Critical Review Form
Clinical Prediction or Decision Rule

PGY-2

Leonard JC, Harding M, Cook LJ, et al. PECARN prediction rule for cervical spine imaging of children presenting to the emergency department with blunt trauma: a multicentre prospective observational study. Lancet Child Adolesc Health. 2024 Jul;8(7):482-490.

Objectives: **"The aim of this study was to derive and validate a paediatric clinical prediction rule that can be incorporated into an algorithm to guide radiographic screening for cervical spine injury among children in the emergency department." (p. 482)**

Methods: **This prospective observational cohort study was conducted at 18 PECARN-affiliated, level-1 pediatric trauma centers across the USA (9 sites contributing to a derivation cohort, 9 to a validation cohort). Children aged 0–17 years presenting with known or suspected blunt trauma were eligible if they met at least one of the following: transport from the scene by emergency medical services, evaluation by a trauma team, or cervical spine imaging obtained at or before arrival to the study site. Children with solely penetrating trauma were excluded; no exclusions were made based on sex, race, ethnicity, or language.**

Before viewing a child's neck imaging results, the attending emergency clinician completed a clinical examination and prospectively documented cervical spine injury risk factors (predisposing conditions, injury mechanism, neck/neurological complaints, and regionalized physical exam findings) via an electronic questionnaire. Cervical spine injury was determined by imaging reports and guardian telephone follow-up 21–28 days after the ED encounter and confirmed by a central pediatric neurosurgeon adjudicator. Factors associated with high risk (>10%) of cervical spine injury were identified using bivariable Poisson regression with robust error estimates; factors associated with non-negligible risk were identified via classification and regression tree (CART) analysis among children lacking high-risk factors. These were combined into a nine-factor prediction rule. The primary outcome was cervical spine injury within 28 days of trauma warranting inpatient observation or surgical intervention.

22,430 children were enrolled overall (11,857 in the derivation cohort, 10,573 in the validation cohort), of whom 433 (1.9%) had confirmed cervical spine injuries. Just over half (51.9%) were aged 0–8 years, and 58.3% were male or undifferentiated sex; falls and motor vehicle crashes were the most common injury mechanisms. Cervical spine injury was more common in the derivation cohort (2.3%) than the validation cohort (1.5%).

Critical Review Form: Clinical Prediction / Decision Rule	
Guide	Comments
Is this a newly derived instrument (Level IV)?	

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. The rule was validated in a separate cohort of patients from 9 level 1 pediatric trauma care centers across the US. This constitutes a level 2 clinical decision rule.
Were all important predictors included in the derivation process?	Yes. The authors considered a wide array of potential predictors for inclusion in the rule, including demographics, mechanism of injury, mode of arrival, predisposing conditions, neck and neurologic complaints, and physical exam findings.
Were all important predictors present in significant proportion of the study population?	Mostly yes. There were few traumas related to assault (2.0% and 2.8% in the derivation and validation cohorts, respectively), and almost no diving injuries (0.2% and 0.1%).
Does the rule make clinical sense?	Yes. The rule includes high-risk and CART (classification and regression tree)-derived risk factors that would be sensibly be associated with increased risk of cervical spine injury. One criteria—"substantial head or torso injury"—is somewhat vague despite being defined as "those that warrant inpatient observation of surgical intervention."
Has the instrument been validated? (Level II or III). If so, consider the following:	
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)?	Validation included prospective patients from multiple study sites.
How well did the derivation/validation study meet the following criteria?	
Did the patients represent a wide spectrum of severity of disease?	Yes. The inclusion criteria selected for a higher risk trauma population than all pediatric patients presenting to the emergency department but allows for a wide range of disease severity and likely included both patients with no significant injury who were discharged from the ED and those with severe injury requiring emergent intervention and ICU admission.
Was there a blinded assessment of the gold standard?	Yes. While there was no single "gold standard" to assess for the primary outcome, "All research personnel who categorised the outcome were blinded to the clinical predictors codified by the emergency department providers in the electronic questionnaires." (p.484)
Was there an explicit and accurate interpretation of the predictor variables & the actual rule without knowledge of the outcome?	Yes. Data on predictor variables were collected prospectively without knowledge of the outcome for both the derivation and validation cohort.
Did the results of the assessment of the variables or of the rule influence the decision to perform the gold standard?	Yes. While the clinical rule was not yet known when data were collected for both cohorts, the results of the variables ultimately included in the rule were known and were undoubtedly used in the decision to perform additional testing, admit for observation, and proceed with surgical treatment.
How powerful is the rule (in terms of sensitivity & specificity; likelihood ratios; proportions with alternative outcomes; or relative risks or absolute outcome rates)?	• Four high-risk factors (GCS 3–8 or unresponsive on AVPU; abnormal airway/breathing/circulation; focal neurological deficit) were identified, with a risk ratio of 8.9 (95% CI 7.1–11.2) for cervical spine injury. • Five additional non-negligible risk factors were identified by CART analysis: neck pain, altered mental status (GCS 9–14), substantial torso injury, substantial head injury, and midline neck tenderness. • The combined nine-factor rule performed in the validation cohort with 94.3% sensitivity (95% CI 90.7–97.9), 60.4% specificity, and 99.9% NPV. The negative likelihood ratio was 0.094.

	• Of 29 children with cervical spine injury missed by the rule, none required surgical intervention.
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:	
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)?	Quite well. It would not have been possible to blind clinical teams to the results of the various predictor variables used to derive the clinical prediction rule. All researchers involved in attributing outcomes were blinded to the clinical predictors and would not have been aware of the clinical prediction rule.
What was the impact on clinician behavior and patient-important outcomes?	A prospective assessment of impact was not performed. Retrospectively applying the rule-based imaging algorithm to the full study population was projected to reduce CT use from 17.2% to 6.9% of children, without increasing plain x-ray use.

Limitations:

1. **Derivation and validation occurred using cohorts from level 1 pediatric trauma care centers in the US. Applicability of this rule in community hospitals and outside of the US remains unclear.**
2. **Results of the variables ultimately included in the rule were known and were undoubtedly used in the decision to perform additional testing, admit for observation, and proceed with surgical treatment (incorporation bias).**
3. **Prospective assessment of the impact of using the rule on imaging rates was not performed.**

Bottom Line:

This multi-center, prospective, derivation and validation study designed to creat an algorithm to guide radiographic screening for cervical spine injury among children in the emergency department resulted in a nine-factor rule with 94.3% sensitivity (95% CI 90.7–97.9), 60.4% specificity, 99.9% NPV, and a negative likelihood ratio of 0.094 in the validation cohort. Retrospectively applying the rule-based imaging algorithm to the full study population was projected to reduce CT use from 17.2% to 6.9% of children, without increasing plain x-ray use.