

When is it safe to forego a CT in kids with head trauma? *J Fam Pract.* 2010;59:159-163.

## Potential PURL Review Form: Diagnostic test

### SECTION 1: IDENTIFYING INFORMATION

1. Citation Kuppermann N, Holmes JF, Dayan PS, et al; for the Pediatric Emergency Care Applied Research Network (PECARN). Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. *Lancet.* 2009;374(9696):1160-1170.
2. Hypertext link to PDF of full article [http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3048&itool=AbstractPlus-def&uid=19758692&nIbid=2985213R&db=pubmed&url=http://linkinghub.elsevier.com/retrieve/pii/S0140-6736\(09\)61558-0](http://www.ncbi.nlm.nih.gov/entrez/utils/fref.fcgi?PrId=3048&itool=AbstractPlus-def&uid=19758692&nIbid=2985213R&db=pubmed&url=http://linkinghub.elsevier.com/retrieve/pii/S0140-6736(09)61558-0)
3. First date published study available to readers October 3, 2009
4. PubMed ID 19758692
5. Nominated By Jim Stevermer
6. Institutional Affiliation of Nominator University of Missouri
7. Date Nominated October 7, 2009
8. Identified Through TOC
9. PURLS Editor Reviewing Nominated Bernard Ewigman
10. Nomination Decision Date October 7, 2009
11. Potential PURL Review Form (PPRF) Type Diagnostic Test
12. Other comments, materials or discussion
13. Assigned Potential PURL Reviewer Gail Patrick
14. Reviewer Affiliation University of Chicago
15. Date Review Due October 22, 2009
16. Abstract 

**BACKGROUND:** Computed tomography (CT) imaging of head-injured children has risks of radiation-induced malignancy. Our aim was to identify children at very low risk of clinically important traumatic brain injuries (ciTBI) for whom CT might be unnecessary.

**METHODS:** We enrolled patients younger than 18 years presenting within 24 h of head trauma with Glasgow Coma Scale scores of 14-15 in 25 North American emergency departments. We derived and validated age-specific prediction rules for ciTBI (death from traumatic brain injury, neurosurgery, intubation >24 h, or hospital admission ≥2 nights).

**FINDINGS:** We enrolled and analysed 42 412 children (derivation and validation populations: 8502 and 2216 younger than 2 years, and 25,283 and 6411 aged 2 years and older). We obtained CT scans on 14,969 (35.3%); ciTBIs occurred in 376 (0.9%), and 60 (0.1%) underwent neurosurgery. In the validation population, the prediction rule for children younger than 2 years (normal mental status, no scalp haematoma except frontal, no loss of consciousness or loss of consciousness for less than 5 s, non-severe injury mechanism, no

palpable skull fracture, and acting normally according to the parents) had a negative predictive value for ciTBI of 1176/1176 (100.0%, 95% confidence interval [CI] 99.7-100.0) and sensitivity of 25/25 (100%, 86.3-100.0). 167 (24.1%) of 694 CT-imaged patients younger than 2 years were in this low-risk group. The prediction rule for children aged 2 years and older (normal mental status, no loss of consciousness, no vomiting, non-severe injury mechanism, no signs of basilar skull fracture, and no severe headache) had a negative predictive value of 3798/3800 (99.95%, 99.81-99.99) and sensitivity of 61/63 (96.8%, 89.0-99.6). 446 (20.1%) of 2223 CT-imaged patients aged 2 years and older were in this low-risk group. Neither rule missed neurosurgery in validation populations.

**INTERPRETATION:** These validated prediction rules identified children at very low risk of ciTBIs for whom CT can routinely be obviated. **FUNDING:** The Emergency Medical Services for Children Programme of the Maternal and Child Health Bureau, and the Maternal and Child Health Bureau Research Programme, Health Resources and Services Administration, US Department of Health and Human Services.

