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# The Effect of Patient Observation on Cranial Computed Tomography Rates in Children with Minor Head Trauma

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## ABSTRACT

**Background:** Management of children with minor blunt head trauma often includes a period of observation to determine the need for cranial computed tomography (CT). Our objective was to estimate the effect of planned observation on CT use for each Pediatric Emergency Care Applied Research Network (PECARN) traumatic brain injury (TBI) risk group among children with minor head trauma.

**Methods:** This was a secondary analysis of a prospective observational study at 10 emergency departments (EDs) in Australia and New Zealand, including 18,471 children <18 years-old, presenting within 24 hours of blunt head trauma, with GCS scores of 14-15. The planned observation cohort was defined by those with planned observation and no immediate plan for cranial CT. The comparison cohort included the rest of the patients, who were either not observed or for whom a decision to obtain a cranial CT was made immediately after ED assessment. The outcome clinically important TBI (ciTBI) was defined as death due to head trauma, neurosurgery, intubation for > 24 hours for head trauma, or hospitalization for  $\geq 2$  nights in association with a positive cranial CT scan. We estimated the odds of cranial CT use with planned observation, adjusting for patient characteristics, PECARN TBI risk group, history of seizure, time from injury, and hospital clustering, using a generalized linear model with mixed effects.

**Results:** The cranial CT rate in the total cohort was 8.6%, and 0.8% had ciTBI. The planned observation group had 4,945 (27%) children compared to 13,526 (73%) in the no planned observation group. Cranial CT use was significantly lower with planned observation (adjusted odds ratio [OR] 0.2, [95% CI: 0.1-0.1]), with no difference in missed ciTBI rates. There was no difference in the odds of cranial CT use with planned observation for the group at very low risk for ciTBI (adjusted OR 0.9, [95% CI: 0.5-1.4]). Planned observation was associated with

32 significantly lower cranial CT use in patients at intermediate-risk (adjusted OR 0.2, [95% CI: 0.2-  
33 0.3]) and high-risk (adjusted OR 0.1, [95% CI: 0.0-0.1]) for ciTBI.

34 **Conclusion:** Even in a setting with low overall cranial CT rates in children with minor head  
35 trauma, planned observation was associated with decreased cranial CT use. This strategy can be  
36 safely implemented on selected patients in the PECARN intermediate and higher-risk groups for  
37 ciTBI.

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## 55 INTRODUCTION

56 Minor head trauma in children is a common emergency department (ED) presentation and is  
57 frequently defined by a Glasgow Coma Scale (GCS) score of 14-15 following head trauma.<sup>1,2</sup>  
58 Cranial computed tomography (CT) to diagnose traumatic brain injury (TBI) after trauma is the  
59 current gold standard investigation, however, the ionizing radiation exposure is associated with  
60 an increased risk of lethal malignancies.<sup>3-6</sup> There has been concern about increasing CT rates in  
61 children presenting to EDs in the United States from 1998 to 2008.<sup>7,8</sup> Retrospective studies on  
62 cranial CT trends in pediatric EDs have noted considerably higher rates in the U.S. (27.6% in

63 2007 to 30.2% in 2015)<sup>9</sup> compared with Australia (9.5% in 2001 to 9.6% in 2010).<sup>10</sup> This  
64 difference has been confirmed with prospective studies in children reporting lower non-risk-  
65 adjusted cranial CT rates in Australia (8.3%) compared to the U.S. (35.3%), with similar rates of  
66 clinically important traumatic brain injuries (ciTBIs).<sup>1,11</sup> Clinical decision rules (CDRs) have  
67 been developed and validated, to aid clinical decision-making, improve the sensitivity of  
68 identifying patients with TBI and optimize cranial CT rates by decreasing unnecessary CT  
69 scans.<sup>1,11-14</sup>

70  
71 With the Choosing Wisely campaign, the American Academy of Pediatrics and the American  
72 College of Emergency Physicians have endorsed the benefit of an observation period for the  
73 management of pediatric head injury.<sup>15,16</sup> Observation reduces cranial CT scan rates for children  
74 with minor blunt head trauma, with no significant impact on the delayed diagnosis of ciTBI.<sup>17,18</sup>  
75 One investigation of 40,113 children reported that observation was associated with lower cranial  
76 CT use when compared with those not observed (adjusted odds ratio [OR] 0.53).<sup>17</sup> In a  
77 subsequent study of 1,605 patients, every hour increase in ED observation was associated with  
78 decreased cranial CT rates across all 3 risk groups of children with minor head trauma at risk for  
79 ciTBI in the clinical decision rule derived by the Pediatric Emergency Care Applied Research  
80 Network (PECARN): very low-risk (adjusted OR 0.47), intermediate-risk (adjusted OR 0.28),  
81 and high-risk (adjusted OR 0.11).<sup>18</sup>

82  
83 We explored the relationship between planned ED observation and cranial CT use in children  
84 with minor blunt head trauma in a clinical setting with low baseline cranial CT rates.  
85 Additionally, we stratified patients according to their risk for ciTBI and estimated the effect of  
86 ED observation on CT rates for children in the different PECARN-defined TBI risk groups  
87 (Table 1) and the impact of observation on missed ciTBI rates.<sup>1</sup>

## 88 89 **METHODS**

### 90 **Study Design**

91 This was a planned secondary analysis of a prospective cohort study of children younger than 18  
92 years of age with minor blunt head trauma, enrolled between April 2011 and November 2014 in  
93 10 pediatric EDs in Australia and New Zealand which are members of the Pediatric Research in

