Accuracy of PECARN, CATCH, and CHALICE head injury decision rules in children: a prospective cohort study

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Summary

Background Clinical decision rules can help to determine the need for CT imaging in children with head injuries. We aimed to validate three clinical decision rules (PECARN, CATCH, and CHALICE) in a large sample of children.

Methods In this prospective observational study, we included children and adolescents (aged <18 years) with head injuries of any severity who presented to the emergency departments of ten Australian and New Zealand hospitals. We assessed the diagnostic accuracy of PECARN (stratified into children aged <2 years and ≥2 years), CATCH, and CHALICE in predicting each rule-specific outcome measure (clinically important traumatic brain injury [TBI], need for neurological intervention, and clinically significant intracranial injury, respectively). For each calculation we used rule-specific predictor variables in populations that satisfied inclusion and exclusion criteria for each rule (validation cohort). In a secondary analysis, we compiled a comparison cohort of patients with mild head injuries (Glasgow Coma Scale score 13–15) and calculated accuracy using rule-specific predictor variables for the standardised outcome of clinically important TBI. This study is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12614000463673.

Findings Between April 11, 2011, and Nov 30, 2014, we analysed 20 137 children and adolescents attending with head injuries. CTs were obtained for 2106 (10%) patients, 4544 (23%) were admitted, 83 (<1%) underwent neurosurgery, and 15 (<1%) died. PECARN was applicable for 4011 (75%) of 5374 patients younger than 2 years and 11 152 (76%) of 14 763 patients aged 2 years and older. CATCH was applicable for 4957 (25%) patients and CHALICE for 20 029 (99%). The highest point validation sensitivities were shown for PECARN in children younger than 2 years (100·0%, 95% CI 90·7–100·0; 38 patients identified of 38 with outcome [38/38]) and PECARN in children 2 years and older (99·0%, 94·4–100·0; 97/98), followed by CATCH (high-risk predictors only; 95·2%; 76·2–99·9; 20/21; medium-risk and high-risk predictors 88·7%; 82·2–93·4; 125/141) and CHALICE (92·3%, 89·2–94·7; 370/401). In the comparison cohort of 18 913 patients with mild injuries, sensitivities for clinically important TBI were similar. Negative predictive values in both analyses were higher than 99% for all rules.

Interpretation The sensitivities of three clinical decision rules for head injuries in children were high when used as designed. The findings are an important starting point for clinicians considering the introduction of one of the rules.

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Introduction

Head injuries in children are a common presentation in acute care settings. The major uncertainty about management of these injuries is whether the child should undergo cranial CT. Most head injuries are mild and do not require neurosurgical management. However, a small proportion of patients might present as having mild injuries but have clinically significant intracranial injuries. Although CT provides definitive and rapid diagnosis to confirm or exclude intracranial injuries, there is concern about radiation-induced cancer, particularly in young patients.[1–3] Furthermore, CT scanners are resource-intensive and sedation might be required for the scan.[4,5] Reports of large increases in CT rates and wide variability in its use for paediatric head injuries are also of concern.[6–9]

Clinical decision rules have been developed to identify children at high risk of intracranial injuries, aiming to assist clinicians to minimise CT scans while still identifying all relevant injuries.[10,11] Three clinical decision rules derived in large multicentre studies with high methodological quality are: the prediction rule for the identification of children at very low risk of clinically important traumatic brain injury (TBI), developed by the Pediatric Emergency Care Applied Research Network (PECARN; USA);[9] the Canadian Assessment of Tomography for Childhood Head Injury (CATCH) rule;[8] and the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE; UK).[12] Unfortunately, a direct comparison of the three rules is not possible because they addressed different questions (who to CT *vs* who not to CT), targeted different

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Research in context

Evidence before this study

We searched MEDLINE, Embase, and the Cochrane Library for reports published from Jan 1, 2006 (the publication year of the CHALICE rule) until June 1, 2016, with the following search terms (with acronyms, synonyms, and closely related words): "craniocerebral trauma", "tomograph, xray computed", "decision support techniques", "newborn, infant, child, adolescent, paediatric", and "Pediatric Emergency Care Applied Research Network, PECARN, clinically-important brain injury, Canadian Assessment of Tomography for Childhood Head Injury, CATCH, Children's Head Injury Algorithm for the Prediction of Important Clinical Events, CHALICE". We did not apply any study design or language restrictions. We identified further studies by examining the reference lists of all included articles and searching relevant websites. We reviewed titles or abstracts for relevance, and assessed original reports and reviews related to PECARN, CATCH, and CHALICE head injury rules. We did not find any external validation studies (not including derivation sites or derivation authors) of the PECARN, CATCH, and CHALICE rules or comparative analysis of the rules in large multicentre samples.

Added value of this study

To our knowledge, this study is the first large, appropriately powered, multicentre study to externally validate the PECARN, CATCH, and CHALICE clinical decision rules. Although all rules had high performance accuracy, the PECARN rules did not miss a single patient requiring neurosurgery.

Implications of all the available evidence

The externally validated performance accuracies of the injury rules are an important starting point for clinicians considering the introduction of one of the rules. Although a number of factors apart from rule accuracy need to be considered as well, PECARN seems to miss the fewest patients.

age groups and injury severities, and used different outcomes (table 1).[10] Despite having undergone only limited external validation,[13–16] these rules are widely used or recommended: the American Academy of Pediatrics suggests that PECARN criteria should be used to determine whether imaging is indicated,[17] elements of CATCH are in the Canadian Paediatric Society position statement,[18] and CHALICE has been incorporated into UK guidance.[19] In some countries, such as Australia and New Zealand, no clinical decision rules predominate.[20]

For clinicians, hospitals, or national bodies contemplating implementation of one of these rules, confirmation and comparison of their accuracy in an appropriately powered external validation study is essential. Two single-centre comparative validation studies have been done, but their results are difficult to translate to practice; one had very wide confidence intervals affecting the interpretation of sensitivities[14] and the other had a very low underlying CT rate.[16]

We designed a multicentre external validation study of these three clinical decision rules for childhood head injuries, aiming to establish their diagnostic accuracy outside their derivation setting and investigate the clinical decision rules' performance in a clinically homogeneous cohort of children with mild head injuries—the population that creates the greatest dilemma for clinicians.

