

## ABSTRACT

**Objective:** To determine the cost-effectiveness of three Clinical Decision Rules (CDRs) in comparison to Australian and New Zealand usual care; the Children's Head Injury Algorithm for the Prediction of Important Clinical Events, the Pediatric Emergency Care Applied Research Network and the Canadian Assessment of Tomography for Childhood Head Injury.

**Methods:** A decision analytic model was constructed from the Australian health care system perspective to compare costs/outcomes of the three CDRs compared to Australian and New Zealand usual care. The study involved multicentre recruitment from 10 Australian/New Zealand hospitals; recruitment was based on the Australian Pediatric Head Injury Rules Study involving 18913 children aged less than 18 years with a head injury of any severity, and with presentation Glasgow Coma Scale 13-15. We determined the cost effectiveness of the three CDRs compared to usual care.

**Results:** Usual care, *CHALICE*, *PECARN* and *CATCH* strategies cost on average AUD\$6390, \$6423, \$6433, \$6457 per patient respectively. It was more effective and less costly than all other strategies and is therefore the dominant strategy. Probabilistic sensitivity analyses showed that when simulated 1000 times usual care dominates all CDRs in 61%, 62% and 60% of simulations, respectively. The difference in cost between all rules was less than \$36 (95%CI -\$7 to \$77) and the difference in quality adjusted life years was less than 0.00097 (95%CI 0.0015 to 0.00044). . Results remained robust under sensitivity analyses.

### Conclusions and Relevance:

This evaluation demonstrated that the three published international pediatric head injury clinical decision rules were not found to be more cost effective than usual care in Australian and New Zealand tertiary EDs.

. Understanding the usual care context and the likely cost-effectiveness is useful prior to investing in implementation of CDRs.

## INTRODUCTION

Pediatric head injury is a common emergency department (ED) presentation.<sup>1,2</sup> Despite high prevalence, few children have a serious outcome.<sup>3,4</sup> Most head injuries are mild, although some children may be at risk of preventable adverse outcomes.<sup>5-7</sup> Cranial computed tomography scanning (CT) offers a sensitive method for the identification of intracranial injuries and is the gold standard investigation for the diagnosis of traumatic brain injuries (TBI).<sup>2,7</sup> Early identification of intracranial injuries can help avert further brain damage by directing appropriate care.<sup>2,7</sup> Early imaging has been associated with improved outcomes and reduces hospital admissions by assisting in brain injury diagnosis.<sup>2,8</sup>

There are risks of CT<sup>1,2,4,9,10</sup>, including ionising radiation-induced malignancies, in which children have increased vulnerability.<sup>11-14</sup> Young children may require sedation to prevent movement with risk of airway and haemodynamic compromise.<sup>2,10</sup>

Rates of CT scans for the assessment of pediatric head injury have increased considerably in recent decades.<sup>1,7,10,11</sup> In addition to health risks there are cost implications for EDs and the health care system more broadly.

Pediatric clinical decision rules (CDRs) have been derived to help clinicians make decisions concerning CT. These aim to avoid scanning without missing TBI and include features of patient history and examination. Recent systematic reviews<sup>2,8,11</sup> indicate the most sensitive are the Children's Head Injury Algorithm for the Prediction of Important Clinical Events (CHALICE),<sup>4</sup> the Pediatric Emergency Care Applied Research Network (PECARN) rule<sup>1</sup> and the Canadian Assessment of Tomography for Childhood Head Injury (CATCH).<sup>10</sup>

The foci of the three CDRs are different<sup>9</sup> and triggers for CT use vary across different settings.<sup>12</sup> A recent prospective, multi-centre, cohort study in Australia and New Zealand determined that the PECARN CDR had higher point sensitivity than CATCH and CHALICE in a cohort of children with mild head injuries.<sup>3</sup>

The aim of this evaluation was to determine the cost effectiveness of the three CDRs compared to usual care in Australia and New Zealand EDs in the evaluation of children with head injury, in a single study population, to guide funding and treatment decisions. The primary outcome is expressed as quality adjusted life years (QALY) incorporating TBI and radiation induced cancer impacts.