94 Emergency Departments International Collaborative (PREDICT) network.<sup>19</sup> The primary study  
95 was designed to validate 3 clinical head injury decision rules: PECARN (USA), CATCH  
96 (Canada), and CHALICE (UK).<sup>1,12,13,20</sup> The individual hospital ethics committee for each  
97 participating site approved the study. The details of the study protocol have been previously  
98 published.<sup>20</sup>

### 99 **Study Setting and Population**

100 The participating EDs were a combination of 2 mixed and 8 free-standing children's hospital  
101 EDs across Australia and New Zealand. The treating clinicians enrolled patients presenting to the  
102 ED with blunt head trauma. A standardized case report form was completed recording  
103 demographic, epidemiologic, and clinical information. After the initial ED assessment, clinicians  
104 documented responses to two questions that were not mutually exclusive: if they planned to  
105 observe the patient ("Do you intend to observe the patient in ED for head injury? yes/no"), and if  
106 they planned to obtain immediate neuroimaging ("Do you intend to perform neuroimaging for  
107 this patient? yes/no") -- if yes, ("What neuroimaging do you intend to perform? CT, MRI, US,  
108 Skull X-ray"). Based on the responses, the planned observation cohort included those with  
109 planned observation and no immediate plan for cranial CT. The comparison cohort included the  
110 rest of the patients, who were either not observed or for whom a decision to obtain a cranial CT  
111 was made immediately after ED assessment. Planned ED observation was defined as "yes" to the  
112 question, "Do you intend to observe the patient in ED for head injury?"

### 113 **Study Protocol**

114 Inclusion criteria: All children younger than 18 years of age presenting to the ED after sustaining  
115 blunt head trauma of any severity were enrolled in the primary study.<sup>11</sup> For this sub-analysis, we  
116 selected the cohort of children with GCS scores of 14-15 presenting within 24 hours of head  
117 trauma, to enable direct comparison with prior published results. Children with multiple ED  
118 visits, with different episodes of head trauma, were eligible for enrollment at each visit.

119 Exclusion criteria: Published in the primary study,<sup>11</sup> which included patients with trivial facial  
120 trauma, if they presented to the ED with neuroimaging for head trauma before study enrollment,  
121 and those with history of blunt head trauma who left the ED without being seen by a physician.

### 122 **Study Measures**

123 Physicians recorded ED data, and research assistants recorded the data regarding hospital  
124 management and conducted structured telephone follow-up on all patients who did not get

125 neuroimaging in the ED 14-90 days after the initial ED visit. Results of cranial CTs performed  
126 on patients who re-presented to the ED were reviewed by the site investigators. Neuroimaging  
127 and neurosurgery reports were reviewed for any patients identified on the follow-up telephone  
128 call to have had medical visits outside the original study hospital. Patients who were admitted to  
129 the hospital or discharged from ED after a cranial CT was obtained, did not receive a follow-up  
130 phone call.

131  
132 All site investigators and research coordinators were trained at the central site prior to  
133 commencing the study. Site clinicians and research assistants were trained by the site  
134 investigators and research coordinators using standardized teaching materials in 1-hour sessions.  
135 This was repeated as needed for new staff throughout the study period. Site investigators and  
136 research coordinators participated in annual updates. The central study coordinator conducted  
137 annual site visits for oversight, compliance, and ongoing updates of site personnel.<sup>20</sup>

138  
139 Timing of events was calculated in hours using information collected on case report forms,  
140 including time from injury to ED arrival, time from ED arrival to physician evaluation, ED  
141 length of stay (LOS), and total LOS. We defined ED LOS as the interval of time from ED arrival  
142 until ED discharge. Data on admission rates included those admitted to short-stay units for  
143 observation, hospital wards, or pediatric intensive care units (PICU). The short-stay unit  
144 admitted patients with anticipated LOS <24 hours. The location of the short-stay units varied  
145 across the participating hospitals (part of ED, separate unit in ED, or a hospital ward). As a  
146 result, for those patients admitted to observation units, but not the hospital wards or PICU, the  
147 ED LOS was the interval of time from ED arrival until hospital discharge. Total LOS was  
148 defined as the time from ED arrival to hospital discharge.

149  
150 To minimize any potential selection bias between the two study cohorts, we stratified the  
151 population by their risk for ciTBI using the age-based PECARN TBI risk groups: very low,  
152 intermediate, and high (Table 1).<sup>1</sup> Children with no predictors for ciTBI were classified as very  
153 low risk. Children with 1 or more risk factors were classified as intermediate or high risk,  
154 depending on the specific risk factor, according to the original PECARN paper.<sup>1</sup> We analyzed  
155 CT use for each of the PECARN TBI risk groups.

156

157 The primary outcome measures were CT and ciTBI rates. Secondary outcome measures were ED  
158 and total LOS, rates of TBI on cranial CT, and hospital admission. The ED clinician's initial  
159 assessment of the patient's GCS score, attending radiologist reports of the CT scans, and  
160 operative reports of neurosurgical interventions were used for each site.

