This document is part of a set of ten education modules which are aimed at improving the appropriateness of referrals for medical imaging by educating health professionals about the place of imaging in patient care.
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1. INTRODUCTION

WHAT IS DVT?

The incidence of deep vein thrombosis (DVT) in Australia is approximately 160 per 100,000. Approximately 14,000 episodes of venous thromboembolism (VTE) are diagnosed per year, 6500 of which are DVT\(^1\)\(^2\). Venous thromboembolism (DVT and PE) remains the most preventable cause of death in hospitalised patients.

Rudolph Virchow, a German pathologist first described the contributing factors to venous thrombosis in 1856. Blood composition (hypercoagulability), blood stasis and vessel wall injury all contribute to clot formation and disease.

CAUSES:

Predisposing factors include prolonged bed rest (due to prior surgery and hospitalisation or other causes, including long standing paralysis of one or both lower limbs), major trauma, and heritable or acquired prothrombotic (thrombophilic) tendencies. Examples of heritable thrombophilia include deficiency of natural anticoagulants (Protein C & S and antithrombin) and factor V Leiden mutation, while acquired causes of thrombophilia include pregnancy and the postpartum period, malignancy, hormone replacement/the oral contraceptive pill and antiphospholipid syndrome.

COMPLICATIONS:

The potential complications of untreated DVT include thrombus propagation, pulmonary embolism (PE) and death from PE. A significant but under-appreciated longer-term complication is post-thrombotic syndrome (PTS) and this can occur in up to 40% of patients with proximal DVT, as a result of venous incompetence and hypertension. A validated CDR is available to diagnosis PTS (The Villalta PTS Scale). Patients with severe PTS can develop venous leg ulcers.

DIAGNOSIS:

After clinical assessment of patients presenting with suspected DVT using a CDR, in conjunction with D dimer assay performed on a sample of venous blood, Doppler US is used to confirm or exclude the presence of DVT in people who cannot have this excluded on the basis of clinical low risk and negative D dimer.

TREATMENT:

The established treatment for proximal DVT is anticoagulation for 3 to 6 months. Calf (or infra-popliteal) DVT may require a shorter duration of treatment. Traditionally, low molecular weight heparin (LMWH) and warfarin are used. Rivaroxaban, a new oral anticoagulant that inhibits coagulation factor Xa with superior pharmacological properties compared with warfarin, is now available to treat DVT and provides the patient with an effective, safe and convenient alternative. Patients with large proximal DVT may be candidates for catheter directed lytic therapy.
Howard can clinical decision rules help to standardise pre-test risk evaluation of patients with DVT?

When evaluating patients with suspected DVT, the key issue to be addressed is whether or not the patient should be investigated using imaging to confirm or exclude DVT. When attempting to make the decision about whether or not to use diagnostic imaging, it is important to focus on features of the history and physical examination that have been found to be associated with the presence of DVT.

At first, it might seem simpler, quicker, and safer to perform an imaging test on everyone with suspected DVT. When the pre-test probability of DVT is not very low, the considerable benefits of earlier diagnosis outweigh the costs and risks of diagnostic imaging. A confirmed diagnosis of DVT will direct appropriate treatment, usually consisting of systemic anticoagulation to prevent morbidity such as post thrombotic syndrome, or embolisation of DVT to the lungs (PE) which can lead to death.

There are a number of disadvantages to the practice of referral of patients for imaging without first considering what the pre-test probability of a condition is likely to be. They include:

- **Financial cost to the patient and health system of unnecessary testing.** These costs are both direct and indirect (the latter due to waiting time in emergency departments, prolonged length of stay in a hospital, time away from work and other responsibilities waiting for imaging to be performed, having it performed, and then waiting for the result).
- **Incidental findings on imaging frequently have no clinical significance for the patient but trigger further imaging follow up to exclude the very small possibility of something significant.**
- **A test other than medical imaging may be a faster, less expensive way of ruling out clinically important pathology.** An example of this is the performance of D dimer in patients with suspected venous thromboembolism (either lower limb DVT or pulmonary embolism) when the pre-test risk is assessed as being low.

