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The Royal Australian and New Zealand College of Radiologists®

Educational Modules for Appropriate Imaging Referrals

CLINICAL DECISION RULES

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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WHAT ARE THEY? HOW ARE THEY DEVELOPED? WHAT DO I NEED TO KNOW TO USE THEM APPROPRIATELY?

Clinical decision rules (CDRs) have been developed by gathering detailed clinical datasets from **large** numbers of patients with a particular condition, such as children presenting to an emergency department following head trauma, and then using this data to produce a set of:

- **examination findings** (such as altered conscious state, amnesia for recent events, reduced oxygen saturation, or focal tenderness over a bony prominence in the foot or ankle); and/or
- **aspects of the history** (such as number of episodes of vomiting, previous cancer, prolonged bed rest or distance fallen down a flight of stairs);

that, when present or absent, ***increase*** **or** ***decrease*** **the likelihood of a particular condition in a clinically important way.**

Examples of a "condition" defined in this way could be:

- Clinically important head injury.
- Pulmonary embolism.
- A CT scan showing evidence of intracranial injury.
- A radiograph (X-ray) demonstrating a fracture involving the ankle or foot.

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 or other further diagnostic testing; and
- **patients who do not have negligible risk** who need imaging or some other investigation to provide a more accurate estimate of the post-test probability of a medical condition. This final post-test probability estimate can be the result of:
    1. one or a series of diagnostic tests; or
    2. the application of a clinical decision rule; or
    3. both 1. and 2.

This estimate will guide treatment decisions, including discharge vs. in-hospital monitoring, specific medical therapy, or even surgery.

CDRs can be thought of as a sort of diagnostic test: they are used as a tool that provides a **clinically useful estimate** of the **"post-test"** probability of a condition (such as clinically important intracranial injury or pulmonary embolism). An accurate estimate of the true likelihood of a condition being present helps clinicians to clarify their decision making processes.

Typically, CDRs relating to diagnosis will make us more confident that we **EITHER** need to:

- **do no further testing** (such as diagnostic imaging) on the patient because the probability of serious disease is so low; or
- **do something more** (such as performing diagnostic imaging or other non-imaging tests) because:
    - **the post-test probability of an important condition is not low enough** that further treatment can be withheld; but
    - **the post-test probability is not high enough** that the treatment can be started. Treatments themselves are associated with risks (such as commencement of anticoagulation that can predispose the patient to serious haemorrhage) as well as costs to the patient and health system.

Therefore, clinicians need to balance the risks and costs of diagnostic testing against those of commencing treatment in a patient who does not have a disease or condition.

HOW WOULD THE USE OF CLINICAL DECISION RULES HELP TO DECIDE IF A PATIENT REQUIRES DIAGNOSTIC IMAGING?

QUESTION 1.

A 48 year old female patient comes to the emergency department on a Sunday night with chest pain.

- **She returned from London by plane last week**
- **She has presented with these findings during the winter months and also has a cough**
- **Her pulse rate is 82 beats per minute and she has no history of cancer or oral contraceptive use**
- **Her oxygen saturation is 97% on room air**
- **She has had no recent trauma or surgery and no current evidence of DVT on physical exam nor a past history of it**

You think she has a low probability of pulmonary embolism (PE) but you wonder if you should perform an imaging test to make sure because you know that untreated PE can be fatal.

Use the Simplified Wells Score (last column, Table 1 below) to help you decide whether she is **likely or unlikely** to have PE (an "unlikely" probably using this CDR equates with a risk of about 13% or less using this particular CDR).

Predictor	Original Wells	Modified Rule	Simplified Rule
Clinical signs and symptoms of DVT (minimum of leg swelling and pain elicited upon palpation of deep veins)	3	2	1
No alternative diagnosis more likely than PE	3	2	1
Heart rate > 100	1.5	1	1
Immobilisation or surgery in previous 4 weeks	1.5	1	1
Previous DVT or PE	1.5	1	1
Haemoptysis	1	1	1
Malignancy (on treatment, treated in last 6 months or palliative)	1	1	1

Risk Category	Original	Modified	Simplified
PE Unlikely	≤4	≤2	≤1
PE likely	>4	>2	>1

TABLE 1: THE WELLS SCORE FOR RISK STRATIFICATION OF PATIENTS WITH SUSPECTED PULMONARY EMBOLISM[1]

Is the patient likely or unlikely to have pulmonary embolism (PE)?