161

162 The outcome, cranial CT, was defined as present if the patient underwent the imaging study  
163 during ED or short stay evaluation. The outcome, ciTBI, was defined as death as a result of  
164 intracranial injury, neurosurgical intervention, intubation for longer than 24 hours for TBI or  
165 hospital admission for 2 nights or longer in association with TBI on CT.<sup>1</sup> Neurosurgical  
166 intervention for TBI included intracranial pressure monitoring, elevation of depressed skull  
167 fracture, ventriculostomy, hematoma evacuation, lobectomy, tissue debridement, dura repair, and  
168 other procedures.<sup>1</sup> Missed ciTBI was defined as the diagnosis of ciTBI on a follow-up ED visit  
169 or identified on the follow-up phone call, with no cranial CT performed on the initial ED visit.  
170 TBI on CT was defined as intracranial hemorrhage or contusion, cerebral edema, traumatic  
171 infarction, diffuse axonal injury, shearing injury, sigmoid sinus thrombosis, midline shift of  
172 intracranial contents or signs of brain herniation, diastasis of the skull, pneumocephalus, and skull  
173 fracture depressed by at least the width of the table of the skull.<sup>1</sup> The attending radiologists at  
174 each hospital site were blinded to the study hypothesis and patient cohorts.

### 175 **Data Analysis**

176 The focus of this analysis was a comparison of the cohort with planned observation, and the  
177 cohort who were either not observed or for whom a decision to obtain a CT was made  
178 immediately after ED evaluation. We described these cohorts with population proportions and  
179 95% confidence intervals (CI). Additionally, we compared the distribution of patients within  
180 each PECARN ciTBI risk group between the two cohorts. We performed a bivariate analysis of  
181 rates of CT scans, ciTBI, missed ciTBI, TBI on CT, and hospital admission between the 2  
182 cohorts, and for each PECARN TBI risk group. The proportion of patients with return ED visits  
183 was calculated for those with follow-up phone calls.

184

185 We compared the time in hours as a categorical variable using median with interquartile range,  
186 and rate difference using the Hodges-Lehmann method, which accounts for different population

187 distributions in the two cohorts.<sup>21</sup> The total LOS (hours) was compared, as well as ED LOS, LOS  
188 for each PECARN TBI risk group, and LOS in patients who had cranial CT scans.

189  
190 Using a generalized estimating equation model, we estimated cranial CT use with multivariable  
191 logistic regression adjusting for patient demographics, PECARN TBI risk group, history of  
192 seizure, and time from injury. History of seizure was not included as a risk factor for ciTBI in the  
193 PECARN head injury rules.<sup>1</sup> The investigators subsequently described the importance of  
194 recurrent seizures as a risk factor associated with TBI on CT.<sup>22</sup> In the current study, history of  
195 seizure had a significant bivariate relationship with CT use. Therefore, it was included in the  
196 multivariate analysis. Because planned observation and cranial CT rates could be correlated with  
197 clinician practice within a hospital site, we controlled for hospital site as a random effect (with  
198 random intercept). Furthermore, because clinician practice could vary across the study time-  
199 period (2011 – 2014), we adjusted for the calendar year as a fixed effect, with 2011 as a  
200 reference. We investigated variance inflation factor values to check for multicollinearity between  
201 the variables, and model residuals and leverage to ensure the absence of outliers and influential  
202 cases. Overall model performance was evaluated via assessment of classification and calibration  
203 (prediction accuracy). Additionally, we performed a sensitivity analysis of the regression model  
204 by adjusting for the individual signs and symptoms and mechanism of injury, instead of the  
205 individual PECARN TBI risk groups. Finally, we estimated the adjusted odds (OR) of CT use  
206 with planned observation for each PECARN TBI risk group.

207  
208 Sample size calculations were performed and published in the primary study,<sup>11,20</sup> and no  
209 additional computations were performed for this planned sub-analysis. Additionally, there were  
210 sufficient events in the outcome measure of cranial CT use (8.6%, 1579 patients), such that  
211 including the 7 covariates ensured a robust regression model. Data analysis was performed with  
212 Stata (version 13; StataCorp, College Station, TX) for the analysis. This manuscript is reported  
213 following the STROBE statement.<sup>23</sup>

214

## 215 **RESULTS**

### 216 **Characteristics of study subjects**

217 Of the 20,137 enrolled patients in the primary study,<sup>24</sup> 18,781 (93.3%) presented within 24 hours  
218 of sustaining head trauma, with GCS scores of 14-15 (Figure). Documented planned observation  
219 and cranial CT status was available for 18,471 (91.7%) of enrolled patients, and all subsequent  
220 analyses were performed on this cohort. There were no differences in demographic  
221 characteristics, cranial CT or ciTBI rates between the 310 (1.5%) patients with no documented  
222 observation plan and the analytic cohorts.

223

#### 224 **Descriptive data**

225 The overall cranial CT rate was 8.6% (range 2-16% across the different hospitals), with a ciTBI  
226 rate of 0.8% and 0.1% of patients receiving a neurosurgical intervention. Cranial CT rates for  
227 each of the PECARN TBI risk groups varied significantly as those at higher risk were more  
228 likely to undergo CT: very low-risk group (1.8% CT rate), intermediate-risk group (10.3% CT  
229 rate) and high-risk group (43.1% CT rate). Similarly, the ciTBI rates varied significantly, with  
230 0.01% in the PECARN very low-risk group, 0.6% in the intermediate-risk and 6.3% in the high-  
231 risk group.