Methods

Study design and participants

The Australasian Paediatric Head Injury Rules Study (APHIRST) was a prospective multicentre observational study in ten paediatric emergency departments in Australia and New Zealand. All emergency departments are members of the Paediatric Research in Emergency Departments International Collaborative (PREDICT) research network.[21] We enrolled all children (<18 years of age) presenting with head injuries of any severity. We excluded all patients with trivial facial injury only,[22] patients referred from emergency department triage to an external provider, those who underwent neuroimaging before transfer to a study site, and those who did not wait to be seen.

The study was approved by the institutional ethics committees at each participating site. We obtained informed verbal consent from parents, guardians, or older adolescents (as per local ethics requirements) apart from instances of life-threatening or fatal injuries where participating ethics committees granted a waiver of consent. The trial protocol was published previously.[22] The study was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN12614000463673.

Procedures

Data were collected on the inclusion and exclusion criteria of the three clinical decision rules, their predictor variables, and outcome measures (table 1), as well as demographic and epidemiological information.[8–10,12] Patients were enrolled by the treating emergency department clinician who collected predictive clinical data before any neuroimaging was done. We used Glasgow Coma Scale (GCS) score as assigned by the emergency department clinician, or if not available, GCS score at triage. The research assistant recorded emergency department and hospital management data after the visit and did a telephone follow-up for patients who had not undergone neuroimaging. Up to six follow-up telephone call attempts were made up to 90 days after injury. In addition, we used outcome data for any patients who had repeat presentations to study hospitals leading to a CT scan within the follow-up period before the

phone call. We requested for review neuroimaging and neurosurgery reports for any patients who presented to other hospitals based on telephone follow-up. We used reports from senior radiologists to extract the results of CT scans and operative reports for patients who underwent neurosurgery.

Research assistants and site investigators abstracted outcome measures from CT and operative reports and consulted locally with site radiologists for interpretation of individual scans. Copies of CT reports were provided to the central site. If there was a question as to the classification of the reports, a central site investigator reviewed them and, if needed, used a third site investigator to resolve disagreements. Research assistants were not blinded to the purpose of the study. Site investigators, research assistants, and participating emergency department clinicians received formal training before and during the study using teaching and study days.

	PECARN <2	PECARN ≥2	CATCH	CHALICE
Inclusion criteria	Age <18 years; presenting within 24 h of head injury	Age <18 years; presenting within 24 h of head injury	Age <17 years All of the following: Blunt trauma to the head resulting in witnessed LOC, definite amnesia, witnessed disorientation, persistent vomiting (two or more distinct episodes of vomiting 15 min apart), persistent irritability in the ED (in children <2 years) Initial GCS score in ED ≥13, as determined by treating physician Injury within the past 24 h	Age <16 years; any history or signs of injury to the head
Exclusion criteria	Trivial mechanism of injury, defined by ground-level fall or walking or running into stationary objects and no signs or symptoms of head trauma other than scalp abrasions and lacerations Penetrating trauma Known brain tumours Pre-existing neurological disorder complicating assessment Neuroimaging at an outside hospital before transfer Patient with ventricular shunt Patient with bleeding disorder GCS score <14	Trivial mechanism of injury, defined by ground-level fall or walking or running into stationary objects and no signs or symptoms of head trauma other than scalp abrasions and lacerations Penetrating trauma Known brain tumours Pre-existing neurological disorder complicating assessment Neuroimaging at an outside hospital before transfer Patient with ventricular shunt Patient with bleeding disorder GCS score <14	Obvious penetrating skull injury Obviously depressed fracture Acute focal neurological deficit Chronic generalised developmental delay Head injury secondary to suspected child abuse Returning for reassessment of previously treated head injury Patients who were pregnant	Refusal to consent
Predictor variables*				
Mechanism of injury	Severe mechanism of injury (MVC with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by motorised vehicle; falls >0·9 m; or head struck by high-impact object)	Severe mechanism of injury (MVC with patient ejection, death of another passenger, or rollover; pedestrian/bicyclist without helmet struck by motorised vehicle; falls >1·5 m; or head struck by high-impact object)	Dangerous mechanism of injury (eg, MVC; fall from elevation ≥3 ft (≥91 cm) or ≥5 stairs; or fall from bicycle with no helmet)	High-speed RTA as pedestrian, cyclist, or occupant (defined as accident with speed >40 miles per h or 64 km/h); fall >3 m in height; or high-speed injury from projectile or object
History	LOC for ≥5 s Not acting normally per parent report	Any or suspected LOC History of vomiting Severe headache	History of worsening headache†	Witnessed loss of consciousness for >5 min ≥3 discrete episodes of vomiting after head injury Amnesia (antegrade or retrograde; >5 min) Suspicion of non-accidental injury (any suspicion by the examining doctor) Seizure in patient with no history of epilepsy
Examination	GCS score <15 Other signs of altered mental status (agitation, somnolence, repetitive questioning, slow response to verbal communication) Palpable or unclear skull fracture Occipital, parietal, or temporal scalp haematoma	GCS score <15 Other signs of altered mental status (agitation, somnolence, repetitive questioning, slow response to verbal communication) Clinical signs of basilar skull fracture (eg, haemotympanum, "raccoon" eyes, otorrhoea or rhinorrhoea of CSF, Battle's sign)	GCS score <15 at 2 h after injury† Irritability on examination† Any sign of basal skull fracture (eg, haemotympanum, "raccoon" eyes, otorrhoea or rhinorrhoea of CSF, Battle's sign) Suspected open or depressed skull fracture† Large, boggy scalp haematoma	GCS score <14, or <15 if aged <1 year Abnormal drowsiness (in excess of that expected by examining doctor) Positive focal neurology (motor, sensory, coordination, or reflex abnormality) Signs of basal skull fracture (haemotympanum, "raccoon" eyes, otorrhoea or rhinorrhoea of CSF, Battle's sign, facial crepitus, or severe facial injury) Suspicion of penetrating or depressed skull injury, or tense fontanelle Presence of bruise, swelling, or laceration >5 cm if aged <1 year