## **METHODS**

### **Study Design and Setting**

Decision analytic health economic modelling was undertaken to compare costs, outcomes and cost effectiveness of the three CDRs compared with Australasian usual care using standard economic evaluation methods.<sup>13</sup> Clinical outcomes and probabilities were based on the Australasian Pediatric Head Injury Rules Study (APHIRST)<sup>3,9</sup>, a multicentre, prospective observational study involving 20,137 children presenting with head injuries to nine tertiary pediatric EDs and one mixed ED across Australia and New Zealand.<sup>14</sup> APHIRST externally evaluated the performance accuracy of the three CDRs.<sup>3,9</sup>

### **Selection of participants**

Children were enrolled in APHIRST if they presented to ED between April 11, 2011, and Nov 30, 2014 and were aged less than 18 years with a head injury. Exclusion criteria were; trivial facial injury only, patients referred from ED triage to an external provider, neuroimaging before transfer to a study site, or did not wait to be medically reviewed.<sup>3,9</sup> This analysis was performed on the APHIRST comparison cohort of 18,913 patients (93.9% of the evaluable cohort) who all had a Glasgow Coma Scale (GCS) of 13-15 and presented within 24 hours of injury. This cohort represents the group of children who create the greatest dilemma for clinicians, and consequently in which a CDR is most likely to be followed. APHIRST patient characteristics are reported in Table 1.

### **Economic Model and Interventions**

The decision analytic economic model was developed in TreeAge Pro 2016 (TreeAge Software Inc., Williamstown, MA). The model compares the three CDRs and Australasian usual care (Figure 1). The usual care strategy was defined as management by clinicians according to current, unstandardized, local practice in Australia and New Zealand which does not follow any one specific CDR but may include knowledge derived from the rules more broadly. In our study cohort, the prevalence of clinically important traumatic brain injury (ciTBI, a composite outcome first published in PECARN and previously used to compare head injury CDRs<sup>1,3</sup>) was 0.8% (160/18913), and 0.1% (24/18913) required neurosurgery. Baseline CT scanning rates are 8.3% of pediatric ED presentations with suspected head injury. Clinicians were not restricted from using a CDR, but during recruitment none of the study institutions had formal processes in place for their use.<sup>12</sup> Clinical management and probabilities for usual care tests and hospitalizations were based on observed APHIRST data. For the three CDRs, probabilities were derived by applying the rules based on indicated computer algorithms without the addition of clinical judgement. All 18,913 children were used for the assessment of each CDR in order to most closely resemble a real life clinical application where front-line clinicians wouldn't usually be aware of all rule-specific inclusion and exclusion criteria. Patients were assessed by the CDRs as high and low-risk according to algorithms and then compared with actual observed outcomes to determine the number of correctly identified and missed brain injuries. This constitutes a pragmatic approach to modelling and compares the rules in a broad and inclusive patient population.

The CHALICE CDR recommends a dichotomous course of action. If one or more predictor characteristics are present then a CT is indicated.<sup>2,4</sup> Similarly, the CATCH CDR recommends a CT if one or more predictor characteristics are present, even though the paper in which the rule was derived separated risk factors into high and medium risk.<sup>2,10</sup> The PECARN CDR recommends not to CT in the absence of predictor variables, however in their presence clinician discretion and observation are used to determine CT use.<sup>1,2</sup>

An adjustment has been developed previously and includes: 'CT recommended', 'observation versus CT on the basis of other clinical factors' and 'CT not recommended.'<sup>1</sup> Essentially, the algorithm

categorises patients into low-risk, intermediate-risk or high-risk. To provide consistency between rule comparisons, as a pragmatic means of modelling patients; intermediate risk patients were re-categorised into high-risk (observation followed by CT) in the presence of two or more intermediate-risk PECARN variables, or low-risk (observation followed by no CT) if they had none or one intermediate-risk PECARN variable. This reflects the suggested actions in the PECARN algorithm<sup>1</sup> and a necessary assumption also used in the previously published cost effectiveness analysis of the PECARN CDR... Alternative scenarios were evaluated that represent the upper and lower bounds of the impact of allocating all intermediate-risk patients to receive observation followed by a CT or observation followed by no CT (see Table 2).