## SECTION 2: CRITICAL APPRAISAL OF VALIDITY

- |   |  |
|---|--|
| 1. Is the spectrum of severity of patients' illness comparable to the patient group typically seen by family physicians and other primary care clinicians?      | Patients presenting to the emergency department (ED) may overall represent a population of higher acuity/severity when it comes to head injury.                                      |
| 2. Is the proportion of patients with the target illness comparable to the patient group typically seen by family physicians and other primary care clinicians? | There is probably a higher overall prevalence of ciTBI in patients presenting to the ED.   |
| 3. The nature of the test being studied is clearly specified.   | Well covered   |
| 4. The test is compared with an appropriate gold standard.  | Well covered<br>Comments: CT findings had been the previous gold standard, but wanted to avoid CT scans due to dangers of ionizing radiation and presence of false-positive results. |
| 5. Where no gold standard exists, a validated reference standard is used as comparator.   | Well covered<br>Comments: Defined a new "gold standard" of clinically important traumatic brain injury (ciTBI).  |
| 6. Patients for testing are selected either as a consecutive series or randomly, from a clearly defined study population.                                       |  |
| 7. The test and gold standard are measured independently (blind) of each other.   | Well covered   |
| 8. The test and gold standard are applied as close together in time as possible.  | Well covered   |

<b>9.</b> Results are reported for all patients that are entered into the study.	Well covered
<b>10.</b> A pretest diagnosis is made and reported.	Well covered  Comments: Not possible, but the previous "gold standard" CT scan would also have been applied before knowing the "outcome" of ciTBI - all data from screening questions were obtained before the outcome of imaging was revealed to providers.
<b>11.</b> How many patients are included in this study? <i>Please indicate number of patients included, with inclusion/exclusion criteria used to select them.</i>	42,412: 33,785 to the derivation group (8502 <2 years old, 25,283 ≥2 years) and 8627 to the validation group (2216 <2 years and 6411 ≥2 years).  Children presenting within 24 hours of head trauma were included; exclusions were trivial mechanism, eg, ground level fall, walking, running into stationary object, and no greater trauma than mild laceration, scrape; also excluded penetrating trauma, known brain tumor or neurologic condition complicating assessment; neuroimaging done outside hospital prior to presentation; this study was limited to GCS score >14, no bleeding disorder or ventriculoperitoneal shunt - there was another arm including those children analyzed separately.
<b>12.</b> What is the prevalence (proportion of people with the disease being tested for) in the population from which patients were selected?	For all patients enrolled: age <2, prevalence is 98/10,620 or 0.9%; age ≥2, prevalence is 278/31,416 or 0.9%.
<b>13.</b> What are the main characteristics of the patient population? <i>Include all relevant characteristics – eg, age, sex, ethnic origin, comorbidity, disease status, community/hospital based</i>	Information on demographics was not reported, but the study was conducted in a national network of urban EDs in medium to large cities.
<b>14.</b> What test is being evaluated in this study?  <i>Consider whether the technology being described is comparable / relevant to the test being considered in the guideline, ie, make sure the test has not been superseded by later developments.</i>	Performance of 6 criteria in predicting the absence of ciTBI, where CT scan may be safely avoided.
<b>15.</b> What is the reference standard with which the test being evaluated is compared?  <i>Indicate whether a gold standard, or if not how this standard was validated.</i>	Presence of ciTBI defined as a death from TBI, neurosurgery, intubation >24 hours, or hospital admission >2 nights with evidence of TBI on CT scan.
<b>16.</b> What is the estimated sensitivity of the test being evaluated? (state	See Figure 2, page 1167, bottom: <2 yo derivation: 98.6%, validation: 100%; ≥2 derivation: 96.7%, validation: 96.8%

95% CI)

*Sensitivity = proportion of results in patients with the disease that are correctly identified by the new test.*

**17.** What is the estimated specificity of the test being evaluated? (state 95% CI)

*Specificity = proportion of results in patients without the disease that are correctly identified by the new test*

**18.** What is the positive predictive value of the test being evaluated?

*Positive predictive value = proportion of patients with a positive test result that actually had the disease.*