Continued increases in healthcare costs are a global problem. More than ever before, medical practitioners are being asked to be accountable for utilisation of finite health care resources and to add value and reduce waste in the care they deliver to patients. Reducing inappropriate use of diagnostic imaging in situations where it is highly unlikely to result in a net benefit to the patient is an important way to reduce waste and improve quality of care.

Clinical decision rules (CDRs) can help you to focus on the aspects of the history and examination that best discriminate between

- **patients with low-to-no risk of significant pathology** who are, therefore, unlikely to benefit from diagnostic imaging; and
- **patients who do not have negligible risk** who need imaging to guide further specific treatment including in some cases in-hospital monitoring, medical therapy, or even surgery.

CDRs have been developed by gathering detailed clinical datasets from large numbers of patients with a particular condition, such as adults presenting to an emergency department with possible DVT. They are comprised of a series of key examination findings (such as side-to-side difference in calf circumference) and aspects of the history (such as current/recent active malignancy, recent immobility or past history of thromboembolism) that have been found, when absent, to be associated with such a low risk (or pre-test probability) of clinically important disease that imaging is not required to further reduce this risk.

The emphasis of the current educational modules is on CDRs that involve risk assessment of patients with regard to their requirement for diagnostic imaging, but CDRs for other outcomes (such as prognosis) have also been developed.

The usefulness of CDRs is that they help to reduce the subjectivity and inter-observer variation involved in the clinical assessment of patients with specific conditions that sometimes, but not always, require imaging. Imaging is sometimes performed in these conditions to allow diagnosis of serious pathology. Using CDRs can help to increase your confidence about the safety of managing your patient without imaging when recognized clinical risk factors for serious pathology are entirely absent.

Documentation in the medical record that you have used a high quality CDR to evaluate your patient and make management decisions based on this is good practice and increases the likelihood that another medical practitioner evaluating your patient would come to the same conclusions as you did about management.
Please see the Clinical Decision Rules Module for more information about:

- what CDRs are;
- how they are developed; and
- what the characteristics of a high quality CDR are.

Resources:

Something that will become apparent as you work through these modules is the difficulty involved in trying to commit the elements of CDR to memory. It is a good idea to refer to an electronic or hard copy of the CDR each time you use it to ensure that you are applying it correctly. To support this, the following resources are provided:

- Printable PDFs of the CDR including inclusion and exclusion criteria.
- “Pocket-sized” PDFs suitable for printing, lamination, and attachment to a lanyard.
- Links to the website MDCalc where you will find a calculator that allows you to enter clinical data for your patient into a clinical decision rule. This website does not feature all published CDRs for a particular condition and does not discuss the reasons for featuring some and not others. This module will help you develop an understanding of how to use the Wells Score and who you can and cannot apply it to in an adult with suspected lower limb DVT. Go to the website now and try out the calculator for the Wells Score for DVT - http://www.mdcalc.com/wells-criteria-for-dvt/.

For more information about specific imaging tests and procedures please see – www.insideradiology.com.au

**WHAT ELSE DO YOU NEED TO THINK ABOUT WHEN YOU CONSIDER IMAGING A PATIENT WITH SUSPECTED DVT APART FROM PRE-TEST RISK?**

- **Test performance** (sensitivity, specificity, positive likelihood ratio (LR+) and negative likelihood ratio (LR-)) in relation to the pathological process(es) you are trying to diagnose or exclude.
- **What is available locally**, especially in an emergency.
- **Radiation dose** (of particular importance in young and pregnant patients).
- **Financial and other costs to the patient and health system of one diagnostic strategy compared with another.**
- **Renal function** in the case of imaging tests that involve the use of iodinated contrast media or gadolinium chelates.
- **Patient preferences** – if two diagnostic tests perform equally well at confirming or excluding the presence of a particular condition, patients may have a preference for one over another for reasons of cost, convenience, risk, or real/perceived discomfort associated with a particular diagnostic test or diagnostic strategy.
2. CLINICAL DECISION RULES

HOW CAN CLINICAL DECISION RULES HELP TO DETERMINE PRE-TEST RISK OF DEEP VEIN THROMBOSIS IN PATIENTS WITH SUSPECTED DVT.