(Table 1 continues on next page)

	PECARN <2	PECARN ≥2	CATCH	CHALICE
(Continued from previous page)				
Primary outcome	Clinically important TBI, defined as death from TBI, neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, haematoma evacuation, lobectomy, tissue debridement, dura repair, or other), intubation of more than 24 h for TBI or hospital admission of 2 nights or more for TBI‡, associated with TBI on CT§	Clinically important TBI, defined as death from TBI, neurosurgical intervention for TBI (intracranial pressure monitoring, elevation of depressed skull fracture, ventriculostomy, haematoma evacuation, lobectomy, tissue debridement, dura repair, or other), intubation of more than 24 h for TBI, or hospital admission of 2 nights or more for TBI‡, associated with TBI on CT§	Need for neurological intervention, defined as either death within 7 days secondary to the head injury or need for any of the following procedures within 7 days: craniotomy, elevation of skull fracture, monitoring of intracranial pressure, or insertion of endotracheal tube for the management of head injury	Clinically significant intracranial injury, defined as death as a result of head injury, requirement for neurosurgical intervention, or marked abnormality on CT (defined as any new, acute, traumatic intracranial pathology as reported by consultant radiologist, including intracranial haematomas of any size, cerebral contusion, diffuse cerebral oedema, and depressed skull fracture)
Secondary outcome	None	None	Brain injury on CT, defined as any acute intracranial finding revealed on CT that was attributable to acute injury, including closed depressed skull fracture (ie, depressed past the inner table) and pneumocephalus, but excluding non-depressed skull fractures and basilar skull fractures	Presence of skull fracture Admission to hospital

We have changed the order in which the variables are presented to facilitate comparison. PECARN=Pediatric Emergency Care Applied Research Network. CATCH=Canadian Assessment of Tomography for Childhood Head Injury. CHALICE=Children's Head Injury Algorithm for the Prediction of Important Clinical Events. ED=emergency department. GCS=Glasgow Coma Scale. LOC=loss of consciousness. MVC=motor vehicle crash. RTA=road traffic accident. CSF=cerebrospinal fluid. TBI=traumatic brain injury. *In each of the three clinical decision rules, the absence of all of the above predictor variables indicates that cranial CT scan is unnecessary. †High-risk predictors for CATCH (need for neurological intervention). ‡Hospital admission for TBI defined by admission for persistent neurological symptoms or signs such as persistent alteration in mental status, recurrent emesis due to head injury, persistent severe headache, or ongoing seizure management. §TBI on CT defined by any of the following descriptions: intracranial haemorrhage or contusion, cerebral oedema, traumatic infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, or skull fracture depressed by at least the width of the table of the skull.

***Table* 1: Inclusion and exclusion criteria, predictor variables, and outcome measures of PECARN, CATCH, and CHALICE clinical decision rules**[8,9,12]

Statistical analysis

Our primary outcome was the diagnostic accuracy (sensitivity, specificity, negative predictive value [NPV], and positive predictive value [PPV]) of each clinical decision rule in our enrolled cohort of patients. We applied rule-specific predictor variables to calculate the number of patients (within cohorts using the specified inclusion and exclusion criteria) that satisfied each rule's specified outcome measures (table 1). We used percentages with 95% CIs to describe sensitivity, specificity, NPV, and PPV. The PECARN rule defined different criteria for children younger than 2 years and those aged 2 years and older; we thus calculated the diagnostic accuracy of PECARN for two groups. The CATCH rule offered four high-risk predictors to identify children who need neurological intervention and three medium-risk predictors to be used alongside the four high-risk predictors to identify those who have brain injury on CT scan (table 1). For CATCH we calculated the validation accuracy of both of these outcomes with the predictors defined.

To overcome difficulties in comparing clinical decision rules due to differences in inclusion and exclusion criteria, particularly age and GCS score, and differences in rule-specific outcomes, we created a homogeneous comparison cohort for secondary analyses. This cohort included all children (<18 years) who presented within 24 h of injury with mild head injuries (GCS scores 13–15 at admission). We selected the PECARN-specific outcome of clinically important TBI as the primary outcome measure in this cohort (table 1).[9] We calculated the diagnostic accuracy of each clinical decision rule for clinically important TBI based on the presence of any rule-specific predictor variables. We also calculated the accuracy for the secondary outcomes of presence of TBI on CT and neurosurgery. For this analysis, we used the presence of any high-risk or medium-risk predictor variables for CATCH.

Data were entered into Epidata (The Epidata Association, Odense, Denmark), and later REDCap,[23] and analysed using Stata version 13. Descriptive statistics were calculated for key variables, with 95% CIs where relevant. Missing predictor variables were treated as missing presumed negative. We did a sensitivity analysis to compare negatively imputed results to those where missing data were excluded (with the exception of any predictor positive variables).