**19.** What is the negative predictive value of the test being evaluated?

*Negative predictive value = proportion of patients with a negative test result that actually did not have the disease.*

**20.** What are the likelihood ratios for the test being evaluated?

*If not quoted in the study, a number of tools are available that simplify calculation of LRs. Please indicate where results are calculated rather than taken from the study.*

**21.** How was this study funded? Does the funding source raise issues of conflict of interest or bias?

*List all sources of funding quoted in the article, whether Government, voluntary sector, or industry.*

See Figure 2, page 1167, bottom:

<2 yo 53.7% in both derivation and validation groups;  
≥2 yo derivation: 58.5%, validation: 59.8%.

See Figure 2, page 1167, bottom:

<2 yo derivation: 1.8%, validation: 2.4%;  
≥2 yo derivation: 2.0%, validation: 2.3%.

See Figure 2, page 1167, bottom:

<2 yo derivation: 99.9%, validation: 100%;  
≥2 yo derivation: 99.95%, validation: 99.95%.

"Negative LR" = likelihood, given all 6 screen questions negative, that ciTBI is present:

See Figure 2, page 1167, bottom:

<2 yo derivation: 0.03 (0.001-0.14), validation: 0.0 (0-0.26);  
≥2 yo derivation: 0.06 (0.03-0.11), validation: 0.05 (0.01-0.19).

Government funded, low risk of bias.

### SECTION 3: REVIEW OF SECONDARY LITERATURE

1. DynaMed excerpts

2. DynaMed citation/access date Decision rules for computed tomography in head injury in children. In: DynaMed [database online]. Available at: [www.DynamicMedical.com](http://www.DynamicMedical.com). Last updated: October 10, 2009. Accessed October 15, 2009

3. Bottom line recommendation or summary of evidence from DynaMed (1-2 sentences) DynaMed recent update includes this article. Otherwise states other decision rules not well validated.

4. UpToDate excerpts

5. UpToDate citation/access date Schutzman S. Minor head injury in infants and children. In: Basow DS, ed. UpToDate [database online]. Waltham, Mass: UpToDate; 2009. Available at: <http://www.uptodate.com>. Last updated June 4, 2009. Accessed October 20, 2009

6. Bottom line recommendation or summary of evidence from UpToDate (1-2 sentences) Up To Date contains essentially all of the rules proposed in this article - the main difference being that the article that we are reviewing offers definitive validation of a six-part rule (8 if you consider GCS score and mechanism of injury as preliminary rules); Up-To-Date and others cite earlier studies that are either small or based on consensus guidelines.

7. PEPID PCP excerpts

Diagnostic Algorithms:

#### Head Trauma (By Risk Group)

(Assumes only care for head injury required)

General Information

1. Stabilize Patient
2. Do History & Physical
3. CT scan if:
  - o GCS <15
  - o ANY suspicion of nonaccidental trauma
  - o <2 years with TINS  $\geq$ 2
    - § TINS, traumatic infant neurological score

Risk Groups (<2 yo)

1. High-risk patients
  - o Clinical findings
    - § Decreased mental status
    - § Focal neuro findings
    - § LOC >1 minute
    - § Protracted vomiting
    - § >5 episodes
    - § >6 hours
    - § Acute skull fracture
    - § Signs of depressed/basilar skull fracture
    - § Bulging fontanelle
  - o Treatment
    - § ALL REQUIRE CT SCAN
2. Intermediate-risk patients
  - o Clinical findings
    - § LOC <1 minute
    - § Vomiting 3-4 times
    - § History of lethargy /irritability (now resolved)
    - § Caretaker concerned about behavior

- § Hematoma (esp. if large or nonfrontal)
- § Nonacute skull Fx
- § >24-48 hrs old
- § Mechanism
- § Fall to hard surface
- § High force mechanism
- § Vague/ no Hx of trauma with signs of trauma
- o Treatment: either
  - § CT scan or
  - § Observe 4-6 hrs, then re-evaluate
- 3. Low-risk patients
  - o Clinical findings
    - § Low-energy injury, eg, fall <3 ft
    - § NO signs or symptoms
    - § >2 hrs since injury
  - o Treatment
    - § Observation
    - § 6 hrs in ED
    - § At home with reliable caretaker

