Critical Review Form
Clinical Prediction or Decision Rule

Reilly BM, et. al., Impact of a clinical decision rule on hospital triage of patients with suspected acute cardiac ischemia in the emergency department, JAMA 2002; 288: 342-350.

Summary

Objective: To determine whether use of a clinical decision rule (CDR) improves physicians' hospital triage decisions for patients with suspected acute cardiac ischemia.

Methods: Analyze the disposition of ED patients with symptoms suspicious for acute cardiac ischemia (ACI) but EP's at Cook County Hospital during three time periods: before implementation of CDR, after introduction of the CDR via intensive training and reminders to utilize the rule, and one year after discontinuation of recommended CDR utilization. Cardiac complications (endpoints) were defined as ventricular fibrillation, cardiac arrest, new complete heart block, insertion of a pacemaker, emergency cardioversion, cardiogenic shock, use of an intra-aortic balloon pump, intubation, and recurrent ischemic chest pain requiring urgent coronary revascularization before hospital discharge.

Guide		Comments
I.	***Is this a newly derived instrument* (Level IV)?**	
A.	Was validation restricted to the retrospective use of statistical techniques on the original database? (If so, this is a Level IV rule & is not ready for clinical application).	No, this is an impact analysis.
II.	**Has the instrument been validated? (Level II or III). If so, consider the following:**	
1a	Were all important predictors included in the derivation process?	Yes, by Goldman et al NEJM 1996; 334: 1498-1504.
1b	Were all important predictors present in significant proportion of the study population?	To answer this question you would need to review the derivation paper by Goldman referenced above.
1c	Does the rule make clinical sense?	Yes, although disposition based upon risk stratification may encounter real-world problems (lack of bed or nursing availability, for instance, mandating a CCU admission be admitted to Telemetry).
2	Did validation include prospective studies on several different populations from that used to derive it (II) or was it restricted to a single population (III)?	To answer this question one needs to review the validation studies by Reilly referenced in Table 1, p. 343: Reilly et. al., Am J Med 1999; 106: 285-291. Reilly et al., Am J Med 2001; 110: 7-11.

3	*How well did the validation study meet the following criteria?*	This critical review form is designed to facilitate the analysis of CDR's at various stage of development, however for our Journal Club format we are reviewing a single paper which has moved beyond the derivation phases of Level II, III, and IV CDR's and is now striving for Level I evidence of benefit. The answers to questions 3-4, therefore, are generally accepted to be "yes", but the critical reader will want to review them personally at some point (just not in this space on this day!).
3a	Did the patients represent a wide spectrum of severity of disease?	Review the above referenced studies.
3b	Was there a blinded assessment of the gold standard?	Review the above referenced studies.
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	Review the above referenced studies.
3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Review the above referenced studies.
4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	Review the above referenced studies.
III.	**Has an impact analysis demonstrated change in clinical behavior or patient outcomes as a result of using the instrument? (Level I). If so, consider the following:**	**This is the strength of this paper.**

1	How well did the study guard against bias in terms of differences at the start (concealed randomization, adjustment in analysis) or as the study proceeded (blinding, co-intervention, loss to follow-up)?	The study design is consistent with the *EBM Working Group* conclusion that "randomization of individual patients is unlikely to be appropriate in the impact analysis of a clinical decision rule" (p. 343). So, they attempted to remove bias by analyzing a pre-intervention group (1997, n=207), an intervention group (1999, n=1008), and a post-intervention group (2000, n=246). These numbers provided 80% power to detect a 10% outcome difference at a two-sided alpha level of 0.05 (p. 345). In other words, the authors calculated the number which they needed to enroll given their hypothesized minimal "treatment effect" for which they would have less than 5% chance of obtaining significantly different results between the two groups by chance alone while also having less than 20% chance of not detecting a true difference between the two groups when a difference truly existed. This study has multiple laudable design strengths: a) no confounding co-interventions were studied; b) physician chart reviewers were blinded to the risk stratification and the CDR form. Though discrepancies were adjudicated by a third blinded chart reviewer, no Kappa analysis or raw agreement were provided. c) follow-up was exceptional: 994/1008 (98.6%) in the main study population and 300/326 consecutive patients in whom ACS was excluded in ED and discharged home. d) results were analyzed in both intention-to-treat and as CDR not utilized (based upon MD survey).

		e) 3 cohorts analyzed to study possibility of temporal trend as alternative explanation for observed triage decisions.
2	What was the impact on clinician behavior and patient-important outcomes?	Two effects studied: a) Safety – proportion of all patients who experienced major cardiac complication with 72 hours who were triaged to coronary care or telemetry unit after ED evaluation; b) Efficiency - proportion of all patients who did not experience major cardiac complications who were triaged to an ED observation unit or unmonitored ward. **Findings:** Use of Goldman's (modified) CDR for patients with ACI in the ED improved the efficiency of physician decision making "primarily by identifying very low risk patients and not admitting them to inpatient telemetry beds" (p. 348). From Table 4 (p. 347) one can see that the efficiency (as defined by the authors above) was 21% when using Goldman's CDR compared with 36% when not using it. Importantly, there was no impact on safety when using the CDR. These results have several-fold importance: a) no other CDR applicable to all ED patients with suspected ACI has achieved the same level of high evidentiary support; b) the present study expands the scope of the original CDR to include those with chest-pain free ACI (anginal equivalent dyspnea, for example); c) this impact analysis links the decisions EP's make with patient, family, clinician, and (last but not least) lawyer important outcomes (occurrence of life-threatening complications with subsequent days).

Conclusions: **This paper, though important and impressive, does leave a few flaws unaddressed. First, the external validity of the findings remain uncertain. The authors reference the ACI-TIPI experience as a prime example of not assuming well-designed study results are widely applicable without accounting for regional variability. For example, applying the results of the current study to your daily patient care requires resource availability (CCU bed available for high risk patients, telemetry for moderate risk patients, etc.). This is often not the case in our overcrowded ED's with patient length of stays exceeding 24 hours are not uncommon, particularly while awaiting a monitored bed. Furthermore, the wide spread application of Goldman's criteria necessitates multi-specialty physician buy-in and uniformity in ED physician diagnosis of USA and EKG interpretation.**

Second, future studies should look at other outcomes important to patients and society including long-term morbidity and mortality and the cost-effectiveness of resource utilization mandated by the use of this CDR. Finally, physicians need to be comfortable with the level of risk which patients entail (of a major cardiac complication within 72 hours), regardless of where they fall within the CDR classification (p. 347):

Stratification	High	Moderate	Low	Very Low
Goldman (1996)	16%	8%	4%	0.6%
Reilly (2002)	11%	4%	6%	0.8%

Bottom Line: **Use of the modified Goldman CDR, utilizing only EKG and simple physical exam findings, can improve the efficiency of hospital triage decisions for patients presenting to the ED with cardiac equivalent symptoms without compromising safety with a higher level of evidentiary support than any other chest pain CDR.**