We had calculated the sample size needed based on the assumed smallest subgroup, that for the PECARN rule for children younger than 2 years. A precision-based calculation required the enrolment of 50 patients with clinically important TBI in this group. If the rule predicted 50 of 50 head-injured patients with PECARN-specific outcomes (ie, clinically important TBI), the rule would be 100% sensitive with a 95% CI of 93% to 100%; if 47 of 50 were predicted, the rule would be 94% sensitive with a 95% CI of 83% to 99%.[22] This precision was similar to the original report for the PECARN rule for children younger than 2 years, sensitivity 100% (95% CI 86·3–100).[9] Based on a rate of clinically important TBI of

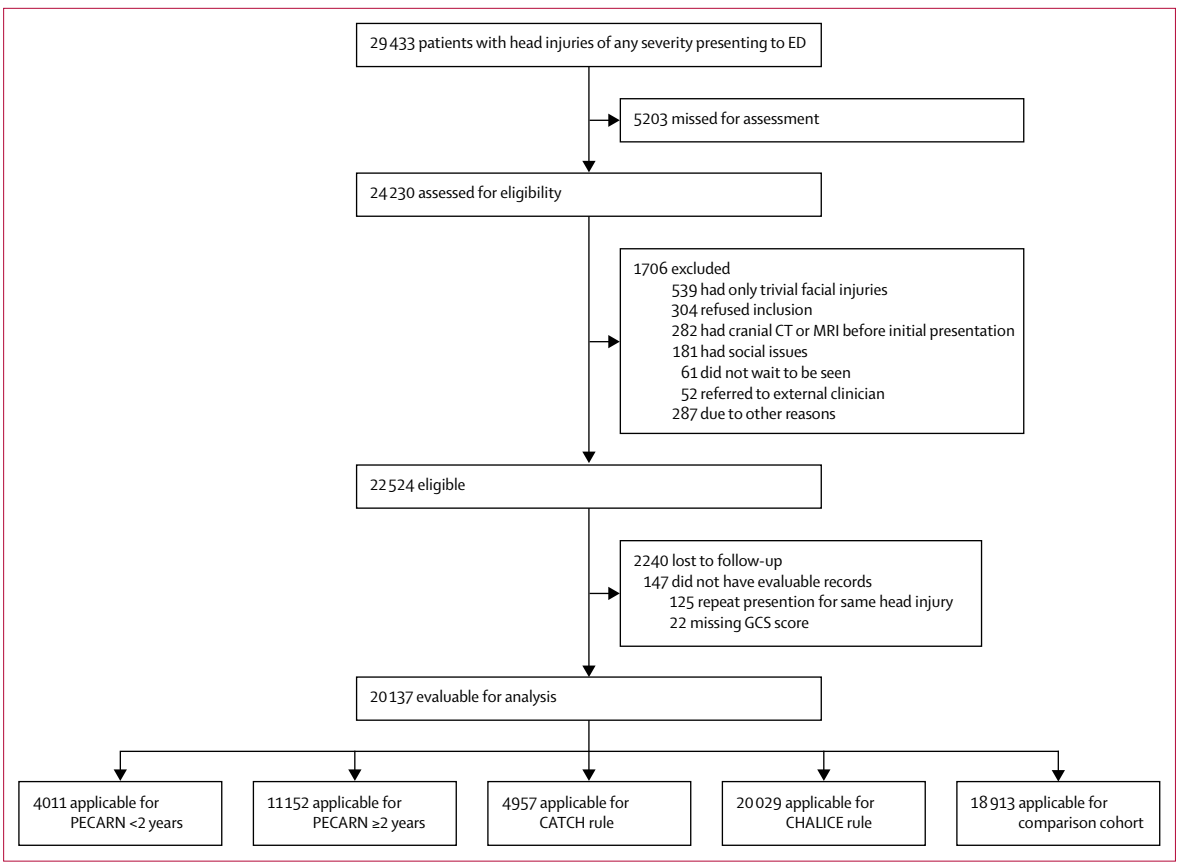

Figure: **Study profile**
ED=emergency department. GCS=Glasgow Coma Scale.

approximately 1% in patients with GCS scores of 14 or 15[9] and equal distribution of children aged younger than 2 years and those aged 2 years and older in our setting,[24] we initially estimated that a total sample of 10 000 patients would be required. However, analysis of the first 1000 enrolled patients[25] showed that children younger than 2 years comprised only 25% of children presenting with head injury, thus requiring an increase in sample size to 20 000 to achieve the desired precision. The sample size of 20 000 was consistent with the sample sizes of the three derivation cohort studies.[8,9,12]

Role of the funding source

The funders of this study had no role in study design; in the collection, analysis, and interpretation of data; in the writing of the report; or in the decision to submit the paper for publication. FEB, CM, KJ, and SDo had access to the raw data. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between April 11, 2011, and Nov 30, 2014, 29 433 patients attended the study emergency departments with head injuries, with 20 137 patients evaluable for analysis (figure). Most (n=19 147; 95%) patients presented within 24 h of injury and nearly all had a GCS score of 13–15 (table 2). 2106 (10%) underwent CT scan, 4544 (23%) were admitted, 83 (<1%) underwent neurosurgery, and 15 (<1%) died (table 2). The most frequent CT findings were intracranial haemorrhage or contusions in 321 patients and depressed skull fractures in 100 (appendix). The most frequent neurosurgical procedures were intracranial pressure monitoring in 51 patients and craniotomy in 48 (appendix). Patients who were eligible but not approached for enrolment (missed patients) had similar characteristics to those included in terms of receipt of CT scans (550 [11%] of 5230) and neurosurgery (30 [1%]). Given that most patients had a GCS score of 14 or 15, our study sample was broadly similar to the original derivation cohorts of PECARN, CATCH, and CHALICE, despite the differences in eligibility criteria (table 2).

