Critical Review Form
Clinical Prediction or Decision Rule

Prospective Validation of the San Francisco Syncope Rule to Predict Patients With Serious Outcomes, *Annals of Emergency Medicine* 2006; 47: 448-454

Objective: **"To validate the decision rule in a prospective cohort of consecutive ED patients by determining whether it can predict short-term serious outcomes not determined during the initial ED evaluation". (p 449)**

Methods:

Prospective cohort study was conducted at the University of California-San Francisco ED from July 2002 – August 2004 with syncope or near-syncope as defined by "transient loss of consciousness with return to baseline neurologic function". In addition to notification of clinicians an electronic tracking system was used. Patients with trauma associated loss of consciousness alcohol/drug related LDC, or definite seizures were excluded as were those with an altered mental status or new neurologic deficits because they were not "transient".

After identification of eligible patients, physicians completed a web-based data form containing the 5-elements of the SFSR, a declaration of whether a serious outcome occurred in the ED presentation and physician comfort level using the rule. Researchers "asked the physicians to treat and admit patients in their usual manner without any specific study intervention". (p 449) Follow-up occurred by contacting the patient or their physician along with Social Security Death Index and medical record review for 30-day outcomes. The following definitions were used:

Short-term serious outcomes – death, MI, arrhythmia, PE, stroke, SAH, hemorrhage/anemia requiring transfusion, or procedural intervention to treat cause of syncope. Also, any patient returning with recurrent syncope who was admitted.

Procedural intervention – dialysis, pacemaker, balloon pump, vasopressors, surgery for AAA or ruptured spleen/ectopic, EGD for varices.

MI - troponin elevation or ECG change with discharge diagnosis of MI.

Arrhythmia – any non-sinus rhythm captured on monitoring equipment thought temporally related to syncope.

PE – positive VQ scan, CT angiogram, or routine angio with treatment.

The study was powered to have a 95% CI <10% for estimates of sensitivity and specificity.

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 a prospective validation on a distinct population different from the derivation cohort.
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, the rule was derived from 50 predictor variables assessed for accuracy and reliability using accepted CDR standards.
1b	Were all important predictors present in significant proportion of the study population?	Yes, as noted by Figure (p 450) the range of prevalence for the 5-predictors was 13-85%
1c	Does the rule make clinical sense?	Yes, the rule has content validity based upon decades old literature. Additionally, the CHESS mnemonic is easy to remember.
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)?	Restricted to a single San Francisco hospital population. Therefore this is a Level III CDR, only appropriate for use in San Francisco.
3	*How well did the validation study meet the following criteria?*	
3a	Did the patients represent a wide spectrum of severity of disease?	No, as reported in Table 2 (p 451). No ectopic or AAA or solid organ ruptures were identified, so the performance of the rule for these etiologies of syncope remains uncertain.
3b	Was there a blinded assessment of the gold standard?	No clear Gold Standard for multiple outcomes.
3c	Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	Yes. "Outcomes were uniformly determined and reported. A trained research nurse and the study investigators independently reviewed outcomes and were blinded to the predicator variables when making their determination of a serious outcome". (p 451)

3d	Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Again, no clear Gold Standard for multiple outcomes, but components of the SFSR undoubtedly influenced clinicians to pursue further work-up.

4	How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	• Syncope patients represented 1.2% of all ED visits and 97% were "enrolled" with 95% 30-day follow-up rate. • Mean age 61-years with 59% admission rate and 13.7% 30-day event rate, including 6.8% (54) not recognized until after ED disposition. • The leading events were arrhythmia (23/54 = 43%), MI (11/54=20%), and significant hemorrhage (7/54=13%). Three deaths were noted. • Physicians accurately interpreted the rule 95% of the time and were comfortable using it in 79% of cases. **Serious Outcome** **Yes** **No** **SFSR+** **52** **290** **SFSR-** **1** **370** Sen 98% Spec 56% LR+ 2.2 (95% CI 2.0-2.4) LR- 0.03 (95% CI 0-0.2) • Investigators only reported results on those with completed data forms who did not have serious outcome apparent in the ED.

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:**	
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)?	This was not an impact analysis but difficult to believe the SF physicians might not sometimes have incorporated the locally derived SFSR in the latter year of decision-making.
2	What was the impact on clinician behavior and patient-important outcomes?	Not formally assessed, but the investigators hypothesize use of rule "would have classified 52% of the patients as high risk, potentially decreasing overall admissions by 7%". (p 451)

Limitations

1. **Single center study with limited external validity outside San Francisco.**
2. **Low number of all "serious outcomes", but complete lack of ruptured organs or ectopic pregnancy. Larger studies on specific outcomes are necessary to elucidate the prognostic tests characteristics for the SFSR.**
3. **Admission following syncope may be for social reasons (lives alone, uncertain etiology), so potential beneficial effect of SFSR use may overstate the actual impact on decreasing admission.**
4. **Reported 30-day outcomes though derivation had assessed 7-day outcomes. Subsequent reports suggest no significant differences between 7- and 30-day outcome assessments.**

Bottom Line

In San Francisco, the SFSR can identify a low-risk subset of syncope or near-syncope ED patients for arrhythmia or MI (LR- = 0.03, 95% CI 0-0.2) reducing the post-test probability from 6.8% to 0.2% (95% CI 0-1.4%). Future research will need to validate these test-characteristics outside of San Francisco before widespread use of this rule can be recommended. The impact of this rule on physician behavior or cost-effectiveness remains undetermined.