#### References

1. Palchak MJ, Holmes JF, Vance CW, et al. A decision rule for identifying children at low risk for brain injuries after blunt head trauma. *Ann Emerg Med.* 2003;42:492-506.
2. The management of minor closed head injury in children. Committee on Quality Improvement, American Academy of Pediatrics. Commission on Clinical Policies and Research, American Academy of Family Physicians. *Pediatrics.* 1999;104:1407.
3. Schutzman SA, Barnes P, Duhaime AC, et al. Evaluation and management of children younger than two years old with apparently minor head trauma: proposed guidelines. *Pediatrics.* 2001;107:983-993.
4. Woestman R, Perkin R, Serna T, et al. Mild head injury in children: Identification, clinical evaluation, neuroimaging, and disposition. *J Pediatr Health Care.* 1998;12:288-298.
5. Mander M, Wencel T, Bazowski P, et al. How should we manage children after mild head injury? *Child Nerv Syst.* 2000;16:156-160.
6. Quayle KS. Minor head injury in the pediatric patient. *Pediatr Clin North Am.* 1999;46:1189-1199.
7. Savitsky EA, Votey SR. Current controversies in the management of minor pediatric head injuries. *Am J Emerg Med.* 2000;18:96-101.
8. Woestman R, Perkin R, Serna T, et al. Mild head injury in children: Identification, clinical evaluation, neuroimaging, and disposition. *J Pediatr Health Care.* 1998;12:288-298.

#### **Evaluation of Head Injuries: AAP Guidelines**

(Assumes only care for head injury required)

If <3 Months Old

1. High suspicion for brain injury
2. Strongly consider CT scan in ALL
  - o CT just about all
    - § If CT negative
      - Discharge with competent observer
    - § If CT positive
      - Transfer to pediatric trauma center
      - Neurosurg evaluation
      - PICU

If >3 Months and <2 Years Old

1. If ANY
  - o Scalp hematoma
    - § Esp. temporal or parietal
  - o Irritability
  - o Lethargy
  - o Protracted vomiting (>6 times)

- o Progressive headache
  - o Focal neuro changes
  - o Do CT scan
    - § If CT negative
      - Discharge with competent observer
    - § If CT positive
      - Transfer to pediatric trauma center
      - Neurosurg evaluation
      - PICU
2. If NO
- o Scalp hematoma
    - § Esp. temporal or parietal
  - o Irritability
  - o Lethargy
  - o Protracted vomiting (>6 times)
  - o Progressive headache
  - o Focal neuro changes
  - o D/C home with competent observer
- 2-20 Years Old
1. If NO LOC
- o Thorough history and exam
  - o If normal, may D/C home
    - § Competent caregiver
    - § Watch for deterioration
2. If LOC and NO symptoms
- o Can observe in ED 6 hrs
    - § Then D/C home with competent observer
  - o Can do CT scan
    - § If CT negative - D/C home with competent caregiver
    - § If CT positive
      - Transfer to pediatric trauma center
      - Neurosurg evaluation
      - May need PICU
3. If LOC AND Symptoms (amnesia, headache, vomiting)
- o CT SCAN
    - § If CT negative - D/C home with competent observer
    - § If CT positive
      - Transfer to pediatric trauma center, neurosurgery consult

#### Reference

1. The management of minor closed head injury in children. Committee on Quality Improvement, American Academy of Pediatrics. Commission on Clinical Policies and Research, American Academy of Family Physicians. *Pediatrics*. 1999;104:1407.

**8. PEPID** citation/access data Pediatric head trauma – algorithms. In: Dynamed [database online]. Available at: <http://www.pepidonline.com>. Accessed October 19, 2009.