See Online for appendix

Using the primary rule-specific outcomes across all evaluable patients, 280 (1%) had clinically important TBI as listed in PECARN; 185 (1%) had a need for neurological intervention as defined by CATCH; and 403 (2%) had clinically significant intracranial injury as defined by CHALICE (table 1, table 2). When applying rule-specific inclusion and exclusion criteria, PECARN was applicable

	Current study cohort (n=20 137)	PECARN cohort (n=42 412)	CATCH cohort (n=3866)	CHALICE cohort (n=22 772)
Demographic characteristics				
Mean age (years)	5·7 (4·7)	7·1 (5·5)	9·2 (NR)	5·7 (NR)
Patients <2 years	5374 (26·7%)	25·3%	7·2%	16·6%
Patients ≥2 years	14 763 (73·3%)	74·7%	92·8%	83·4%
Boys	12 828 (63·7%)	NR	65%	65%
Girls	7309 (36·3%)	NR	35%	35%
Clinician-assigned GCS score				
3–8	121 (0·6%)	..	..	NR
9–12	96 (0·5%)	..	..	NR
13	135 (0·7%)	..	2·5%	0·3%
14	578 (2·9%)	3·2%	7·3%	1·0%
15	19 207 (95·4%)	96·8%	90·2%	96·6%
Example symptoms and signs				
Known or suspected LOC	2707 (13·5%)	15·4%	32·8%*	5·2%*
History of amnesia	1688 (8·4%)†	NR	58·5%	3·2%
History of vomiting	3452 (17·1%)	13·2%	40·9%‡	21%
Headache	4127 (20·5%)†	46·1%†	NR	21%
Witnessed disorientation	2943 (14·6%)	NR	53·8%	NR
Mechanism of injury				
Fall-related	14 119 (70·1%)	44·2%	44·9%	NR
Motor vehicle incident	849 (4·2%)	8·8%	3·0%	NR
Head hit by high-impact object or projectile	1320 (6·6%)	NR	NR	2·0%
Suspected NAI	112 (0·6%)	NR	2·6%	0·3%
Outcomes				
Cranial CT	2106 (10·5%)	35·3%	52·8%	3·3%
Neurosurgery	83 (0·4%)	0·3%	0·6%	0·6%
Hospital admission	4544 (22·6%)§	14·0%	NR	NR
Death	15 (0·1%)¶	..	..	..
Clinically important TBI (PECARN)	280 (1·4%)	1·0%	NR	NR
Need for neurological intervention (CATCH)	185 (0·9%)	NR	0·6%	NR
Clinically significant intracranial injury (CHALICE)	403 (2·0%)	NR	NR	1·2%

Data are mean (SD) or n (%), unless otherwise stated. PECARN=Pediatric Emergency Care Applied Research Network. CATCH=Canadian Assessment of Tomography for Childhood Head Injury. CHALICE=Children's Head Injury Algorithm for the Prediction of Important Clinical Events. NR=not reported. GCS=Glasgow Coma Scale. LOC=loss of consciousness. NAI=non-accidental injury. TBI=traumatic brain injury. *Known LOC only. †Does not include pre-verbal children. ‡≥2 episodes. §Admission rates defined as admitted to inpatient ward, short-stay ward, or intensive care unit ¶Death due to head injury alone (n=13); due to multi-trauma with head injury (n=2).

Table 2: **Patient characteristics in current study, given alongside those from original PECARN, CATCH, and CHALICE validation studies[8,9,12]**

for 4011 (75%) children younger than 2 years and 11 152 (76%) aged 2 years or older (figure, table 3). CATCH was applicable for 4957 (25%) patients and CHALICE for 20 029 (99%). Reasons for non-applicability are listed in the appendix.

In the validation analysis, all clinical decision rules had high sensitivity (table 4). PECARN did not miss any patients younger than 2 years, but did miss one patient aged 2 years or older who did not require neurosurgery. CATCH (high-risk predictors) did not identify a patient with a bleeding disorder who required neurosurgery. CHALICE missed 31 patients, two of whom required neurosurgery (appendix). The specificity of the two PECARN rules was lower than CATCH and CHALICE (table 4). All clinical decision rules had high NPVs with the lower boundary of the 95% CI being 99% or higher. The CATCH rule using both medium-risk and high-risk predictors to identify brain injury on CT had a lower point sensitivity and specificity than the CATCH rule using just high-risk predictors to identify need for neurological intervention (table 4). A sensitivity analysis excluding missing data showed no change to sensitivity, PPV, or NPV, and some reduction in specificity (appendix).

In the comparison cohort analysis, 18 913 patients (94% of the evaluable cohort) had a GCS score of 13–15 and presented within 24 h of injury. Sensitivity of identifying clinically important TBI was higher for PECARN than for CHALICE and CATCH (using medium-risk and high-risk predictor variables) but the 95% CIs overlapped for all examined clinical decision rules and so none were superior (table 5). PECARN did not miss any clinically important TBI when applied to children younger than 2 years, and missed one patient age 2 years or older who did not require neurosurgery but was admitted for more than 2 days (table 5). This patient was positive for basal skull fracture criteria for CHALICE (defined to include serious facial injury), but not PECARN, which includes signs of basilar skull fracture as a predictor variable but not signs of serious facial injury. The patient was not positive for any CATCH predictors. CATCH missed 13 patients with clinically important TBI, including one who required neurosurgery. CHALICE missed 12 patients with clinically important TBI, two of whom required neurosurgery (appendix). The specificity of CATCH and CHALICE was higher than the two PECARN clinical decision rules. All rules had similar NPVs. For the secondary outcomes of TBI on CT and need for neurosurgery, the sensitivity and specificity patterns were similar to those for clinically important TBI (table 5).