The economic model took a lifetime horizon and both the economic and health care payer perspective comprised the Australian health care system (all hospitals in the study are government funded). The main assumption was that any patient categorised as low-risk for a TBI did not receive a CT and that high-risk children did immediately. In addition, it was assumed that CT scanning is 100% sensitive and specific in detecting TBI.<sup>2,15</sup> The CT scan is the gold-standard and a very accurate diagnostic tool for identification of structural pediatric head injury. APHIRST outcome measures focused on TBI and neurosurgery where a CT was required and shown to have positive (abnormal) findings. CT was therefore assumed to be 100% sensitive and specific for the purpose of the modelling, as have other published economic evaluations.<sup>15</sup> For patients categorised as low-risk (no CT), it was assumed that they were discharged home, with the types and lengths of hospital observation and intervening management as recorded in APHIRST. Low-risk patients with missed TBIs were assumed to represent to hospital (additional ED presentation and a CT).

## **Outcomes**

Performance accuracy and clinical outcomes for applying the CATCH, CHALICE and PECARN CDRs versus usual care for APHIRST have been previously reported<sup>3</sup> but are presented here in the format used for the economic evaluation (Table 2).

Patient outcomes after TBI were estimated by applying the gold standard Glasgow Outcome Scale Extended Pediatric (GOS-E Peds) consisting of levels 1 to 8.<sup>16</sup> Transition probabilities from each injury state were based on clinical data for the subset of patients from the APHIRST cohort who sustained TBIs at the Royal Children's Hospital in Melbourne (n=39). After reviewing medical records, a senior emergency department clinician (JAC) categorised each patient using the GOS-E Pediatric scale. Probabilities were then calculated for different combinations of risk (high or low) and outcome. Patients who did not sustain a TBI in either the high or low-risk groups were assumed to live in full health and were allocated to the highest category – upper good recovery.

GOS-E Pediatric utility weights have been previously mapped<sup>17</sup> and these values were included in the economic model (Appendix 1). For patients who sustained brain injuries (*ciTBI with or without neurosurgery*), but were missed by either the CDR or usual care, a utility decrement of 10% was applied to reflect a worse outcome through delayed treatment. . Utility values were discounted at 5% per annum as per Australian convention.<sup>18</sup>

The estimated cancer risk of 0.12 and the quality of life decrement from a single cranial CT scan of 0.0130 were used based on the age five and aged 4-9 years results, respectively of a meta-analysis conducted by Stein et al, (2008)<sup>19</sup> (Web Appendices).

## **Costs**

Resource costs and associated probabilities are listed (Table 3). All costs are reported in 2016 Australian dollars and earlier data were inflated using the general consumer price index (CPI) from the Reserve Bank of Australia (20th July 2017) as per current economic evaluation guidance.<sup>20</sup>

An assumed 10% loading, or additional cost was applied to costs for children whose TBI (with or without neurosurgery) was missed on initial presentation to account for the likely greater severity attached to an injury that was initially missed compared to the same injury treated immediately.

## **Analysis**

The economic evaluation results are presented as a cost per QALY gained because of TBI (short and long-term management and care) and radiation-induced cancers for the usual care group compared to the three CDRs. Incremental cost effectiveness ratios (ICER) were calculated to compare each strategy with usual care ( difference in costs divided by difference in QALYs). Multiple comparisons of the three CDRs were made according to published reporting guidance.<sup>20</sup> Results are reported according to the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guideline.<sup>21</sup> Statistical preparation of original data was performed using STATA (version 14.0, Texas, USA).

### **Sensitivity Analyses**

Probabilistic sensitivity analysis using 1000 simulations was conducted to investigate the impact of parametric uncertainty (see Table 4, Figure 2 and Web Appendices for parameters and distributions). The 95% CIs for utility and cost decrements (see Web Appendices) for missed brain injuries, costs of CT, probability of cancer, GOSE utility values, other hospital costs, utility decrement of cancer, cancer cost and GOSE costs were used in one way sensitivity analyses along with varying discount rates (3.5% and 6%) and varying cancer latency periods (5 and 20 years).