A number of CDRs exist that are applicable to patients with suspected DVT. A high performing CDR has been defined by McGinn et al\textsuperscript{1} as one with a sensitivity of >95\% (with a lower limit of the 95\% confidence interval for sensitivity of 95\%) and a LR for a negative result, when using the CDR, of 0.1 or less.

This means that a patient with a “negative result” using a high performing CDR has less than a 5\% chance of having the clinically important outcome that the CDR is designed to exclude. The best CDRs are high performing, i.e. highly sensitive at identifying all patients with the target condition, and they have been extensively validated in multiple clinical settings and have been shown repeatedly to perform just as well as at the site(s) other than where they were originally derived. The best CDRs often have been studied with regard to whether clinicians actually use them in practice, when they have the choice not to, and whether use of the CDR reduces healthcare costs, or volume of imaging tests performed, or changes clinician behaviour or management decisions in some way.

Things to consider when you use clinical decision rules:

- Not all CDRs with high quality development methods meet these rigorous criteria of high performance, extensive validation, and impact analyses. This is especially true of clinical decision rules designed for or validated in paediatric populations where rule performance tends to be lower and validation studies less frequent, in part due to the relative infrequency of the condition of interest (such as intracranial injury) in a group of at risk patients. This makes it more expensive to conduct a validation study because of the larger numbers of subjects required.

- CDRs that have not been validated in multiple clinical settings may not perform as well in practice as they did at the site(s) at which they were derived due to special training, expertise, and other factors peculiar to the people who participated in the original research that led to the development of the CDR.

Nevertheless, even when these limitations are present, CDRs can be useful in guiding the clinical evaluation of the patient to ensure you look for specific examination or historical features that are known to increase the likelihood of actual pathology. Greater judgement needs to be exercised by the clinician when using lower performance rules if they yield a negative result, however, because the likelihood of serious pathology may be higher than when using a higher performing CDR.

The following CDRs for patients with suspected DVT have been identified through a systematic search of the literature to be the best performing tools available for this patient group. Information about the CDRs for this clinical condition is provided below as follows:

1. A short summary of the nature of each CDR that includes:
   a. an overview of the performance of the rule;
   b. general inclusion and exclusion criteria;
   c. precautions about routine clinical use of the CDR.

2. More detailed information about these aspects of the theses CDRs can be found in the evidence table (Appendix One) at the end of the module. It allows rapid comparison of the performance, inclusion and exclusion criteria for each CDR.

3. Appendix One – Evidence Summary Table provices a summary of:
   a. The performance of the individual rules based on the derivation study and/or the first validation if this was performed in conjunction with the derivation study.
   b. Inclusion and exclusion criteria for each CDR. Note that the CDR or algorithm alone does not tell you the characteristics of patients to whom you can apply the CDR. Knowing the situations in which you CAN and CANNOT use a CDR is just as important as knowing the elements of the CDR itself. Common exclusion criteria include patient age, whether the person is an inpatient (rather than an ambulatory outpatient), and use of anticoagulation.
   c. Validation studies that have been identified for the CDR including their performance and inclusion and exclusion criteria if these differ from the derivation study.

4. Links to the full text derivation studies for the individual CDRs.

Throughout this module, you will be presented with questions that will evaluate module content and also your ability to apply this to real clinical situations.
The Wells Score for Patients with Suspected Lower Limb DVT

Summary Statement:
This study by Wells et al. established that in ambulatory outpatients with suspected lower limb DVT and a Wells Score of less than 2, it is safe to exclude DVT by performing a D dimer assay which, if negative, obviates the need for imaging to exclude DVT. The lower limit of the negative predictive value of the combination of a score <2 and negative D dimer was found to be 96.7%, making it very comparable with the negative predictive value of a normal ventilation perfusion lung scan in a patient with suspected pulmonary embolism. It has been extensively validated by investigators apart from those who developed it.