232

233 The strategy of planned observation was made for 4,945 (26.8%) patients (Table 2), with a range  
234 of 21% to 49% across the participating hospitals. Those in the planned observation cohort were  
235 slightly older and included 33.0% at very low risk, 54.9% at intermediate risk, and 12.2% at  
236 high-risk for ciTBI.

237

238 The median time from injury to ED arrival in the cohort with planned observation was not  
239 statistically different from those with no observation (Table 3). The increase in ED LOS with  
240 cranial CT use was significant with planned observation, and for each of the PECARN risk  
241 groups. The total LOS was greater with planned observation for patients at very low-risk and  
242 intermediate-risk, and lower for those at high-risk for ciTBI than those with no planned  
243 observation.

244

#### 245 **Main Results**

246 The unadjusted cranial CT rate was significantly lower in those with planned observation (4.4%)  
247 than those in the no planned observation cohort (10.1%), as was the ciTBI rate (0.4% vs. 0.9%;

248 Table 2). There was a significant difference in the ward and PICU admission rates for the  
249 patients with planned observation (6.4% and 0.3%) compared to those not observed (4.0% and  
250 0.1%). There was no difference in the rates of missed ciTBI between the cohorts. Two patients in  
251 the intermediate PECARN risk group, both with planned observation, were admitted for ciTBI at  
252 the follow-up ED visit. Neither patient required neurosurgery. The details of these patients have  
253 been published.<sup>24</sup> There were no deaths in either cohort.

#### 254 PECARN TBI Risk Groups

255 There was no difference in the unadjusted cranial CT, ciTBI, and TBI on CT rates for the cohorts  
256 with and without planned observation, for the group at very low risk for ciTBI (Table 2). The  
257 planned observation group at intermediate risk for ciTBI had significantly lower CT use (4.4%)  
258 than the group without planned observation (13.3%), and there were no differences in rates of  
259 ciTBI (0.5% vs. 0.6%) or TBI on CT (0.7% vs. 1.1%). The planned observation group at high  
260 risk for ciTBI had significantly lower cranial CT use (11.7%) than those without planned  
261 observation (62.5%), with significantly lower rates of ciTBI (1.2% vs. 9.4%) and TBI on CT  
262 (2.0% vs. 14.1%).

#### 263 Multivariable Analysis

264 After adjusting for age, sex, PECARN TBI risk group, history of seizure, calendar year, and time  
265 from injury, the cohort with planned observation had significantly lower cranial CT use (adjusted  
266 OR 0.2, [95% CI: 0.1-0.2]; Table 4). Additionally, there was no evidence of multicollinearity,  
267 with variance inflation factor of less than 1.5 for all variables in the model (except the non-  
268 independent calendar years variable). A sensitivity analysis of the generalized linear model,  
269 adjusting for the mechanism of injury and individual signs and symptoms of TBI rather than  
270 PECARN risk group produced similar results (adjusted OR 0.2, [95% CI: 0.1-0.2]; Supplement  
271 1). Good model fit was found, and the classification rate was high (94%; sensitivity 38%,  
272 specificity 99%). There was no difference in cranial CT use across calendar years for the total  
273 cohort and each individual PECARN TBI risk group.

274  
275 Multivariate logistic regression for each of the PECARN TBI risk groups demonstrated that  
276 planned observation was significantly associated with lower CT use in patients at intermediate-  
277 risk (adjusted OR 0.2, [95% CI: 0.2-0.3]) and high-risk (adjusted OR 0.1, [95% CI: 0.0-0.1]) for  
278 ciTBI (Supplement 1). Good model fit was found, with high classification rates: high risk 83%

279 (sensitivity 78%, specificity 86%); intermediate risk 90% (sensitivity 7.5%, specificity 99%).  
280 The difference in cranial CT use between those with and without planned observation at very  
281 low risk for ciTBI was not significant (adjusted OR 0.9, [95% CI: 0.5-1.4]), with a poor model  
282 fit.

283

## 284 **DISCUSSION**

285 This multicenter prospective study evaluated the strategy of planned ED observation and cranial  
286 CT use in children with minor head trauma. Despite the low baseline cranial CT rate, planned  
287 observation of patients was associated with 80% lower adjusted odds of CT use. Although the  
288 cohorts with and without planned observation were dissimilar in individual patient  
289 characteristics, after adjusting for patient characteristics, signs, symptoms, and risk factors for  
290 ciTBI, planned observation was independently associated with lower cranial CT use in all but  
291 those at very low risk of ciTBI.

292

293 The primary study protocol defined ED observation as an ongoing assessment for less than 6  
294 hours after the initial clinical evaluation. Admission was defined as assessment requiring more  
295 than 6 hours to either an observation or short stay unit, inpatient or intensive care unit.<sup>20</sup>  
296 Although there was no defined period of observation in the study protocol, in a subsequent  
297 analysis, a hospital length of stay greater than 4 hours was used as a proxy to evaluate the effect  
298 of observation.<sup>24</sup> ED length of stay is affected by many factors that are often out of the  
299 clinician's control. Therefore, the impact of planned ED observation on CT use in patients for  
300 whom there was no plan for an immediate cranial CT, provides the most accurate effect of time  
301 on clinical decision-making. The total LOS was greater for the cohort with no planned  
302 observation at high risk for ciTBI than those with planned observation. This was likely as a result  
303 of more children at high risk for ciTBI getting immediate cranial CTs (62.5%), having TBI on  
304 CT (14.1%), or ciTBI (9.4%); either of which may have been associated with hospital admission.