## **RESULTS**

Usual care, *CHALICE*, *PECARN* and *CATCH* strategies cost on average AUD\$6390, \$6423, \$6433, \$6457 per patient respectively (*Table 4*). The CT scanning rates for the CDRs were 8.3% Usual Care, 17.6% PECARN, 22.0% CHALICE and 30.2% CATCH. From an Australian health care system perspective, the usual care strategy was more effective in detecting TBIs using fewer CT scans. The magnitude of differences in cost and QALYs between the CDRs was small. Usual care was more effective and least costly and therefore dominated all other strategies. When multiple comparisons of CDRs were made CHALICE is mostly likely to be cost effective. The cost effectiveness results are presented in Table 4.



Sensitivity analysis showed that when intermediate-risk PECARN patients are allocated to low-risk this rule becomes closer in cost to usual care, but less effective (due to reduced CT scanning with a greater number of missed injuries). Under this scenario usual care remains dominant. When intermediate-risk PECARN patients are moved to high-risk this rule becomes costlier (more CTs) and more effective, however usual care remains dominant. The model is sensitive to the reallocation of intermediate-risk PECARN patients but under neither scenario is PECARN likely to be cost-effective or preferred according to economic evaluation results.

The results of probabilistic sensitivity analyses are presented in Table 4 and Figure 2a and show that for 61%, 62% and 60% of simulations, usual care is the dominant compared to CATCH, CHALICE and PECARN. The cost-effectiveness acceptability curve (Figure 2b) shows that for a willingness-to-pay of \$50,000 per QALY gained more than 70% of the simulations indicate usual care as the preferred strategy. Cost effectiveness results remained robust to a number of sensitivity analyses performed (Figure 3). The usual care strategy remained the dominant strategy under all sensitivity analyses performed. The economic model was most sensitive to the number and cost of cranial CTs, the method for allocation of PECARN intermediate patients, the probability of cancer, and the rate at which future outcomes and costs are discounted. The model trades off the loss of utility and increased costs associated with missed head injuries against the additional cost of imaging. For example, a scenario where no patients are given a CT leads to a lower price compared to usual care but also less QALYs and is not likely cost-effective.

## **LIMITATIONS**

This evaluation has several limitations. Cost data from a single centre may limit generalisability of results. Nevertheless, results remained robust under sensitivity analyses when cost inputs were varied (Figure 3) and the same cost data were applied to usual care and all three CDRs. The usual care

strategy involves additional periods of patient observation which are associated with an opportunity cost for another patient who may have been treated in that cubicle or bed in their place. The cost of the ED and SSU are based on minutes in cubicle or bed and are incorporated but additional benefits to another patient are not included. Long-term outcomes for children with neurosurgical TBIs was based on a small sample of 39 children from APHIRST, however the model was not overly sensitive to these utility values. . The ability to use original data from the same study to inform the distribution of longer term outcomes for the economic evaluation could be considered a strength compared to other published economic evaluations that rely on secondary data from a different sample.<sup>15,22</sup>

Treating physicians collected information on all CDR predictor variables and it is possible that the collection of data influenced decision making. This may have led to increased effectiveness and therefore cost-effectiveness of the usual care strategy. However, the overall rate of CT use in the prospective APHIRST study is consistent with a previous retrospective report in the same setting.<sup>5,23</sup>

Although we did not find systematic or large-scale use of CDRs based on a survey we conducted across the PREDICT network prior to the study,<sup>12</sup> clinicians may have used one or all of the rules for their individual decision making. *It remains possible that usual care includes principles from the CDRs gathered through training and practice and that the CDR's represent formal or informal supplements to care.* However, it is worthwhile noting that widespread use any of the rules should have increased the “usual care” CT rate over the known long term stable pre-study baseline; this did not happen. *A further limitation relates to the inclusion of clinical discretion in the usual care strategy but not for CDR strategies, which is inevitable given the data source. In practice CDRS are always implemented with clinical discretion.*<sup>3,23</sup> There could be significant variation of usual practices across the ten sites. The usual care group demonstrates that high quality decisions are being made by clinicians, but further research using the APHIRST dataset would be needed to quantitatively describe usual care.