1A. PE likely

1B. PE unlikely

CORRECT ANSWER

Question 1 - Using the Wells Score is PE likely or unlikely?

1B. PE unlikely

The Simplified Wells Score tells us that PE is unlikely in this woman. However, a risk of less than 13% is not a low enough post-test probability to send her home without further tests to exclude PE, so you need to further refine her probability of PE to EITHER:

- **shift this probability up** (to make it worth the risk of commencing her on anticoagulants); or
- **shift this probability down** (to make it safe to withhold any treatment because of the very low risk of PE).

To refine the patients probability of PE, the Pulmonary Embolism Rule-out Criteria (PERC – Table 2 below) can be used for patients with a low (<15%) probability of having pulmonary embolism to determine whether PE is so unlikely (<3%) that the patient requires no further testing to exclude it.

QUESTION 2.

Use the PERC Rule to determine if this patient needs further diagnostic testing to rule out PE as the cause for her chest pain.

Pulmonary Embolism Rule-out Criteria
Variable
Age <50 years
Pulse <100 beats per minute
SaO_2 ≥95% on room air
No haemoptysis
No exogenous oestrogen use
No prior venous thromboembolism
No surgery or trauma requiring hospitalization within the past 4 weeks
No unilateral leg swelling

Table 2: The Pulmonary Embolism Rule-out Criteria (PERC)[2]

Patients at low or very-low risk of PE (the population for whom the rule is intended), who meet the rule criteria (i.e. answer YES to the 8 clinical variables), are deemed PERC negative.

The authors found that PERC negative patients have a probability of PE <1.8%, and hence, are safe to have PE excluded without further diagnostic testing, since the post-test probability of PE after a negative VQ scan is greater than 1.8%

Tick the correct alternative:

2A. More testing needed

2B. No further testing needed

CORRECT ANSWER

Question 2: Using PERC, what next?

2B. No further testing needed

The usefulness of **CDRs is that they help to reduce the subjectivity and inter-observer variations** 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.

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.

Key messages about CDRs:

- **Using CDRs can help to increase your confidence** about the safety of managing your patient without imaging when recognised 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 not only good practice but increases the likelihood that another medical practitioner evaluating your patient would come to the same conclusions as you did about management.

- **You need to be aware of the patients to whom a given CDR can and cannot be applied in order to use it correctly.** In the example provided above, the patient described had no criteria that would preclude use of either the Simplified Wells Score of the PERC tool. However, if she had been pregnant or anticoagulated for more than 72 hours, for example, the Simplified Wells Score could not be used as patients in both of these situations were specifically excluded from the cohort of subjects whose clinical data was used to develop the Simplified Wells Score.

ASSESSING THE QUALITY OF A CLINICAL DECISION RULE

HOW GOOD DOES IT HAVE TO BE, TO BE USEFUL?

A high performing CDR has been defined by McGinn et al[3] as one with a sensitivity of >95% with a lower limit of the 95% confidence interval for sensitivity of 95% and a likelihood ratio 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.

This definition is useful when the purpose of the CDR is to reduce the likelihood of clinically important disease to a level where no further investigation or treatment is needed. Many CDRs that relate to decision making about diagnostic imaging work this way. They include:

- NEXUS[4, 5]
- The Canadian C-Spine Rule[6, 7]
- The Canadian CT Head Rule[8-10]
- The Ottawa Ankle Rules[11]
- The Pulmonary Embolism Rule-out Criteria (PERC)[2]
- The Children's Head Injury Algorithm for predicting Important Clinical Events (CHALICE)[12]
- The PECARN algorithm for children with head trauma[13]

These CDRs reduce post-test likelihood of an important condition into the range where imaging is not indicated when the CDR yields a "negative" or "low risk" result.