305

306 Although the primary study of which this was a sub-analysis was designed to validate the  
307 existing head injury decision rules, clinicians did not report using any particular guideline for  
308 their decision-making.<sup>25</sup> Additionally, with a stable cranial CT rate in the decade prior to the  
309 study,<sup>10</sup> and no difference in cranial CT use across calendar years in the current study, suggests

310 that the clinicians did not alter their practice during the study period. The comparison cohort was  
311 comprised of patients with different risk profiles for ciTBI, consisting of those who were either  
312 not observed (e.g., asymptomatic children with minor mechanisms of injury) or for whom a  
313 decision to obtain a cranial CT was made right after ED evaluation (e.g., symptomatic children at  
314 higher risk for TBI). This is similar to a prior study in which 72% of children at very high risk  
315 for ciTBI were in the non-observed group.<sup>18</sup> They reported a cranial CT rate of 5% in the patients  
316 who were observed prior to the decision of imaging compared with 30% in the non-observed  
317 cohort.

318  
319 Stratifying the cohorts by the PECARN TBI risk groups allowed for a comparison of cranial CT  
320 rates in patients at similar risk for ciTBI. There were no differences in the rates ciTBI and TBI  
321 on CT for the very low and intermediate-risk patients between the two cohorts, indicating a  
322 similar risk profile. After risk adjustment, however, planned ED observation was associated with  
323 significantly lower cranial CT use in the groups at intermediate and high risk for ciTBI. The  
324 group at very low risk for ciTBI who were observed did not have a statistically lower rate of  
325 cranial CT use compared to those not observed. This is not surprising as cranial CT is not  
326 recommended in this low-risk group, and therefore it would be unlikely that observation would  
327 have much impact.

328  
329 The results of this study validate the published literature from North America, where ED  
330 observation is associated with lower cranial CT rates in children after minor blunt head  
331 trauma.<sup>17,18</sup> Prior research on the CT rates of each of the PECARN TBI risk predictors in the US  
332 was reported as 13% of low risk, 54% of intermediate, and 82.5% of high-risk groups.<sup>26</sup>  
333 Published evidence of the clinical practice in Australia and New Zealand for pediatric minor  
334 head trauma termed as “usual care” report lower cranial CT rates than with the use of decision  
335 rules.<sup>10,24</sup> Those publications report much lower CT rates for each of the PECARN TBI risk  
336 groups (1.7% of very low risk, 9.9% of intermediate, and 44% of high risk) with similar ciTBI  
337 rates.

338  
339 In addition to differences in clinical practice, this study highlights the use of short-stay units in  
340 EDs in Australia and New Zealand. The Australian National Emergency Target (NEAT) or the

341 4-hour rule was introduced in 2011, and a similar 6-hour target in New Zealand was  
342 implemented in 2009, in response to ED overcrowding.<sup>27,28</sup> These targets/rules require a certain  
343 proportion of patients based on their triage acuity to be discharged, admitted or transferred  
344 within 4 hours of ED presentation, with a potential loss of financial incentives when 90% of  
345 targets are not met. Because admissions to short-stay units stop the NEAT target clock, they are  
346 commonly used to decompress the ED. Perhaps developing similar short-stay units in pediatric  
347 EDs in North America might aid with longer observation periods of children with minor head  
348 trauma and result in fewer CT scans.

349  
350 The increase in lifetime attributable risk of cancer associated with ionizing radiation of cranial  
351 CT scans has been reported worldwide.<sup>4-6</sup> The cumulative iatrogenic radiation in children might  
352 triple the risk of leukemia and brain tumors, a large retrospective study reports.<sup>6</sup> With increasing  
353 awareness of these risks, it has become important to educate health care providers and parents  
354 that CT decisions can often be undertaken as a shared decision-making process.<sup>29</sup> Furthermore,  
355 implementation of clinical decision tools has resulted in decreased CT rates for minor head  
356 trauma at pediatric and general EDs.<sup>30-33</sup> A recent study of 7 health systems in the US and  
357 Ontario report a decreasing trend in cranial CT rates for children <18 years from 2006 to 2016.<sup>8</sup>  
358 However, this has not been the case at the national level in the US, with no apparent decrease in  
359 cranial CT rates in children between 2007 and 2015.<sup>9</sup>

360  
361 The PECARN age-based CDRs identify those patients at very low risk for ciTBI, and for whom  
362 cranial CT is usually not recommended.<sup>1</sup> Incorporating decision support in the electronic medical  
363 record based on the PECARN rules reduces cranial CT rates in the ED for children at very low  
364 risk for ciTBI.<sup>33</sup> The average cranial CT rates across all the intervention EDs decreased from  
365 5.3% to 4.2%. Furthermore, it is possible to achieve overall cranial CT rates of ~15% in all  
366 children with minor blunt head trauma with GCS scores of 14-15.<sup>33</sup> We report no benefit from  
367 planned observation in patients at very low risk for ciTBI, and cranial CT rate of 1.7%, without  
368 any missed ciTBI in this group. Following this analysis, we intend to evaluate the cost-  
369 effectiveness of observation as a strategy to reduce CT use while minimizing missed ciTBI.