Algorithm:

![Diagram of the Wells Score for DVT](image)

FIGURE 1: APPLYING THE WELLS SCORE FOR PATIENTS WITH SUSPECTED DVT
QUESTION 1.
Which of the following are clinical factors that increase the likelihood of DVT being present according to the Wells Score? Select all possible answers.

1A: Oral contraceptives
1B: Active malignancy
1C: Breast cancer treated with radiation and chemotherapy 5 years ago with no evidence of active disease and not currently on treatment
1D: Paralysis of both lower limbs due to previous gunshot wound to spine
1E: Calf diameter difference of 1 cm with no evidence of distended superficial veins

CORRECT ANSWER:
The following are clinical factors that increase the likelihood of DVT being present according to the Wells Score:
1B: Active malignancy
1D: Paralysis of both lower limbs due to previous gunshot wound to spine

QUESTION 2.
When can the Wells Score not be used? Select all possible answers.

2A: Pregnancy
2B: Non ambulatory hospital inpatient 3 days post laparotomy for small bowel obstruction
2C: Patients aged over 65
2D: Suspected upper limb DVT
2E: Anticoagulation for the past 48 hours

CORRECT ANSWER:
The Wells Score cannot be used in the following situations:
2B: Non ambulatory hospital inpatient 3 days post laparotomy for small bowel obstruction
2D: Suspected upper limb DVT
2E: Anticoagulation for the past 48 hours

FEEDBACK: Pregnancy is incorrect because although use of the Wells Score is not specifically precluded in pregnancy, it tends not to be useful due to physiological elevation of D dimer after the first trimester, so ultimately virtually all pregnant patients will need lower limb duplex Doppler venous ultrasound to exclude the possibility of DVT regardless of their risk status.
RULING OUT DEEP VENOUS THROMBOSIS IN PRIMARY CARE. A SIMPLE DIAGNOSTIC ALGORITHM

Summary Statement:
This CDR was developed by Oudega et al. for use in general practice to determine the need for referral of patients for ultrasound. Unlike the Wells Score, this test informs the decision:

“Does this patient need a lower limb venous duplex ultrasound to determine whether they have a DVT?” whereas the Wells Score answers the question: “Which test, D dimer or lower limb venous duplex ultrasound, does this patient need?”

Patients aged over 18 who had clinical suspicion of DVT based on pain and/or swelling and/or redness of the lower limb that suggested a possible DVT to the general practitioner were eligible for enrolment in this study. Although this approach to excluding the diagnosis of DVT had a negative predictive value comparable to the Wells Score, the specificity was much lower and this may relate to the difference in approach of the two CDRs.

Oudega et al utilises D dimer to screen all patients with suspected DVT before then allocating some to ultrasound (US). The scoring system results in all patients with positive D dimer receiving ultrasound and if D dimer is negative, 3 or more criteria need to be met before ultrasound is required to rule out DVT. This rule has not been validated by investigators other than those who developed it. Therefore, the Wells Score should be used in patients with possible DVT as it has a high negative predictive value, has been extensively validated, and is more specific than the CDR developed by Oudega et al which could be expected to lead to more lower limb venous ultrasound studies being performed in patients with no DVT as well as D dimer being performed unnecessarily in higher risk patients who should preferentially be referred directly for ultrasound of the lower limb venous system.

NOTE: It is important to note that both CDRs are for use in ambulatory outpatients, not hospital inpatients.