Discussion

In this large, robustly powered, multicentre validation study, external to the original derivation settings, we have shown that the PECARN, CATCH, and CHALICE clinical decision rules[8,9,12] have good performance accuracy in identifying children with clinically significant head injuries. Head injury decision rules need to have very high sensitivities in identifying injuries and very high negative predictive values, indicating that patients designated as low risk do not include patients with substantial intracranial injuries. In the validation analysis, PECARN had high point sensitivities in both age cohorts (<2 years and ≥2 years), similar to the original derivation study.[9] The PECARN

rule missed one clinically important TBI, and this patient did not require neurosurgery. CATCH sensitivity was similar to the derivation study,[8] with wide confidence intervals (76% to 100% *vs* 86% to 100% in derivation study[8]), at least in part because it could only be applied to a relatively small proportion of the total population (25%). CHALICE sensitivity was lower than in the derivation study[12] (99%, 95% CI 96–100), and it missed 31 patients of whom two required neurosurgery. All clinical decision rules had negative predictive values of 99% to 100%. Results were similar when patients with missing predictor variables were excluded from the analysis.

Because of differing outcome measures and inclusion and exclusion criteria (table 1),[10] the three rules are impossible to directly compare. Thus, in a secondary analysis we assessed all three rules for a common outcome. Clinically important TBI was chosen as the outcome of interest by consensus in the research team because it was felt to most closely reflect the issues of greatest importance to families, clinicians, and health-care systems. The CATCH primary outcome (death or neurosurgical intervention) was deemed too restrictive and at risk of missing possible considerable morbidity associated with head injury. Although it also encompassed death and neurosurgery, the CHALICE outcome includes CT abnormality alone which was deemed to not clearly relate to clinical consequences. Although not using the rules as designed, this cohort reflects real-world practice; clinicians may not recall the detailed inclusion and exclusion criteria for the individual clinical decision rules. Further, if clinicians use PECARN they might apply the PECARN clinical decision rules to the 25% of patiens with head injuries in which they do not strictly apply; similarly, if CATCH is used, clinicians might apply CATCH to the 75% of patients with head injuries in which this clinical decision rule does not strictly apply.

Although this study was not designed or powered to compare the rules statistically, we found that all three rules had high sensitivities (table 4) and overlapping confidence intervals in detecting clinically important TBI in a homogeneous cohort (table 5). Sensitivities in detecting TBI on CT and identifying patients requiring neurosurgery were similar to the detection of clinically important TBI (table 4). Our results indicating the fewest missed patients with PECARN are similar to the results of a single-centre comparison of the rules by Easter and colleagues[14] using the same outcome measure. Compared with the other rules, CATCH missed patients mainly because they were vomiting or had a change in mental status, both of which are inclusion criteria of the CATCH rule. The features present in patients with missed injuries according to CHALICE were falls less than 3 m, fewer than three vomiting episodes, and change in mental status besides abnormal drowsiness.

	Validation cohort	Comparison cohort
PECARN		
PECARN in children aged <2 years		
GCS score <15	94/4011 (2·3%)	134/5046 (2·7%)
Other signs of altered mental status	267/4011 (6·7%)	318/5046 (6·3%)
Palpable or unclear skull fracture	131/4011 (3·3%)	146/5046 (2·9%)
Scalp haematoma (occipital, parietal, or temporal)	552/4011 (13·8%)	622/5046 (12·3%)
History of loss of consciousness for ≥5 s	144/4011 (3·6%)	153/5046 (3·0%)
Severe mechanism of injury	991/4011 (24·7%)	1034/5046 (20·5%)
Acting abnormally per parent report	525/4011 (13·1%)	611/5046 (12·1%)
PECARN in children aged ≥2 years		
GCS score <15	413/11 152 (3·7%)	554/13 867 (4·0%)
Other signs of altered mental status	921/11 152 (8·3%)	1080/13 867 (7·8%)
Signs of basilar skull fracture	64/11 152 (0·6%)	71/13 867 (0·5%)
History of loss of consciousness	1665/11 152 (14·9%)	1783/13 867 (12·9%)
History of vomiting	1976/11 152 (17·7%)	2244/13 867 (16·2%)
Severe mechanism of injury	3852/11 152 (34·5%)	4154/13 867 (30·0%)
Severe headache	109/11 152 (1·0%)	122/13 867 (0·9%)
CATCH		
GCS score <15 at 2 h after injury	316/4957 (6·4%)	477/18 913 (2·5%)
Suspected open or depressed skull fracture	52/4957 (1·1%)	173/18 913 (0·9%)
History of worsening headache	92/4957 (1·9%)	160/18 913 (0·9%)
Irritability on examination	441/4957 (8·9%)	618/18 913 (3·3%)
Any sign of basal skull fracture	38/4957 (0·8%)	92/18 913 (0·5%)
Large, boggy haematoma of the scalp	155/4957 (3·1%)	460/18 913 (2·4%)
Dangerous mechanism of injury	1763/4957 (35·6%)	4733/18 913 (25·0%)
CHALICE		
Witnessed loss of consciousness >5 min	98/20 029 (0·5%)	64/18 913 (0·3%)
History of amnesia >5 min	706/20 029 (3·5%)	694/18 913 (3·7%)
Abnormal drowsiness	651/20 029 (3·3%)	545/18 913 (2·9%)
≥3 vomiting episodes after head injury	1252/20 029 (6·3%)	1106/18 913 (5·9%)
Suspicion of non-accidental injury	107/20 029 (0·5%)	81/18 913 (0·4%)
Seizure after head injury	331/20 029 (1·7%)	281/18 913 (1·5%)
GCS score <14, or GCS <15 if aged <1 year	402/20 029 (2·0%)	182/18 913 (1·0%)
Suspicion of penetrating or depressed skull fracture or tense fontanelle	261/20 029 (1·3%)	177/18 913 (0·9%)
Signs of basal skull fracture	328/20 029 (1·6%)	276/18 913 (1·5%)
Positive focal neurology	289/20 029 (1·4%)	232/18 913 (1·2%)
Bruise, swelling, or laceration >5 cm if aged <1 year	85/20 029 (0·4%)	58/18 913 (0·3%)
High-speed RTA as pedestrian, cyclist, or vehicle occupant	202/20 029 (1·0%)	168/18 913 (0·9%)
Fall >3 m	156/20 029 (0·8%)	138/18 913 (0·7%)
High-speed injury from a projectile or an object	1302/20 029 (6·5%)	1228/18 913 (6·5%)

