

The Nitty-Gritty of Clinical Decision Rules

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ANNALS CASE

How are clinical decision rules (CDRs) applied (and maybe misapplied) in emergency medicine? This question arose after we read the article by Babl et al.¹ Here, they compared clinician gestalt with 3 decision rules for head injury in children. Surprisingly, CDR use would not have increased sensitivity and may have led to increased use of imaging! Aren't CDRs supposed to aid judgment and reduce unnecessary testing? We had hoped yes, but unfortunately, they sometimes lead us astray.

CDRs, otherwise known as prediction rules or prediction models, combine multiple patient historical and examination variables, test results, and other disease characteristics to estimate the probability of either a diagnosis or a prognosis.² The term "rule" is a misnomer in that CDRs are not inflexible or absolute, but should function more to supplement clinical judgment.³ Hence, many providers prefer the term "clinical decision tools." (To avoid a superfluous acronym, we will stick with CDRs.)

CDRs CAN BE A BIG HELP

In many ways, medical decisionmaking boils down to playing the percentages and predicting risk of outcomes. Being able to do this for every disease process is difficult, and CDRs can factor in many different variables to reach a consistent outcome.⁴ CDRs can also help by organizing which clinical features play a significant role in predicting bad outcomes, formalizing a standardized method for physicians to approach a disease process, serving as a great

tool for new learners developing their clinical gestalt, and supporting clinical decisions in our documentation. Furthermore, several prediction models have been shown to be more accurate than clinical judgment alone.⁴

NOTHING COMES WITHOUT RISK

Although CDRs have many benefits, they also have some inherent problems. They may themselves have poor generalizability or weak external validity, or physicians may misapply them, confuse variables, or not know how to incorporate their own gestalt.⁵ Let's discuss some of the major pitfalls some people face with CDRs, and offer up some pearls as well!

THE PEARLS AND PITFALLS

Wrong Population

CDRs are often made for specific patients in a specific population. If derived at a different hospital, with a different practice style, or with a different patient population, that CDR may not be right for you! For example, the pediatric blunt abdominal trauma CDR created by Holmes et al⁶ excludes focused assessment sonography for trauma ultrasonographic results. Therefore, it may not apply to hospitals that regularly perform serial examinations on their patients for focused assessment sonography for trauma. Individual hospitals and practice environments should decide which CDRs are applicable to their setting.^{7,8}

Wrong Patient

The derivation studies for CDRs have specific inclusion and exclusion criteria.⁵ Keep in mind that the patient in front of you may have certain characteristics that would exclude him or her from the CDR: young age, malignancy, dementia, pregnancy, intoxication, anticoagulation, or immunocompromised state. For example, patients with penetrating trauma were excluded by both the CATCH rule (Canadian Assessment of Tomography for Childhood Head Injury) for head trauma and the National Emergency X-Radiography Utilization Study C-spine rule.^{9,10}

The specific inclusion criteria are important too because the CDR should not be generalized to patients who don't

meet the inclusion criteria used in the derivation and validation studies. For example, the pulmonary embolism rule-out criteria (PERC) included only patients with less than 15% pretest probability of pulmonary embolism (PE), whereas the CENTOR score (cough absent, exudate, nodes, temperature [fever], young or old modifier) in dysphagia can be applied only for sore throat of less than 3 days' duration.^{11,12} Have a patient with a high pretest probability of PE? Don't use PERC! Sore throat for 4 days? Don't use CENTOR! Or at least proceed with caution.

One-way Versus Two-way Rules

There are 2 types of CDRs, each providing the user with a different set of recommendations. In a one-way rule the patient either meets the criteria and the CDR recommends a specific outcome or the patient does not meet the criteria and no recommendation is made. One example of this is the PERC rule.¹¹ In a patient with a suspected PE and with a pretest probability of less than 15%, a negative PERC score means a less than 2% chance of PE, and thus the diagnosis is effectively "ruled out." If the PERC score is positive, it does not necessarily mean the patient "must" receive a D-dimer or computed tomography (CT) pulmonary angiogram. It just means the diagnosis was not ruled out by this rule alone.

This is in contrast to a 2-way rule, in which either a positive or negative CDR result leads to a recommendation. The CHALICE and Pediatric Emergency Care Applied Research Network rules are examples of 2-way decision rules to help decide whether head CT is required for a child with head injury. A patient should generally receive imaging if the CHALICE or Pediatric Emergency Care Applied Research Network criteria are positive and generally should not receive it if they are negative.^{13,14} A quality 2-way decision rule tells you both when you should and should not act.

Misidentifying a one-way rule as a 2-way rule can be significant. For example, not every patient older than 50 years and with chest pain requires a PE evaluation, even though all such patients are PERC positive!¹⁵

CDR Not Validated

To ensure accuracy, CDRs typically progress through the following steps: needs assessment, derivation phase, prospective validation, implementation into clinical practice, assessment for cost-effectiveness, and plan for dissemination.⁷ Many published CDRs looked great during the derivation phase, but later have mixed or even poor results in other stages of development.¹⁶ This problem is observed throughout the literature, including, for example, many head injury rules,^{17,18} the Laboratory Risk Indicator for Necrotizing Fasciitis score for necrotizing fasciitis¹⁹

(lacks validation), and even the San Francisco Syncope Rule (poor sensitivity and specificity in the validation phase).²⁰

Subjectivity

Although CDRs are meant to aid physician medical decisionmaking, the components used may be subjective. For example, the Wells criteria score for PE includes "PE is #1 likely diagnosis."²¹ In the HEART score (history, ECG, age, risk factors and troponin) for acute coronary syndrome, the history is subjectively rated as "slightly," "moderately," or "highly" suspicious.²² The subjectivity built into these scores can muddy interrater reliability. Even in the seemingly objective variables of the National Emergency X-Radiography Utilization Study C-spine rule, evidence reports poor provider agreement!^{10,23}

Overtesting and Neglecting Clinical Gestalt

Many CDRs are designed as screening tools, and thus typically have higher sensitivity than specificity. This is why CDRs have classically boasted superiority over clinical gestalt in catching pathology.^{24,25} However, CDR implementation may lead to increased (and unnecessary) laboratory tests, imaging, treatments, and even admission rates. In fact, most studies of CDRs do not compare their use to clinical gestalt and those that do often find the CDR to be inferior to gestalt.^{26,27}

Too Many Scores!

Oftentimes the sheer number of CDRs makes their use confusing. For example, we counted 6 different head injury CDRs, each using different predictor variables and suggesting different courses of action.¹⁶ Oftentimes variables can be confused for the wrong score, making the outcome inaccurate. Sometimes people purposefully combine variables from multiple scoring systems into a Frankensteinian "super-rule," like a previous combination of the National Emergency X-Radiography Utilization Study C-spine rule and the Canadian C-Spine Rule.^{10,28} This carries potential dangers because these rules were derived and validated as they were written, and not in a piecemeal fashion.

FINAL THOUGHTS

Holmes et al⁶ stated that "prediction rules aid and empower clinicians by providing evidence with regard to risk but must be used in conjunction with sound clinical judgment to provide optimal care." This means that CDRs are not meant to be followed blindly, but rather are helpful decision tools. Now go off and predict some outcomes!

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