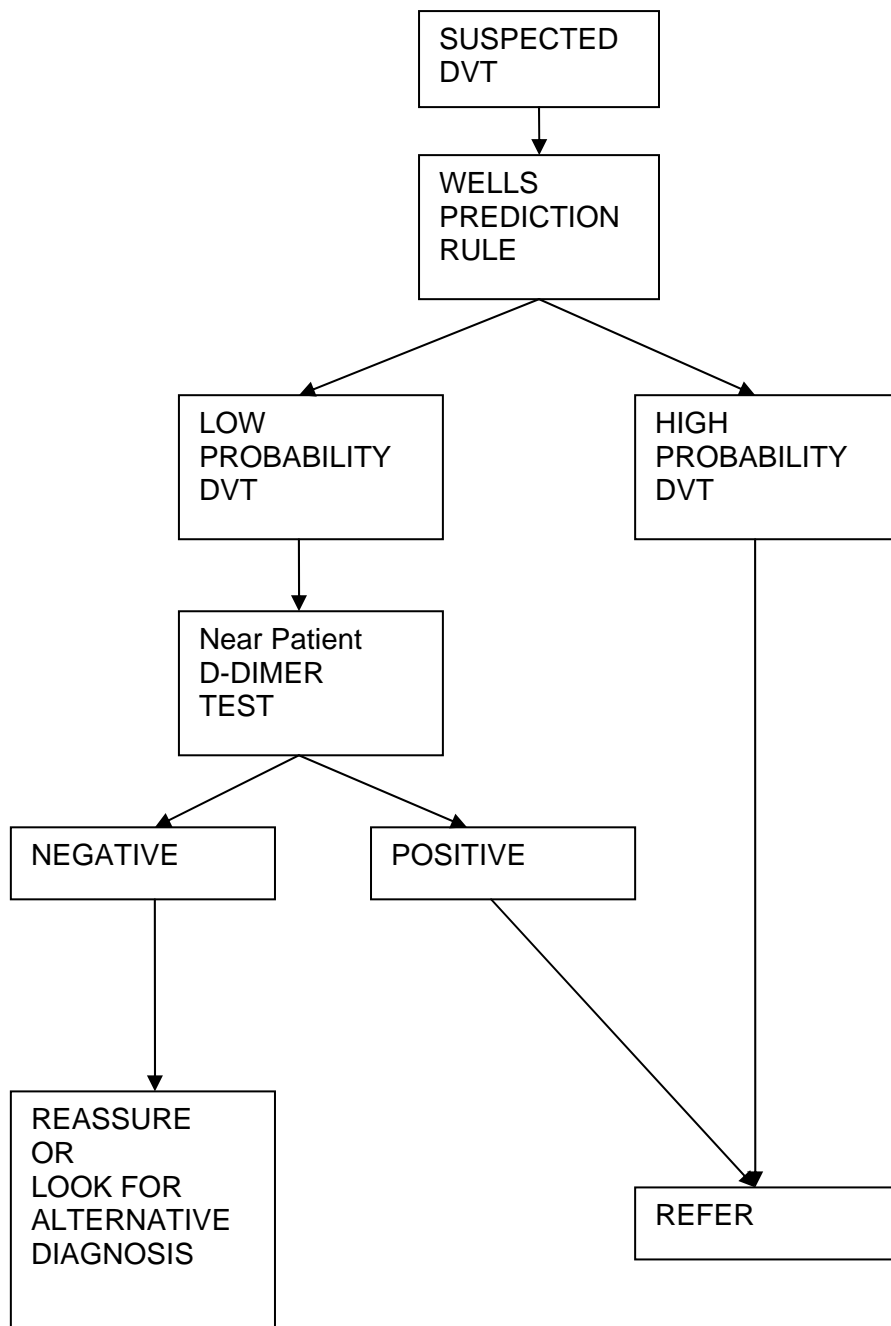


Figure 1: Proposed Pathway for management of suspected DVT

Patient Experience

Of the three questions, this is probably the easiest to answer. To replace a return journey to either New Cross or Russells Hall Hospital and a possible considerable wait when there with a clinical assessment and test in the community is likely to be regarded by most as an improvement.

Cost Effectiveness

No figures are available for the numbers or costs of suspected DVTs currently referred to secondary care. An estimate has therefore been made from the information detailed above:

SPLCG population		= 45,000 patients
Annual incidence of DVT in Seisdon Peninsula	0.1%	= 45 patients/yr
Number of patients screened to reach this diagnosis* screened/yr		= 180 patients
40% excluded by use of clinical predictor tool & D-Dimer		= 72 patients/yr
Estimate of patients having D-Dimer after clinical predictor		= 80 patients/yr

* 75% of suspected DVT do not have this diagnosis (2)

Enquiries at New Cross Hospital reveal that we are charged an HRG typically between £500-£600 for patients with a suspected DVT. Figures for Russells Hall Hospital are awaited.

Cost of 72 patients referred currently to secondary care @£500 = £ 36,000

Two types of near patient testing for D-Dimer are considered here:-

Cobas h232 made by Roche (www.cobas-roche.co.uk)
Clearview Simplify D-Dimer made by Inverness Medical (www.clearview.com)

There are several differences between the two systems although both manufacturers promote their products for ruling out DVT. All prices quoted below exclude VAT.

No costs for GP Practice reimbursement are included in the figures and this will need further discussion within the Locality Commissioning Group.

Cobas h232

The Cobas h232 system is a hand-held machine for on-the-spot diagnoses of a number of cardiovascular diagnoses using different specific test strips, of which D-Dimer is one. A venepuncture sample is required. Reaction time is 8minutes and the result is numerical. Figures of 96.9% sensitivity and 60.8 %specificity are quoted by the manufacturer. Training is included in the purchase price of the machine.