**9. PEPID** content updating 1. Do you recommend that PEPID get updated on this topic?  
Yes, there is important evidence or recommendations that are missing

If yes, which PEPID Topic, Title(s):  
Same topic - if we decide this is a PURL

**10. Other** excerpts (USPSTF; other guidelines; etc.)

11. Citations for other excerpts

12. Bottom line recommendation or summary of evidence from Other Sources (1-2 sentences)

#### SECTION 4: CONCLUSIONS

**1. Validity:** How well does the study minimize sources of internal bias and maximize internal validity? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly) 1

2. If 4.1 was coded as 4, 5, 6, or 7, please describe the potential bias and how it could affect the study results. Specifically, what is the likely direction in which potential sources of internal bias might affect the results?

**3. Relevance:** Are the results of this study generalizable to and relevant to the health care needs of patients cared for by “full scope” family physicians? Give one number on a scale of 1 to 7 (1=extremely well; 4=neutral; 7=extremely poorly) 1

4. If 4.3 was coded as 4, 5, 6, or 7, please provide an explanation.

**5. Practice-changing potential:** If the findings of the study are both valid and relevant, does the practice that would be based on these findings represent a change from current practice? Give one number on a scale of 1 to 7 (1=definitely a change from current practice; 4=uncertain; 7=definitely not a change from current practice) 1

6. If 4.5 was coded as 1, 2, 3, or 4, please describe the potential new practice recommendation. Please be specific about what should be done, the target patient population and the expected benefit.

**7. Applicability to a Family** 1

**Medical Care Setting:**

Is the change in practice recommendation something that could be done in a medical care setting by a family physician (office, hospital, nursing home, etc), such as a prescribing a medication, vitamin or herbal remedy; performing or ordering a diagnostic test; performing or referring for a procedure; advising, educating or counseling a patient; or creating a system for implementing an intervention? Give one number on a scale of 1 to 7 (1=definitely could be done in a medical care setting; 4=uncertain; 7=definitely could not be done in a medical care setting)

8. If you coded 4.7 as a 4, 5, 6 or 7, please explain.

**9. Immediacy of** 1

**Implementation:** Are there major barriers to immediate implementation? Would the cost or the potential for reimbursement prohibit implementation in most family medicine practices? Are there regulatory issues that prohibit implementation? Is the service, device, drug or other essentials available on the market? Give one number on a scale of 1 to 7 (1=definitely could be immediately applied; 4=uncertain; 7=definitely could not be immediately applied)

10. If you coded 4.9 as 4, 5, 6, or 7, please explain why.

**11. Clinical meaningful** 1

**outcomes or patient oriented outcomes:** Are the outcomes measured in the study clinically meaningful or patient oriented? Give one number on a scale of 1 to 7 (1=definitely clinically meaningful or patient oriented; 4=uncertain; 7=definitely not clinically meaningful or patient oriented)

12. If you coded 4.11 as a 4, 5, 6, or 7, please explain why.

## SECTION 5: EDITORIAL DECISIONS

1. FPIN PURLs editorial decision Pending PURL  
(select one)

2. Follow up issues for Pending  
PURL Reviewer

3. FPIN PURLS Editor making  
decision Bernard Ewigman

4. Date of decision

5. Brief summary of decision

This was a well-done, extremely large study that seems to provide definitive evidence for using this clinical rule to determine the need for CT scan in children of all ages after head injury. These rules are relevant for family doctors in an outpatient setting, as all criteria can be determined in clinic. Five of 6 can be determined over the phone in a discussion with a parent or caregiver (probably not presence of skull fracture). The fact that children presenting to clinic are likely to have less severe injuries (prevalence lower) improves the performance of this clinical rule. Implementation of this clinical rule is likely to avoid use of CT scans in a manner that appears to be safe for the patients—a further benefit to children by decreasing exposure to ionizing radiation. There is a small chance that this is a confirmatory update from the research literature instead of a PURL, depending on how people interpret the currently available data on the topic.