However, other CDRs work by increasing the post-test probability of disease and thus, when positive, they suggest the need for imaging. These are used for conditions where the pre-test likelihood of disease is already so low that imaging is generally not required. They help to identify individuals whose risk is higher than average and thus who may benefit more than average if imaging is performed. Examples of such tools include:

- Henschke et al[14] decision tools for identification of patients with acute low back pain who have higher than **average** risk of fracture or malignancy as a cause for the low back pain; and
- CATCH,[15] a decision tool used to identify children at higher risk of significant intracranial injury after head trauma.

High quality CDRs of this type have a high positive likelihood ratio (LR+) for identifying patients with significant disease rather than a low negative likelihood ratio (LR-). They tend to be used in situations where the baseline prevalence of serious disease is very low, and thus a CDR with a low LR- is not helpful as it simply reduces this still further.

For example, **an unselected group of adult patients with acute low back pain presenting to general practitioners have a 1% chance of serious pathology such as tumour, fracture, infection, or cauda equina syndrome as the cause for the low back pain**. We would generally not perform imaging in a patient with a 1% likelihood of serious pathology in this situation because we would need to image 100 patients to find one with serious pathology requiring specific treatment. Reducing the likelihood of serious pathology still further with a CDR that works to reduce the likelihood of serious pathology from 1% to less than 1% does not change the decision making process. **A CDR with a high LR+ is more useful when the condition of interest is very uncommon or rare** as it changes our decision from not performing imaging to performing it.

Some CDRs take both approaches by identifying patients who have either higher and lower than average risk. These include:

- The Canadian C-Spine Rule;
- The Canadian CT Head Rule; and
- The PECARN algorithm for children with blunt head trauma.

The best CDRs have often been studied with regard to:

1. whether clinicians actually use them in practice, when they have the choice not to;
2. whether use of the CDR reduces healthcare costs or volume of imaging tests performed.

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 performance tends to be lower and validation studies less frequent , partly 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.

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 (suggesting no serious pathology is present) because the likelihood of serious pathology may be higher when you use these than it would be if a better performing CDR were used.

WHAT ELSE DO YOU NEED TO THINK ABOUT WHEN YOU CONSIDER IMAGING A PATIENT CONDITION APART FROM ESTIMATING THE RISK OF SERIOUS PATHOLOGY?

1. **Test performance** (sensitivity, specificity, LR+ and LR-) in relation to the pathological process(es) you are trying to diagnose or exclude.

   A reminder about the definitions of the key diagnostic test performance metrics – these are derived from the 2 X 2 table representing disease state and the results of tests with binary outcomes (i.e. normal/abnormal, positive/negative)

	Disease +	**Disease -**	**Calculations**
Positive test result	TP	FP	PPV = TP / (TP +FP)
Negative test result	FN	TN	NPV = TN/ (TN + FN)
Calculations	Sens = TP/ (TP + FN)	Spec = TN / (TN + FP)	Accuracy = (TP + TN) / (TP + TN + FP + FN)