Costs

Cost of near patient Cobas h232 D-Dimer test machine	= £ 1065-00
Cost of single test strip	= £ 8-06
Cost of test strips to test 80 patients above	= £ 644-80
Cost of 2 sets of internal quality control strips	= £ 63-50
Cost of 2 control sets (2x6chks each)	= £ 74-78
Consumables (disposable syringe pipettes)	= £ 50-28

Cost of 80 patients/yr tested using Cobas h232 = £ 1898-36 in Year 1
= **£ 833-36 in Years 2/3**

Packets of strips to undertake 10 tests are supplied although it is assumed that two test strips per packet are used as controls. The unit price per test strip quoted above takes this into account.

It can be seen that the number of patients that potentially could have a diagnosis of DVT excluded each year in the community is relatively small and for each practice is on average less than one patient per month. It is therefore proposed that for this option, rather than equipping each of the eight practices in the Locality with a separate machine, to purchase one machine to be located centrally with the Intermediate Care Team. This is not only more cost effective but has the added advantages of familiarity of use, training and facilitation of quality assurance issues. This pathway, using the Cobas h323 system and the Intermediate Care Team, has apparently being adopted by Walsall PCT.

No costings have been included for the Intermediate Care Team and this will need to be clarified.

Clearview Simplify D-Dimer

The Clearview Simplify D-Dimer uses the monoclonal antibody 3B6 which is highly specific for D-Dimer and does not cross-react with other fibrin degradation molecules. The two step procedure requires no expensive instrumentation and gives a positive/negative result in ten minutes. The test cartridge itself is a slide similar in appearance to a professional use pregnancy test and requires only a finger prick drop of blood, followed by two drops of a buffer solution to complete. The manufacturer quotes 100% sensitivity (90-100%)* and 52.9% specificity (41.8-63.8%)* and state that no specialised training is necessary.

*= 95% Confidence Interval

Costs

Cost of single Clearview Simplify D-Dimer test	= £ 20-42
Cost of Clearview tests to test 80 patients	= £ 1633-60
Simplify D-Dimer Controls (1kit/practice@ £56-90)	= £ 455-20

Cost of 80 patients/yr tested using Clearview Simplify D-Dimer = £ 2088-80/yr

Complete kits to undertake 10 tests are supplied, although it is assumed that two tests per kit are used as controls. The unit price per test quoted above takes this into account. The Clearview Simplify test has the advantage of being carried out in the surgery and not having to involve the Intermediate Care Team. This pathway, using the Clearview Simplify D-Dimer test performed in practices, has apparently being adopted by East Sussex Downs & Weald PCT.

Quality Control & Assurance

Dr Harrison made the point that a programme such as this should have both internal quality control measures and external quality assurance measures in place to ensure the accuracy of the measurement of D-Dimer. Costs for the internal quality control measures to check the performance of the Cobas h232 system are included in the above figures, as are the costs of external control measures for both the Cobas h232 and Clearview

systems. Dr Harrison kindly offered the help of his department in organising further external quality assurance.

Conclusion

The proposal is to provide GP practices with the facility for near patient D-Dimer testing. A patient presenting to the GP with a suspected thrombosis would have a clinical prediction of DVT made by using the Wells tool. If there is a low probability of DVT, a D-Dimer test would be performed. If negative, a diagnosis of DVT could safely be excluded.

Both near-patient systems will deliver a cost saving on current practice. The Cobas h232 system is marginally cheaper and, by using the Intermediate Care Team, would offer a robust centralised resource for the locality. The Clearview Simplify D-Dimer test has some advantages over the Cobas h232 system with regard to simplicity of use and convenience of location offering a practice based resource.

Whichever system of D-Dimer measurement is chosen, this proposed redesign of the current service is safe, cost effective and would improve the patient experience.

The Locality Commissioning Group need to discuss:-

- The preferred system of near-patient testing for D-Dimer
- The issue of G.P Practice reimbursement

Dr Tim Dukes 2/5/09

References

- 1:- Does this patient have Deep Vein Thrombosis. Wells et al. JAMA Vol.295 No.2, Jan 11, 2006
- 2:- Combined use of rapid D-Dimer testing and estimation of clinical probability in the diagnosis of deep vein thrombosis: systematic review. Fancher et al. BMJ 2004;329:821
- 3:- Review of the Evidence on Diagnosis of Deep Vein Thrombosis and Pulmonary Embolus. Segal et al. Annals of Family Medicine 5:63-73 (2007)
- 4:- Evaluation of D-Dimer in the diagnosis of Suspected Deep Vein Thrombosis. Wells et al. NEJM Vol 349:1227-1235 Sept 2003

APPENDIX A.

From Wells et al: NEJM Reference 4 above

Table 1. Clinical Model for Predicting the Pretest Probability of Deep-Vein Thrombosis.*	
Clinical Characteristic	Score
Active cancer (patient receiving treatment for cancer within the previous 6 mo or currently receiving palliative treatment)	1
Paralysis, paresis, or recent plaster immobilization of the lower extremities	1
Recently bedridden for 3 days or more, or major surgery within the previous 12 wk requiring general or regional anesthesia	1
Localized tenderness along the distribution of the deep venous system	1
Entire leg swollen	1
Calf swelling at least 3 cm larger than that on the asymptomatic side (measured 10 cm below tibial tuberosity)	1
Pitting edema confined to the symptomatic leg	1
Collateral superficial veins (nonvaricose)	1
Previously documented deep-vein thrombosis	1
Alternative diagnosis at least as likely as deep-vein thrombosis	-2

* A score of two or higher indicates that the probability of deep-vein thrombosis is likely; a score of less than two indicates that the probability of deep-vein thrombosis is unlikely. In patients with symptoms in both legs, the more symptomatic leg is used.