370

371 To our knowledge, this is the first study to validate the impact of planned ED observation as a  
372 strategy to lower cranial CT use for each PECARN TBI risk group, in a large cohort of children  
373 with minor blunt head trauma. Despite the lower overall use of CT in this study, our findings are  
374 in agreement with the previous study of planned observation conducted on a different  
375 continent.<sup>17</sup> Selective observation of patients with minor head trauma at intermediate risk of  
376 ciTBI could provide time for resolution of symptoms and/or reassurance of the lack of ciTBI and  
377 decrease the need for cranial CT. We found no increased risk of missed ciTBI in the observation  
378 without a CT cohort, even among selected patients at higher risk of ciTBI. Therefore, this  
379 strategy can be safely implemented on selected patients in the PECARN intermediate and higher-  
380 risk groups for ciTBI.

381

### 382 **LIMITATIONS**

383 Our study has several limitations. First, the questions asked of the clinicians on the case report  
384 forms regarding planned observation and planned immediate cranial CT were not mutually  
385 exclusive. Additionally, the questions did not clarify the reasons for planned observation, and in  
386 particular, the patients for whom the decision to obtain an immediate cranial CT was already  
387 made. However, there was no difference in the cranial CT rates between these patients and those  
388 who received an immediate cranial CT scan and were not observed. As a result, we believe the  
389 effect of observation on the cranial CT rate is accurately reflected in the cohort with planned  
390 observation and no plan for immediate cranial CT. Second, there were significant differences  
391 between the patients with planned observation and those without planned observation. The  
392 patients who received an immediate CT were more symptomatic, with frequent severe  
393 mechanisms of injury, and at a higher risk for ciTBI than the cohort with planned observation.  
394 Although we used multivariable logistic regression to adjust for risk factors of ciTBI to estimate  
395 the independent effect of planned observation on cranial CT use, there could be some  
396 unaccounted-for residual confounding or bias.

397

398 Third, we did not collect data on the time between physician evaluation to the time of the cranial  
399 CT order. Therefore, we cannot measure the incremental effect of observation time on cranial CT  
400 use. Further research in this area will guide the recommended length of ED observation. Finally,  
401 because we did not have time stamps regarding the time of completion of case report forms, it is

402 not clear if the decision for neuroimaging was made because of the progression of symptoms or  
403 other factors not recorded at the time the case report form was completed. As the data collected  
404 were static, we do not know if the data accurately represent the dynamic nature of the evolution  
405 of disease and clinicians' decision-making.

406

407 **CONCLUSION**

408 Planned observation, as a strategy for the management of minor blunt head trauma, is associated  
409 with lower cranial CT use, even in a setting of low baseline CT rates. Children at very low risk  
410 for ciTBI, do not benefit from observation as a strategy to lower cranial CT use. Our results  
411 validate planned observation as an appropriate strategy for selected patients at intermediate and  
412 higher risk for ciTBI, with lower adjusted odds of cranial CT use and no significant difference in  
413 missed ciTBIs.

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**Figure.** Patient flow diagram

ED, emergency department; GCS, Glasgow Coma Scale; CT, computed tomography; ciTBI, clinically important traumatic brain injury

**Table 1.** Children with minor head trauma (GCS $\geq$ 14): PECARN TBI risk groups.

PECARN TBI Risk Group	Children Age <2years	Children Age $\geq$ 2 years
High	Altered mental status*	Altered mental status*
Intermediate	Palpable skull fracture	Signs of basilar skull fracture <sup>§</sup>
	Severe injury mechanism <sup>¶</sup>	Severe injury mechanism <sup>¶</sup>
	History of loss of consciousness $\geq$ 5secs	History of any loss of consciousness
	Non-frontal scalp hematoma	History of vomiting
Very Low	Not acting normally per parents	Severe headache in the ED
	None	None

GCS, Glasgow Coma Scale; PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury; ED, emergency department

\* GCS =14, agitation, sleepiness, slow response, or repetitive questioning.

<sup>§</sup> Post-auricular bruising (battle sign), periorbital bruising (raccoon eyes), cerebrospinal fluid otorrhea, or hemotympanum.

## Patient Observation and Cranial Computed Tomography Use

<sup>¶</sup> Motor vehicle crash with patient ejection, death of another passenger, or rollover; pedestrian or bicyclist without helmet struck by a motorized vehicle; falls of higher than 3 feet for children younger than 2 years of age and higher than 5 feet for children older than 2 years of age; or head struck by a high-impact object.

**Table 2.** Patient demographics, PECARN TBI risk groups and patient outcomes

	Planned observation		No planned observation		Rate Difference
	n (%)		n (%)		% (95% CI)
	4,945	(26.8)	13,526	(73.2)	-46.4 (-47.8 to -44.9)
<b>Demographic characteristics</b>					
Age (years)					
Mean (SD)	6.2	(5.1)	5.5	(4.4)	0.7 (0.6 - 0.9) <sup>a</sup>
Median (IQR)	4.5	(1.8 - 10.7)	4.0	(1.9 - 8.1)	0.3 (0.2 - 0.4) <sup>b</sup>
Age <2 years	1,393	(28.2)	3,566	(26.4)	1.8 (0.4 - 3.3)
Sex [male]	3,102	(62.7)	8,671	(64.1)	-1.4 (-3.0 to 0.2)
<b>PECARN TBI risk group</b>					
Very low	1,630	(33.0)	8,201	(60.6)	-27.7 (-29.2 to -26.1)
Intermediate	2,714	(54.9)	4,273	(31.6)	23.3 (21.7 - 24.9)
High	601	(12.2)	1052	(7.8)	4.4 (3.4 - 5.4)
<b>CT performed</b>					
<b>PECARN TBI risk group</b>					
Very low: n (within-group %)	25	(1.5)	138	(1.7)	-0.2 (-0.8 to 0.5)

