Critical Review Form
Clinical Prediction or Decision Rule

Quinn JV, et al. Derivation of the San Francisco Syncope Rule to Predict Patients with Short-term Serious Outcomes, *Annals EM* 2004; 43: 224-232

Objective: To derive a clinical decision rule to help predict short-term serious outcomes after ED evaluation for the chief complaint of syncope.

Methods: Prospective screening of University of California-San Francisco ED patients with the complaint of syncope, loss of consciousness, fall, collapse, seizure, lightheadedness, tachycardia, bradycardia, shortness of breath, or chest pain. Subjects were excluded if they had altered mental status, alcohol or drug-related loss of consciousness (LOC), a definite seizure, or head-trauma related LOC. Attending physicians made the final decision on enrollment. Physicians then completed a structured data form including 50 predictor variables (34 from history, 11 from physical exam, and 5 laboratory/radiography/EKG variables) which were identified by "a review of the literature and a consensus of experts". (pp 225-226) A Kappa analysis of agreement between attending and resident physicians was performed on variables requiring subjective interpretation. Outcomes included death, myocardial infarction, arrhythmia, stroke, subarachnoid or other significant intracranial hemorrhage, or syncope related ED recidivism with subsequent hospital admission. These outcomes were strictly defined and not subject to interpretation. All outcomes were assessed at 7 days by medical record review. Variables were included in the analysis if they were associated with the outcomes with $p < 0.1$ and Kappa > 0.5. The model was derived by recursive partitioning to obtain the combination with the highest sensitivity while maintaining reasonable specificity.

Guide		Comments
I.	***Is this a newly derived instrument* (Level IV)?**	Yes
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).	"Applying the rule to this derivation set of patients would result in a sensitivity (for identifying serious outcomes) of 96.2% (92-100%) and specificity of 61.9% (58-66%) thus yielding a 10% absolute reduction in the admission rate in this cohort (p. 228).

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?	See Table 2 and Table 3 for predictor variables analyzed. List appears complete.
1b	Were all important predictors present in significant proportion of the study population?	Prevalence of individual predictors in the derivation cohort is not provided here. Based upon the low prevalence of certain etiological causes (like SAH or ruptured ectopic pregnancy), though, one can guess that some variables like headache or vaginal bleeding were under-represented relative to other variables.
1c	Does the rule make clinical sense?	Yes – all variables included in the derivation are commonly elicited in ED syncope patients because they are felt to offer important clues to the etiology of syncope.
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)?	No, so Level IV CDR.
3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	Wide spectrum of disease processes as illustrated by Table 1, but predominantly cardiac etiology. Also, derivation cohort is predominantly middle-aged to older adults.
3b	Was there a blinded assessment of the gold standard?	No true "gold standard" for syncope; rather the criterion standard depends upon the presumed etiology of syncope (PE, dysrhythmia, vasovagal, etc.) and the "gold standard" for that particular cause of syncope (pulmonary angiogram for PE, documented symptom-related dysrhythmia, or Tilt-table testing, respectively).
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	Using explicit criteria and a trained research nurse, the primary investigators reviewed outcomes blinded to the predictor variables.

3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Again, no "gold standard" for diagnosing adverse outcomes, but interpreted by reasonable, explicit criteria. Unknown variables affected subsequent ED management as no intervention arm in this study.
4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	See answer Ia above.
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:**	No impact analysis performed (yet)
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)?	No impact analysis.
2	What was the impact on clinician behavior and patient-important outcomes?	No impact analysis.

Limitations

1) **< 100% sensitivity observed, so the SFS CDR should be used to risk stratify, NOT to replace clinical judgment.**
2) **Level IV CDR with only retrospective validation. NOT ready for widespread use!**
3) **Lack of (quoted) consensus conference (Cardiologists, Neurosurgeons, Neurologists, PCP's, EP's) to uniformly identify clinically significant outcomes and important variables to assess in deriving the model (as was done in the case of the Canadian Cervical spine rules).**
4) **Rare etiologies of syncope were not substantially represented and may therefore may not be predicted by this CDR (examples include ruptured ectopic pregnancy and ruptured spleen).**

Bottom Line

Utilizing the pneumonic CHESS (CHF history, hematocrit < 30%, abnormal EKG, shortness of breath, initial systolic blood pressure < 90 mm Hg), clinicians can rapidly identify a high-risk subset of patients for 7-day serious adverse outcomes and thereby prompt early decisions to admit or obtain further diagnostic evaluation. Further multi-center validation of this CDR may permit wide-spread dissemination and subsequent impact analysis.