Algorithm:

<table>
<thead>
<tr>
<th>Predictor</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male Gender</td>
<td>+1</td>
</tr>
<tr>
<td>Oral Contraceptive Use</td>
<td>+1</td>
</tr>
<tr>
<td>Presence of Malignancy (active cancer &lt;6/12)</td>
<td>+1</td>
</tr>
<tr>
<td>Recent Surgery (&lt;4/52)</td>
<td>+1</td>
</tr>
<tr>
<td>Absence of trauma (&lt;4/52)</td>
<td>+1</td>
</tr>
<tr>
<td>Vein distension</td>
<td>+1</td>
</tr>
<tr>
<td>Calf difference ≥3 cm</td>
<td>+2</td>
</tr>
<tr>
<td>Abnormal D dimer test</td>
<td>+6</td>
</tr>
</tbody>
</table>

TABLE 1 – CRITERIA OF THE SIMPLIFIED DIAGNOSTIC ALGORITHM

The score could range from 0 to 14. Patients in the very low risk group (≤ 3) do not require referral for ultrasound investigation or further work up to exclude DVT.
3. **What else do you need to think about, other than pre-test probability of a condition, when you are considering performing diagnostic imaging in a patient with suspected DVT?**

**Urgency:**

D dimer testing is available in most emergency departments on a 24/7/365 basis but ultrasound services may not be. Imaging of patients with suspected DVT, but no suspicion of pulmonary embolism, should be performed within 24 hours of the diagnosis being suspected but is generally not considered to be as urgently required as imaging in a patient with suspected PE. Initiation of anticoagulation while the patient is waiting for imaging is not a uniform practice.

**Should imaging be the first test?**

1. Imaging with duplex compression ultrasound is the test of choice in patients who:
   a) do not have low probability of DVT using the Wells Score; or
   b) have a low probability but a positive D dimer result.

   This is because D dimer has a high enough sensitivity to allow anticoagulation to be withheld if the patient is low risk and D dimer is negative. However, patients at higher risk who have a negative D dimer do not have sufficiently low post test probability to allow them to go untreated without imaging being performed to exclude DVT. Therefore, D dimer is not a useful extra step in patients who do not have a low pre-test risk, because when D dimer is negative in these patients, it does not prevent the need for imaging.

2. Pre-test probability assessment with a high quality CDR is thus an essential pre-requisite before testing occurs in a patient with DVT to enable the right test to be chosen and to avoid non-contributory D dimer testing in those at higher risk.
## MODALITY TABLE

<table>
<thead>
<tr>
<th>MODALITY</th>
<th>STRENGTHS</th>
<th>WEAKNESSES</th>
<th>COMMENTS</th>
</tr>
</thead>
</table>
| Duplex ultrasound (combining B mode compression ultrasound and Doppler) | • This is the imaging test of choice for suspected DVT and is highly sensitive for femoropopliteal DVT.  
• Caval and iliac vein thrombosis is diagnosed with colour Doppler ultrasound alone as these veins cannot be compressed with the ultrasound probe.  
• No ionising radiation.  
• Simple to perform.  
• Safe in pregnancy. | • Somewhat less sensitive for deep venous thrombosis in the calf veins.  
• Considerably less sensitive for common iliac and IVC thrombosis due to shadowing of these structures by overlying bowel gas which prevents penetration of the ultrasound beam.  
• Ultrasound availability after normal working hours varies but DVT rarely requires urgent exclusion and can usually wait until the next morning. | In obese patients or those with markedly edematous lower limbs, visualisation and compression of veins can be difficult.  
Ultrasound cannot be performed through bandages or plaster (if the patient has a lower limb fracture). If there is serious suspicion of DVT in this situation the plaster and/or dressings may be temporarily removed and then replaced. |
| CT venography | • Requires iodine containing contrast to be administered.  
• Investigation of choice for suspected common iliac and/or caval thrombosis. | • Rarely if ever performed for femoral, popliteal, or calf veins.  
• Flow artifacts from unopacified venous tributaries and in the inferior vena cava can mimic thrombus.  
• Relatively high radiation dose.  
• Risks associated with intravenous injection of iodinated contrast (anaphylactoid reaction, renal function impairment). | |
| Contrast Venography | • Performed in the fluoroscopy suite using tourniquets on the thigh and calf and injection of iodinated contrast medium into a superficial vein on the dorsum of the foot. Imaging is performed using x-rays while the radiologist injects and observes the veins filling with contrast medium.  
• Was the investigation of choice for suspected DVT prior to the advent of duplex ultrasound in the 1980s.  
• Now rarely performed.  
• Injection of contrast into the femoral vein under fluoroscopic control is routinely performed by radiologists prior to attempted insertion of an inferior vena caval filter. Caval filters are used for patients who suffer repeated pulmonary emboli despite anticoagulant therapy. | Risks associated with:  
• Ionising radiation.  
• Iodine contrast administration.  
• Uncomfortable/painful for the patient compared with ultrasound.  
• Achieving satisfactory filling of veins with contrast medium does not always occur. | |
QUESTION 3.
A 59 year old woman returns by plane to Australia after a walking holiday in the UK. 3 days later she notices aching in her right popliteal fossa and presents to the emergency department. On examination she has some local tenderness and swelling in the popliteal fossa. Her right calf does not look swollen and measures 1 cm more in diameter than the left one. The superficial veins are not distended and the leg is not tender anywhere except the popliteal fossa. She has no history of cancer or DVT.