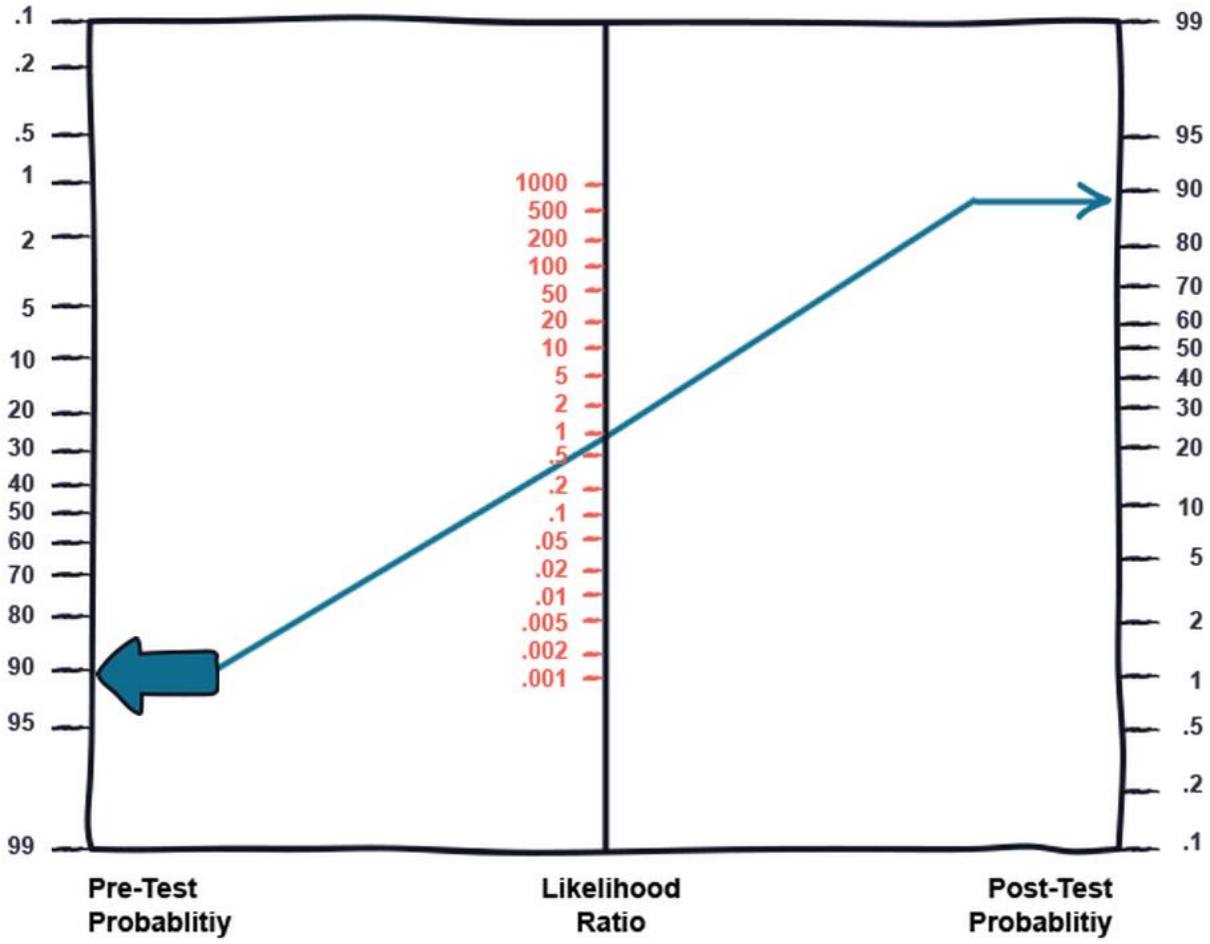
   Definitions:

   - True positive (TP) = number of patients in whom the test result is positive when disease is present
   - False positive (FP) = number of patients in whom the test result is positive when disease is not present
   - False negative (FN) = number of patients in whom the test result is negative when disease is present
   - True negative (TN) = number of patients in whom the test result is negative when disease is not present
   - Sensitivity = proportion of patients WITH disease who have a positive test result
   - Specificity = proportion of patients WITHOUT disease who have a negative test result
   - $\text{LR+} = \frac{\text{proportion of patients WITH disease who have a positive test result (SENSITIVITY)}}{\text{proportion of patients WITHOUT disease who have a positive test result (1 – SPECIFICITY)}}$
   - $\text{LR-} = \frac{\text{proportion of patients WITH disease who have a negative test result (1 – SENSITIVITY)}}{\text{proportion of patients WITHOUT disease who have a negative test result (SPECIFICITY)}}$

   Note:

   - **High quality diagnostic tests have LR+ > 10 and LR- <0.1**
   - **A test with a LR+ or LR- = 1 is associated with no change in the post-test probability of disease and therefore is not diagnostically useful**

As stated on the previous page; a **test with a LR+ or LR- = 1 is associated with no change in the post-test probability of disease and therefore is not diagnostically useful**. This example is drawn on the nomogram below and shows a pre-test probability of 90 with a likelihood ratio of 1.



Try this yourself by drawing a line from any pre-test probability through a likelihood ratio of 1 to see what the post-test probability is.

2. **What is available locally**, especially in an emergency.
3. **Radiation dose,** of particular importance in young and pregnant patients.
4. **Financial and other costs** to the patient and health system of one diagnostic strategy compared with another.
5. **Renal function in the case of imaging tests** that involve the use of iodinated contrast media or gadolinium chelates (used for MRI).
6. **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.

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