## Patient Observation and Cranial Computed Tomography Use

Intermediate: n (within-group %)	120 (4.4)	569 (13.3)	-8.9 (-10.2 to -7.6)
High: n (within-group %)	70 (11.7)	657 (62.5)	-50.8 (-54.7 to -46.9)
<b>Patient outcomes</b>			
<b>ciTBI</b>	20 (0.4)	126 (0.9)	-0.5 (-0.8 to -0.3)
Neurosurgical intervention	2 (0.0)	21 (0.2)	-0.1 (-0.2 to -0.0)
Intubation for >24 hours	0 (0.0)	2 (0.0)	0.0 (-0.0 to 0.0)
Hospital admission $\geq$ 2 nights with +CT	20 (0.4)	125 (0.9)	-0.5 (-0.8 to -0.3)
Death from head injury	0	0	-
<b>PECARN TBI risk group</b>			
Very low: n (within group %)	0 (0.0)	1 (0.01)	-0.01 (-0.04 to 0.01)
Intermediate: n (within group %)	13 (0.5)	26 (0.6)	-0.1 (-0.5 to 0.2)
High: n (within group %)	7 (1.2)	99 (9.4)	-8.3 (-10.2 to -6.3)
<b>TBI on CT</b>	32 (0.7)	195 (1.4)	-0.8 (-1.1 to -0.5)
<b>PECARN TBI risk group</b>			
Very low: n (within group %)	0 (0.0)	1 (0.01)	-0.01 (-0.04 to 0.01)
Intermediate: n (within group %)	20 (0.7)	46 (1.1)	-0.3 (-0.8 to 0.1)
High: n (within group %)	12 (2.0)	148 (14.1)	-12.07 (-14.5 to -9.7)
<b>Hospital Admission rate</b>	2,238 (45.3)	1,811 (13.4)	31.9 (30.4 - 33.4)
Short stay admission	2,056 (41.6)	934 (6.9)	34.7 (33.3 - 36.2)
Ward admission	199 (4.0)	864 (6.4)	-2.4 (-3.1 to -1.7)
PICU	3 (0.1)	46 (0.3)	-0.3 (-0.4 to -0.2)
<b>Return ED visit<sup>c</sup></b>	703 (14.9)	1,457 (12.0)	2.8 (1.6 - 3.9)

Patient Observation and Cranial Computed Tomography Use

**Missed ciTBI** 2 (0.04) 0 (0.0) 0.04 (-0.02 to 0.1)

SD, standard deviation; IQR, interquartile range; CI, confidence interval; GCS, Glasgow Coma Scale; PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury; CT, computed tomography; ciTBI, clinically important traumatic brain injury; CI, confidence interval; PICU, pediatric intensive care unit

<sup>a</sup> Difference between means (95% CI)

<sup>b</sup> Difference between medians (95% CI)

<sup>c</sup> If had follow-up interview: Planned observation n=4,773; No planned observation n=12,208

**Table 3.** Median intervals: planned observation vs. no planned observation

Interval [hours]	Planned observation			No planned observation			Time Difference	
	n	Median	(IQR)	n	Median	(IQR)	Median	95% CI
Injury to ED arrival	4,892	1.3	(0.8 - 2.2)	13,293	1.3	(0.8 - 2.9)	-0.1	(-0.1 to -0.1)
ED arrival to physician evaluation	4,936	0.4	(0.2 - 0.7)	13,502	0.5	(0.2 - 1.0)	-0.1	(-0.2 to -0.1)
<b>ED LOS [hours]</b>								
Overall	4,935	3.7	(2.7 - 5.2)	13,495	1.9	(1.2 - 3.1)	1.7	(1.6 - 1.7)
<b>PECARN TBI Risk Group</b>								
Very low risk	1,628	3.4	(2.4 - 4.5)	8,186	1.6	(1.1 - 2.5)	1.6	(1.5 - 1.7)
Intermediate risk	2,707	3.7	(2.8 - 5.3)	4,261	2.2	(1.3 - 3.5)	1.5	(1.4 - 1.6)
High risk	600	4.4	(3.3 - 7.3)	1,048	3.9	(2.4 - 6.4)	0.7	(0.4 - 0.9)
Cranial CT								

Patient Observation and Cranial Computed Tomography Use

Obtained	213	6.0 (4.0 - 13.0)	1,360	4.9 (3.5 - 7.5)	1.2 (0.6 - 1.9)
Not obtained	4,722	3.6 (2.7 - 5.1)	12,135	1.7 (1.1 - 2.7)	1.8 (1.8 - 1.9)
<b>Total LOS [hours]</b>					
Overall	4,934	3.7 (2.7 - 5.5)	13,484	1.9 (1.2 - 3.3)	1.7 (1.6 - 1.8)
<b>PECARN TBI Risk Group</b>					
Very low risk	1,628	3.4 (2.5 - 4.7)	8,184	1.7 (1.1 - 2.6)	1.6 (1.6 - 1.7)
Intermediate risk	2,706	3.8 (2.8 - 5.6)	4,259	2.2 (1.3 - 3.8)	1.5 (1.4 - 1.6)
High risk	600	4.6 (3.4 - 10.5)	1,041	6.9 (2.9 - 24.9)	-1.5 (-2.3 to -0.9)
<b>Cranial CT</b>					
Obtained	213	11.8 (4.6 - 22.0)	1,351	14.4 (4.5 - 36.6)	-0.7 (-1.9 to 0.3)
Not obtained	4,721	3.7 (2.7 - 5.2)	12,133	1.7 (1.1 - 2.8)	1.8 (1.8 - 1.9)

