Study Title: Performance of prediction rules for pediatric blunt trauma in trauma centers without current guidelines: a retrospective study

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Background:

The majority of children evaluated in the emergency setting in the United States are evaluated at general emergency departments (ED) as opposed to a pediatric ED. In the trauma setting, access to care in many regions leads to children being resuscitated at an adult trauma center (ATC), not a pediatric trauma center (PTC)[1]. The 2022 standards for trauma verification[2] require "Pediatric Readiness" for all trauma centers, citing data indicating pediatric mortality drops with a higher pediatric readiness score, and many trauma hospitals have a score no better than the national average[3].

A component of optimal care of children is minimizing radiation by limiting CT scans and using pediatric scanning protocols, while not missing injuries. CT scans expose children to ionizing radiation, which due to size, life expectancy and rate of growth makes them more atrisk for malignancy as a result. Despite this, there are more scans typically performed even on adolescents at ATC versus PTC.[4] The Pediatric Readiness toolkit5 includes guidance on existing guidelines for the evaluation of minor blunt head trauma, but no detailed guidelines on blunt abdominal trauma in children. For head trauma, the most widely accepted prediction models are the PECARN[6], CHALICE[7], and CHANCE[8] rules, with the PECARN as the most sensitive and most widely used in the US. There is no universally accepted rule for abdominal imaging in pediatric blunt abdominal trauma, with the PECARN[9], BATiC[10], and Streck[11,12] being the most recently studied.[13]

We hypothesize that many trauma centers do not currently have institutional protocols or guidelines guiding their decision to do a CT scan of the head or abdomen in a pediatric patient. Application of head and abdominal prediction rules to a retrospective dataset will allow quantification of how many children at centers currently not using any guidelines could have avoided this radiation if rules applied based on their exam and labs, and if any clinically important injuries would have been missed.

There is no universally accepted clinical prediction rule for head trauma, with the PECARN6 rule being the most widely used in the United States. This rule, developed in a prospective cohort in the US from 2004-2006, estimates clinically important traumatic brain injury in minor blunt head trauma (GCS 14-15) ages under 2, or over 2. This rule has been validated in 4 additional studies with a sensitivity of 100% in under age 2 and 96.8% in over age 2.

The CHALICE7 rule, derived in the UK, and the CATCH8 study from 10 EDs in Canada, have similar sensitivity but fewer validating studies, and the studies differ in their inclusion criteria. PECARN includes "nontrivial" head trauma within 24 hours with a GCS of 14-15, so is designed

to study mild TBI, CHALICE includes all times and all GCS scores, and CATCH includes trauma within 24 hours with a GCS 13-15. A study comparing the three found they all worked well when applied to the population for which they were designed[14.]
For blunt abdominal trauma, there is also a PECARN database study9 that developed a 7variable prediction rule based on history and physical alone, without labs, which did fail to identify some clinically important injuries while having a high negative predictive value for acute intervention. The PedSRC group[11,12] attempted to improve upon this by adding laboratory values and developing a then validating a five-variable model which is also referred to as the "Streck" rule. This rule has a high sensitivity with only 0.7% risk of intraabdominal injury, and no clinically important missed injuries, if all 5 variables are normal.
A recent publication13 comparing these two rules with a modification of the BATiC rule, which combines some laboratory values and ultrasound results to predict injury10, showed these two to out-perform the BATiC rule in both sensitivity and specificity.

Overall, children who present with blunt injury are more likely to be evaluated with CT4,15 at an adult trauma center than at a pediatric center, with little data available on how centers make these decisions.

Clinical prediction rules for evaluation of blunt trauma in children were developed and validated primarily in pediatric-specific environments. It is unclear how these apply in the setting of a center without pediatric-specific guidelines, and if these could be applied in all environments with the same outcomes. Evidence that these clinical prediction rules accurately predict clinically important injury even in the setting of centers who do not routinely evaluate traumatically injured children would be a step toward prospective study of guidelines in these settings.
The goal overall would be to decrease in the number of CT scans performed at centers without missing any clinically important injuries. This in turn would decrease future malignancies.
While dedicated Pediatric Trauma Centers are important for the care of injured children, many children are injured closer to an adult trauma center. Improving pediatric care, then needs to be seen as improving the system overall.
This study will contribute to determining the sensitivity and specificity of clinical prediction rules for blunt pediatric injury in different settings, and allow quantification of how much radiation could potentially be avoided if scans were chosen according to prediction models.