See table 1 for detailed definitions. PECARN=Pediatric Emergency Care Applied Research Network. CATCH=Canadian Assessment of Tomography for Childhood Head Injury. CHALICE=Children's Head Injury Algorithm for the Prediction of Important Clinical Events. LOC=loss of consciousness. GCS=Glasgow Coma Scale. RTA=road traffic accident.

***Table 3*: Presence of PECARN, CATCH, and CHALICE predictor variables in the validation and comparison cohort analysis**

In both validation and comparison cohorts, CATCH and CHALICE had higher specificities than PECARN (tables 4, 5). Although there is a balance to be struck, it is difficult to accept an increased specificity at the cost of

	PECARN		CATCH		CHALICE
	<2 years (n=4011)	≥2 years (n=11 152)	All patients eligible within rule criteria (n=4957)	All patients eligible within rule criteria (n=4957)	All patients eligible within rule criteria (n=20 029)
Predictors included	All	All	4 high-risk predictors	7 medium-risk and high-risk predictors	All
Outcome assessed*	Clinically important traumatic brain injury	Clinically important traumatic brain injury	Need for neurological intervention	Brain injury on CT	Clinically significant intracranial injury
Positive on criteria					
With outcome (n)	38	97	20	125	370
Without outcome (n)	1834	5987	779	2100	4303
Negative on criteria					
With outcome (n)	0	1	1	16	31
Without outcome (n)	2139	5067	4157	2716	15 352
Sensitivity (95% CI)	100·0% (90·7–100·0)	99·0% (94·4–100·0)	95·2% (76·2–99·9)	88·7% (82·2–93·4)	92·3% (89·2–94·7)
Specificity (95% CI)	53·8% (52·3–55·4)	45·8% (44·9–46·8)	84·2% (83·2–85·2)	56·4% (55·0–57·8)	78·1% (77·5–78·7)
PPV (95% CI)	2·0% (1·4–2·8)	1·6% (1·3–1·9)	2·5% (1·5–3·8)	5·6% (4·7–6·7)	7·9% (7·2–8·7)
NPV (95% CI)	100·0% (99·8–100·0)	100·0% (99·9–100·0)	100·0% (99·9–100·0)	99·4% (99·1–99·7)	99·8% (99·7–99·9)

PECARN=Pediatric Emergency Care Applied Research Network. CATCH=Canadian Assessment of Tomography for Childhood Head Injury. CHALICE=Children's Head Injury Algorithm for the Prediction of Important Clinical Events. PPV=positive predictive value. NPV=negative predictive value. *See table 1 for detailed definitions.

Table 4: **Diagnostic accuracy of PECARN, CATCH, and CHALICE clinical decision rules when analysed using rule-specific inclusion criteria, exclusion criteria, predictor variables, and outcome measures**

LR+:2,16; LR-: 0 LR+:1,83; LR-: 0,02 LR+:6,3; LR-: 0 LR+:2; LR-: 0,2 LR+:4,2; LR-: 0,1

reduced sensitivity in our health-care setting given the mortality and morbidity associated with missing an intracranial lesion requiring neurosurgery. Both patients and clinicians therefore prioritise a very high sensitivity.[8,9,12]

Our findings will provide a useful starting point for individual clinicians as well as hospitals or regional bodies contemplating the introduction or modification of one of the clinical decision rules. However, it will be important to relate the findings to a number of other factors before implementation. These include the baseline CT use rate in a particular setting, the effect of the rules on the projected CT rate, the baseline clinician diagnostic accuracy and experience, parental expectations, the medicolegal climate, and economic considerations. Our CT rate across any severity head injuries was 10·5% overall. In the comparison cohort analysis, this rate was 8·9% overall and 8·3% when the initial presentation only was considered. Applying CHALICE or CATCH to this latter cohort would increase the CT rates to 4166 (22·0%) of 18 913 and 5707 (30·2%) of 18 913, respectively, a 150–250% rise (table 5). The projected CT rate should PECARN be used is more difficult to determine because patients who are not low risk (8812 [46·6%] of 18 913) might either undergo CT scanning or be observed.[9] Studies assessing the effect of implementing PECARN in clinical practice showed an effective reduction in CT rate in a setting with a high CT use[26] and no increase in a setting with a low CT rate.[27]