ED, emergency department; LOS, length of stay; TBI, Traumatic brain injury; PECARN, Pediatric Emergency Care Applied Research Network; CT, computed tomography; IQR, interquartile range; CI, confidence interval

**Table 4.** Adjusted likelihood of cranial CT use

	<b>Total Cohort</b>	
	N = 17,969	
	AOR (95% CI)	
Age ≥2 years	Reference	
<2 years	0.4	(0.4 - 0.5)*
Sex (male)	1.11	(0.97 - 1.3)

## Patient Observation and Cranial Computed Tomography Use

### PECARN TBI risk

Very low	Reference
Intermediate	8.1 (6.7 - 9.7)*
High	77.0 (62.8 - 94.5)*
History of seizure	4.6 (3.2 - 6.5)*
Time from injury (hours)	1.03 (1.02 - 1.04)*

### Observation status

Not observed	Reference
Planned observation	0.2 (0.1 - 0.2)*

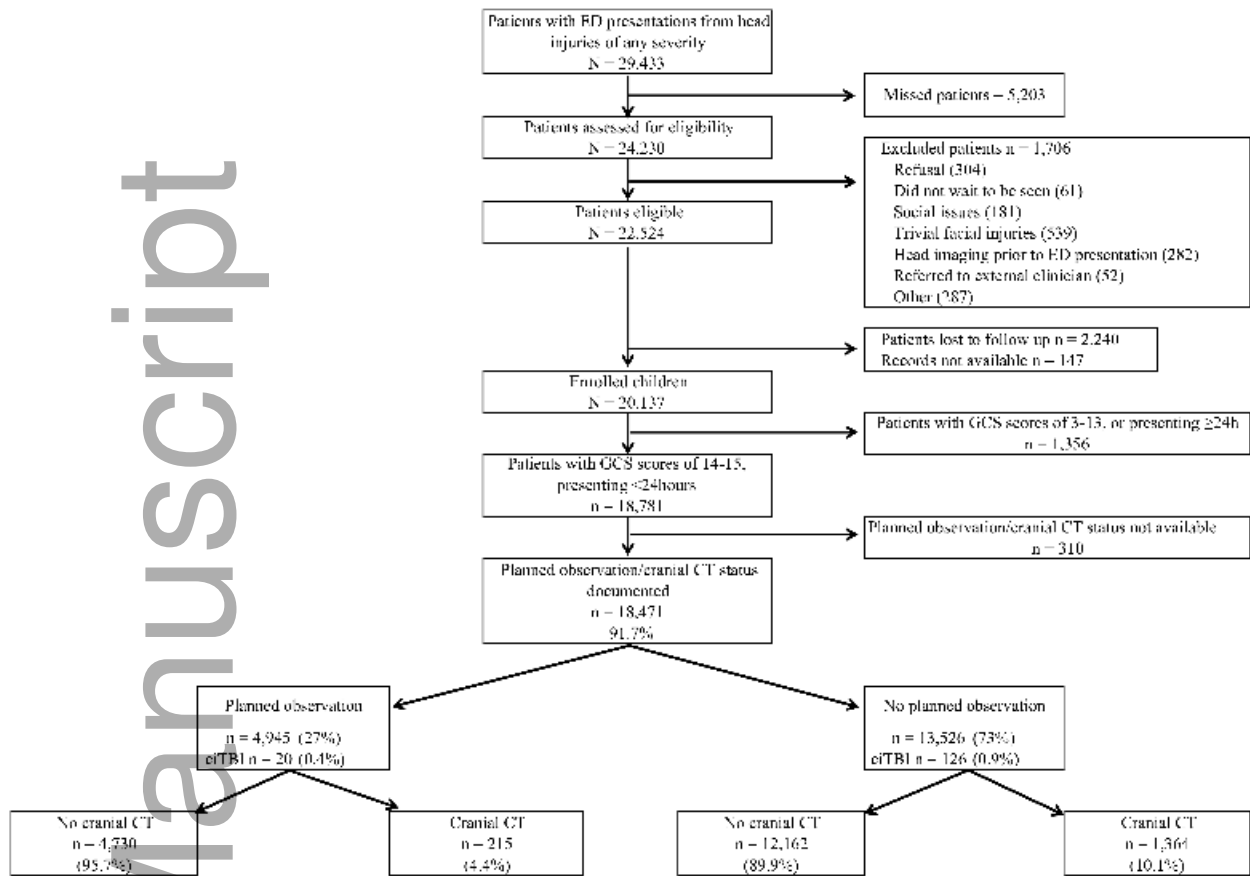
### Year

2011	Reference
2012	0.9 (0.6 - 1.2)
2013	0.8 (0.6 - 1.0)
2014	0.8 (0.6 - 1.0)

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Clustered by hospital site; \*  $p \leq 0.001$

CT, computed tomography; AOR, adjusted odds ratio; CI, confidence interval; PECARN, Pediatric Emergency Care Applied Research Network; TBI, traumatic brain injury



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