Primary aim: To determine if validated pediatric imaging guidelines for head and abdominal imaging after trauma can be applied without missing clinically significant injuries in trauma centers without current imaging guidelines.

Secondary aim: To determine the number of CT scans that are currently performed outside of these validated models, increasing radiation dose to children evaluated at centers without pediatric imaging guidelines.

Study Type: Retrospective

Inclusion Criteria: Pediatric blunt trauma patients (<15 years of age) initially evaluated at any trauma center that does not currently have a formal pediatric-specific guideline or protocol for CT imaging of the head AND/OR does not have a formal guideline for abdominal imaging from 2018-2022.

Exclusion criteria: Trauma patients age 15 and over, penetrating trauma patients, patients without a traumatic injury mechanism, patients evaluated at a center which has both a guideline for head imaging and one for abdominal imaging of pediatric (<15 years) trauma patients, pregnant patients.

This is a retrospective study with no therapeutic interventions.
Data will be analyzed to determine which patients would get a CT scan according to predictive rules (medium or high risk) for head and/or abdominal blunt injury and compare this to the populations of patients who got a CT at the evaluating institution.
Head: Number of pediatric patients who had intracranial injury identified by CT whose injury would have been missed if PECARN rules applied according to the exam and history at the center.
Abdomen: Number of pediatric patients who had intraabdominal injury identified by CT whose injury would have been missed if PECARN, Streck or BATiC rules applied according to the exam and history at the center.

Primary and Secondary Outcomes:

1. Number of CT heads performed with no intracranial injury which were not indicated per PECARN prediction rule.
2.Number of pediatric patients with no clinically important intraabdominal injury identified by CT who would not have had imaging per PECARN, Streck or BATiC rules applied according to the exam and history at the center.

Data collection: Data collection will be performed at individual institutions and uploaded in a de-identified manner to the primary site. Data sheet attached.

Only de-identified data (no protected health information) will be provided to the coordinating institution via REDCap.

Data Analysis:
Low risk" will be defined as the "low risk" for the PECARN head study, a score of zero for the PECARN abdominal rule or the Streck rule, and a score < 5 for BATiC. Others will be "some" or "high" risk and placed in a category that would have gotten a scan for this study. Intracranial injury or intraabdominal will be determined by ICD-10 codes.

Univariate analysis comparing groups who did or did not get head or abdominal CT to look for independent predictors of getting a CT will be performed using Chi-Square analysis for categorical variables and a t-test for continuous variables. Multivariate logistic regression will

be performed with and without adjustment based on univariate analysis. Sensitivity, specificity and NPV for the PECARN head injury rule in our population will be calculated. The three intraabdominal injury rules will be compared for sensitivity, specificity and negative predictive value and compared using McNemars test for paired binomial responses.

A power analysis was performed based on previous data comparing the performance of the three abdominal imaging protocols in a single-center study. Using a Chi-squared test to compare the number of intraabdominal injuries in a group who would get a CT according to each prediction rule versus the number in those who would not (potential missed injuries), we would need at least 117 in each group, for a total of 234 patients to demonstrate a difference with the least sensitive test. NTDB data show approximately an average of 5 pediatric (0-14 year) patients per year at adult trauma facilities. We need enrollment of 9 centers at this low number, with potentially fewer centers if adult centers that see more children are included.

Request for waiver of consent:
Since we are evaluating both head and abdominal prediction waiver of informed consent is requested, without which the research could not be practically conducted. Data will be recorded by participating sites on a data sheet, and transferred to a secure RedCap database without patient identifiers. Patient identifiers will not leave the referring institution and data at the primary site will be deidentified.