The rules were applied in a pragmatic manner where all children in the comparison cohort were made eligible for assessment with each CDR. The APHIRST cohort assessed with each rule is therefore

different from the cohorts in the derivation studies which maintained varied eligibility criteria. This could impact the performance accuracy of the CDRs. However, this method constitutes a ‘real world’ approach and may reflect the practices and population in which the rules will be implemented. The economic model relies on a computer algorithm applied to data and in real life clinician judgement would play a significant role. Additionally, the PECARN rule was developed to allow for clinician discretion (with regards to observation for intermediate-risk patients<sup>1</sup>) and in applying PECARN to the dataset we have no way of including this. In a ‘real world’ application of the CDRs, in particular the PECARN rule, all of these factors may result in different probabilities than those imputed, which could impact results. We have carefully varied the assumptions around the allocation of PECARN intermediate risk patients to high and low-risk categories to assess the impact of this assumption.

## **DISCUSSION**

This economic evaluation for the first time directly compares the cost effectiveness of three CDRs and Australasian usual care for the assessment of pediatric head injuries presenting to EDs. The results of the economic modelling demonstrate that the three published head injury CDRs are not more cost effective than Australian and New Zealand usual care strategy. The absolute differences between the rules were small with the largest difference in bootstrapped cost of \$36 (95%CI -\$7 to \$77) and 0.00097 (95%CI 0.0015 to 0.00044) QALYs per child (equating to an additional 8.5 hours of quality adjusted life). The cost effectiveness results were robust under all one-way and probabilistic sensitivity analyses. It is therefore unlikely in this patient setting the economic evaluation results would suggest the use of any specific CDR over another.

The strengths of the analysis include; a large dataset, the use of multiple centres, and that the analysis was able to compare the rules hypothetically using standardised modelling techniques and assumptions.

The CDRs were derived to optimise the balance between identifying significant brain injuries, and minimising the exposure of the developing brain to radiation. However, the results presented here do not indicate high value in investing in strategies to switch from usual care, or from one rule to another in our setting. In comparison, a cost effectiveness analysis conducted in the USA by Nishijima et al<sup>15</sup> reported that PECARN was the dominant strategy when compared with usual care (characterised by 33.8% CT rate).<sup>15</sup> Another cost-effectiveness analysis conducted in the UK by Holmes et al<sup>22</sup> investigated CHALICE and PECARN and demonstrated both are a cost effective approach. The comparators for this study were not usual practice, but theoretical - CT for all patients and discharge all without testing. It is possible that implementing CDRs in countries where the baseline CT rate is significantly higher than the 8.3% scanning rate in Australia and New Zealand will lead to more advantageous cost-effectiveness ratios. Interventions to appropriately reduce existing imaging rates are likely to be more cost-effective in countries known to have higher unit costs of health care such as the United States. . It is likely that patterns of usual care are critical to the choice of CDR. Initiatives such as Choosing Wisely,<sup>24-26</sup> that aim to inform evidence based on cost-effective practice choices, should more fully account for usual care contexts when making recommendations. Australian and New Zealand usual care remained cost effective indicating no economic imperative for investing in change. We failed to observe important differences in cost or effectiveness between the rules, indicating a lack of economic imperative for switching from any rule to another. Other important factors to the decision are likely to include physician experience and rule specific sensitivities and specificities for outcomes, which were not considered in this economic evaluation. The use of CDRs outside of specialist pediatric hospitals or by clinicians who are less experienced in evaluating children may generate different results.

In summary, the practice of usual care in our setting is an effective strategy and is cost saving. When compared to usual care in the Australasian specialized pediatric hospital setting, the CATCH, CHALICE and PECARN CDRs are all projected to scan more children and may miss more neurosurgical and non-neurosurgical traumatic brain injuries which are likely to result in increased

hospital costs with a potential reduction in positive health outcomes. These results were robust under several one-way and probabilistic sensitivity analyses. Further analysis is required to provide a comprehensive definition as to what usual care constitutes. This evaluation highlights the importance of understanding usual practice before investing in the implementation of international CDRs derived within other health care settings and countries.

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