What would you do next?
3A: Whole blood D dimer assay as she is unlikely to have DVT and a negative result would mean imaging is not required
3B: Duplex compression ultrasound as she is at high risk of DVT

CORRECT ANSWER:
What would you do next?
3A: Whole blood D dimer assay as she is unlikely to have DVT and a negative result would mean imaging is not required

FEEDBACK: Her Wells Score is -2 as the most likely diagnosis is rupture of a Baker’s cyst. She is therefore suitable to have DVT excluded with D dimer

QUESTION 4.
A 28 year old woman who is currently 29 weeks pregnant presents with a painful swollen left calf. She denies any trauma. On examination the calf is visibly swollen compared with the right one but not hot or red.

Which of the following are true? Select all possible answers.
4A: Although pregnancy is not an exclusion criterion for use of the Wells Score, physiological elevation of D dimer means that the vast majority of patients will require imaging even if they are “low risk: according to the Wells criteria
4B: It would be reasonable to proceed directly to lower limb duplex Doppler ultrasound evaluation of the veins of the left lower limb in this situation
4C: If the patient also has symptoms and/or signs of pulmonary embolism (PE) she should have imaging to diagnose or exclude PE first
4D: None of the above

CORRECT ANSWER:
Which of the following are true:
4A: Although pregnancy is not an exclusion criterion for use of the Wells Score, physiological elevation of D dimer means that the vast majority of patients will require imaging even if they are “low risk: according to the Wells criteria
4B: It would be reasonable to proceed directly to lower limb duplex Doppler ultrasound evaluation of the veins of the left lower limb in this situation
4C: If the patient also has symptoms and/or signs of pulmonary embolism (PE) she should have imaging to diagnose or exclude PE first.

FEEDBACK: If imaging for PE is positive it is unlikely that the use of lower limb US, to diagnose DVT, will be needed as finding DVT in this situation will generally not change acute management
QUESTION 5.
A 33 year old man presents with a painful swollen left arm. He has no relevant past medical history but reports painting the ceilings and replacing light fittings in his new flat over the past week. You suspect he may have an upper limb DVT.

What would you do next?
SA: Use the Wells Score to determine if he is low risk and therefore could have DVT excluded using D dimer rather than imaging
SB: Perform duplex Doppler ultrasound on the veins of the left upper limb

CORRECT ANSWER:
What would you do next?
SB: Perform duplex Doppler ultrasound on the veins of the left upper limb

FEEDBACK: The Wells Score is for patients with suspected lower limb DVT
REFERENCES:


Other papers:


IV. Scarvelis D, Wells PS. Diagnosis and treatment of deep-vein thrombosis. CMAJ. 2006; 175(9): 1087-92.


## APPENDIX ONE: EVIDENCE SUMMARY TABLE

<table>
<thead>
<tr>
<th>Author and date</th>
<th>Name of CDR</th>
<th>Derivation or validation</th>
<th>Inclusion</th>
<th>Exclusion</th>
<th>Sensitivity (95% CI)</th>
<th>Specificity (95% CI)</th>
<th>NPV (95% CI)</th>
<th>LR- (95% CI)</th>
<th>High performance* (y/n)</th>
<th>Hierarchy **</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wells (2003)¹</td>
<td>Wells Score + D-dimer in outpatients</td>
<td>Validation</td>
<td>1) Adult (&gt;18yrs) with suspected DVT in ambulatory clinics AND 2) “DVT unlikely” Wells Score &lt;2 with negative d-dimer.</td>
<td>1) Suspected PE 2) Life expectancy &lt;3 months 3) Current anticoagulant therapy (INR&gt;2.0 or treatment doses of LMWH) for more than 48 hrs 4) Resided where they were inaccessible to follow-up 5) Symptoms had resolved for more than 72hrs prior to presentation 6) Refused/Unable to consent</td>
<td>88.9% (95% CI: 61.62-98.08)</td>
<td>72.24% (95% CI: 66.79-77.24)</td>
<td>99.1% (95% CI: 96.72-99.86)</td>
<td>0.15 (95% CI: 0.04-0.57)</td>
<td>N</td>
<td>III</td>
</tr>
<tr>
<td>Oudega (2005)²</td>
<td>Ruling out DVT in primary care</td>
<td>Derivation and validation</td>
<td>1) Adult AND 2) Suspected DVT (pain and/or redness and/or swelling in lower limb)</td>
<td>1) Symptoms exist for &gt;30 days. AND/OR 2) Suspicion of PE</td>
<td>99.31% (95% CI: 97.52-99.90)</td>
<td>28.93% (95% CI: 26.14-31.84)</td>
<td>99.32% (95% CI: 97.55-99.90)</td>
<td>0.02 (95% CI: 0.01-0.10)</td>
<td>N (very close)</td>
<td>IV</td>
</tr>
</tbody>
</table>

*High performance (Y/N) for the derivation study defined as:
- Sens > 0.95 AND
- Lower limit of 95% CI for sensitivity >0.95 AND
- LR-<0.1 AND
- Upper limit of LR-95% CI < 0.1
- Likelihood ratio for negative test result = $\frac{\text{proportion of patients WITH disease who have a negative test result (1 - SENSITIVITY)}}{\text{proportion of patients WITHOUT disease who have a negative test result (SPECIFICITY)}} = \frac{(1 - \text{SENSITIVITY})}{\text{SPECIFICITY}}$

**Hierarchy (see reference I. below)
- Level I: can be used in a variety of clinical settings and includes at least one validation study (external) and at least one impact analysis showing favourable change in clinician behaviour when the CDR is used/implemented.
- Level II: can be used in various setting with confidence about accuracy (1 prospective validation in heterogeneous population or several smaller ones).
- Level III: use with caution in narrowly defined group of patients (validated in one narrow prospective sample).
- Level IV: CDRs requiring more evaluation before they are implemented (no validation or only validated with statistical techniques or retrospective databases, or split samples).

## APPRAISAL TABLE REFERENCES:


APPENDIX TWO: THE WELLS SCORE FOR PATIENTS WITH SUSPECTED LOWER LIMB DVT

Applying the Wells Score for DVT

Inclusion Criteria:
- Ambulatory adult patients (>18yrs)
- with suspected DVT

Exclusion Criteria:
- Suspected PE
- Life expectancy <3 months
- Current anticoagulant therapy (INR>2.0 or treatment doses of LMWH) for more than 48 hrs
- Symptoms had resolved for more than 72hrs prior to presentation

WELLS SCORE
Active cancer (patient receiving treatment for cancer within the previous 6 months 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 weeks requiring general or regional anaesthesia +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 oedema confined to the symptomatic leg +1
Collateral superficial veins (non-varicose) +1
Previously documented deep-vein thrombosis +1
Alternative diagnosis at least as likely as deep-vein thrombosis -2

≥2 “DVT likely”

<2 “DVT unlikely”

No further investigation to exclude DVT

Quantitative Whole Blood D dimer assay
- ve

+ ve

Ultrasound

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