This study has some limitations. CT scans were obtained on a minority of patients; it would have been unethical to obtain CT scans on patients the clinicians did not think required them. When we developed the data report forms, we recreated the rule-specific information based on the derivation publications,[8,9,12] not the original data report forms used in the derivation studies. Although this should more accurately reflect the real-world use of the clinical decision rules in an external validation, it might have introduced an element of imprecision. Due to the pronounced heterogeneity of the eligibility criteria and outcome measures in the derivation studies, the only way to realistically compare performance accuracy between the clinical decision rules was to create a homogeneous cohort. Furthermore, we believe this pragmatic approach reflects how the clinical decision rules are used by clinicians. We included patients with GCS scores from 13 to 15 in the comparison group, similar to other studies.[8,14,28,29] Patients with a GCS score of 13 might be regarded as routinely requiring CT and be excluded from an analysis of mild head injuries.[9] In our sample, none of the 135 patients with a GCS score of 13 were missed by any of the rules. The use of clinically important TBI, the PECARN primary outcome variable, might have biased the results in favour of the PECARN rule. However, given that the secondary outcomes of neurosurgery and TBI on CT also favoured PECARN, this effect is unlikely. 10% of patients were lost to telephone follow-up and excluded from analysis (if they did not have neuroimaging during the follow-up period) because we could not determine with 100% certainty the presence or absence of the outcome of interest in the various analyses undertaken. However it remains unlikely that these patients had subsequent abnormal neuroimaging;

	PECARN		CATCH	CHALICE
	<2 years (n=5046)	≥2 years (n=13 867)		
Clinically important traumatic brain injury*				
Positive on criteria				
With outcome (n)	42	117	147	148
Without outcome (n)	2047	6606	5560	4018
Negative on criteria				
With outcome (n)	0	1	13	12
Without outcome (n)	2957	7143	13193	14735
Sensitivity (95% CI)	100·0% (91·6–100·0)	99·2% (95·4–100·0)	91·9% (86·5–95·6)	92·5% (87·3–96·1)
Specificity (95% CI)	59·1% (57·7–60·5)	52·0% (51·1–52·8)	70·4% (69·7–71·0)	78·6% (78·0–79·2)
PPV (95% CI)	2·0% (1·5–2·7)	1·7% (1·4–2·1)	2·6% (2·2–3·0)	3·6% (3·0–4·2)
NPV (95% CI)	100·0% (99·9–100·0)	100·0% (99·9–100·0)	99·9% (99·8–99·9)	99·9% (99·9–100·0)
Traumatic brain injury on CT*				
Positive on criteria				
With outcome (n)	70	180	220	227
Without outcome (n)	2019	6543	5487	3939
Negative on criteria				
With outcome (n)	0	1	31	24
Without outcome (n)	2957	7143	13175	14723
Sensitivity (95% CI)	100·0% (94·9–100·0)	99·4% (97·0–100·0)	87·6% (82·9–91·5)	90·4% (86·1–93·8)
Specificity (95% CI)	59·4% (58·0–60·8)	52·2% (51·4–53·0)	70·6% (69·9–71·3)	78·9% (78·3–79·5)
PPV (95% CI)	3·4% (2·6–4·2)	2·7% (2·3–3·1)	3·9% (3·4–4·4)	5·4% (4·8–6·2)
NPV (95% CI)	100·0% (99·9–100·0)	100·0% (99·9–100·0)	99·8% (99·7–99·8)	99·8% (99·8–99·9)
Neurosurgery*				
Positive on criteria				
With outcome (n)	6	18	23	22
Without outcome (n)	2083	6705	5684	4144
Negative on criteria				
With outcome (n)	0	0	1	2
Without outcome (n)	2957	7144	13205	14745
Sensitivity (95% CI)	100·0% (54·1–100·0)	100·0% (81·5–100·0)	95·8% (78·9–99·9)	91·7% (73·0–99·0)
Specificity (95% CI)	58·7% (57·3–60·0)	51·6% (50·7–52·4)	69·9% (69·2–70·6)	78·1% (77·5–78·6)
PPV (95% CI)	0·3% (0·1–0·6)	0·3% (0·2–0·4)	0·4% (0·3–0·6)	0·5% (0·3–0·8)
NPV (95% CI)	100·0 (99·9–100·0)	100·0% (99·9–100·0)	100·0% (100·0–100·0)	100·0% (100·0–100·0)

PECARN=Pediatric Emergency Care Applied Research Network. CATCH=Canadian Assessment of Tomography for Childhood Head Injury. CHALICE=Children's Head Injury Algorithm for the Prediction of Important Clinical Events. PPV=positive predictive value. NPV=negative predictive value. *See table 1 for detailed definitions.

***Table 5*: Diagnostic accuracy of PECARN, CATCH, and CHALICE clinical decision rules in the comparative analysis of all patients with mild injury presenting within 24 h**

four sites are isolated regional paediatric neurosurgical centres, with a fifth site being a feeder hospital to one; four sites are the only regional paediatric neurosurgical centres within two cities; and one site was located in a city with another non-participating paediatric neurosurgical centre, although both hospitals are part of the same network. While a survey preceding the study did not indicate preferential or widespread use of any of the studied clinical decision rules at the study sites, we do not know if individual clinicians followed any of the published rules.[20] Finally, patients reflect an Australian and New Zealand cohort, with a bias towards tertiary children's hospitals, and the neuroimaging rate in our setting is much lower than that reported from the USA and Canada, which also mainly included tertiary children's hospitals.[8,9]

Contributors

FEB conceived the study, obtained grant funding, designed the study, provided overall supervision, interpreted the data, and wrote the initial draft of the paper. MB, NP, AK , SDa, MM, JAC , YG, JF, JN, MDL, SB, LC, EO, and SRD designed the study, obtained the data, provided supervision, interpreted the data, and drafted or revised the manuscript critically. SDo designed the study, supervised the analysis of the data, contributed to the interpretation of the data, and revised the paper critically. CM and KJ analysed the data, contributed to the interpretation of the data, and revised the paper critically. BW, AW, and AB supervised acquisition of the data, contributed to the interpretation of the data, and revised the paper critically. All authors gave final approval to be published and agreed to be accountable for all aspects of the work.

Declaration of interests
We declare no competing interests.

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