References:

1. Nance ML, Carr BG, Branas CC. Access to Pediatric Trauma Care in the United States. Arch Pediat Adol Med. 2009;163(6):512-518. doi:10.1001/archpediatrics.2009.65
2. Verification, Review, and Consultation Program, American College of Surgeons. Resources for Optimal Care of the Injured Patient (2022 Standards). Resources for Optimal Care of the Injured Patient, 2022. https://www.facs.org/quality-programs/trauma/quality/verification-review-and-consultation-program/standards/
3. Remick K, Gaines B, Ely M, Richards R, Fendya D, Edgerton EA. Pediatric Emergency Department Readiness Among US Trauma Hospitals. J Trauma Acute Care. 2018;Publish Ahead of Print(NA;):NA; doi:10.1097/ta.0000000000002172
4. Walther AE, Falcone RA, Pritts TA, Hanseman DJ, Robinson BRH. Pediatric and adulttrauma centers differ in evaluation, treatment, and outcomes for severely injured adolescents. J Pediatr Surg. 2016;51(8):1346-1350. doi:10.1016/j.jpedsurg.2016.03.016
5. EMSC Innovation and Improvement Center. National Pediatric Readiness Project.https://emscimprovement.center/domains/pediatric-readiness-project/
6. Kuppermann N, Holmes JF, Dayan PS, et al. Identification of children at very low risk ofclinically-important brain injuries after head trauma: a prospective cohort study. Lancet. 2009;374(9696):1160-1170. doi:10.1016/s0140-6736(09)61558-0

7. Dunning J, Daly JP, Lomas JP, et al. Derivation of the children's head injury algorithm forthe prediction of important clinical events decision rule for head injury in children. Arch Dis Child. 2006;91(11):885. doi:10.1136/adc.2005.083980
8. Osmond MH. The CATCH Rule: A Clinical Decision Rule for the Use of ComputedTomography of the Head in Children with Minor Head Injury. Acad Emerg Med. 2006;13(5Supplement 1):S11-S11. doi:10.1197/j.aem.2006.03.008
9. Holmes JF, Lillis K, Monroe D, et al. Identifying Children at Very Low Risk of ClinicallyImportant Blunt Abdominal Injuries. Ann Emerg Med. 2013;62(2):107-116.e2. doi:10.1016/j.annemergmed.2012.11.009
10. Karam O, Sanchez O, Wildhaber B, Chardot C, Scala GL. Blunt abdominal trauma inchildren: a score to predict the absence of organ injury. Crit Care. 2009;13(Suppl 1):P421. doi:10.1186/cc7585
11. Streck CJ, Vogel AM, Zhang J, et al. Identifying Children at Very Low Risk for Blunt IntraAbdominal Injury in Whom CT of the Abdomen Can Be Avoided Safely. J Am Coll Surgeons. 2017;224(4):449-458.e3. doi:10.1016/j.jamcollsurg.2016.12.041
12. Arbra CA, Vogel AM, Plumblee L, et al. External validation of a five-variable clinicalprediction rule for identifying children at very low risk for intra-abdominal injury after blunt abdominal trauma. J Trauma Acute Care. 2018;85(1):71-77. doi:10.1097/ta.0000000000001933
13. Ozcan A, Ahn T, Akay B, Menoch M. Imaging for Pediatric Blunt Abdominal Trauma WithDifferent Prediction Rules. Pediatr Emerg Care. 2022;38(2):e654-e658. doi:10.1097/pec.0000000000002346
14. Babl FE, Borland ML, Phillips N, et al. Accuracy of PECARN, CATCH, and CHALICEhead injury decision rules in children: a prospective cohort study. Lancet. 2017;389(10087):2393-2402. doi:10.1016/s0140-6736(17)30555-x
15. Gerber N, Munnangi S, Vengalasetti Y, Gupta S. Trauma center variation of headcomputed tomography utilization in children presenting with mild traumatic brain injury. Clin
Imag. 2023;94:125-131. doi:10.1016/j.clinimag.2022.11.024
16. Gerber N, Sookraj K, Munnangi S, et al. Impact of the Pediatric Emergency Care AppliedResearch Network (PECARN) guidelines on emergency department use of head computed tomography at a level I safety-net trauma center. Emerg Radiology. 2019;26(1):45-52. doi:10.1007/s10140-018-1645-4