Generation of Evidence and Translation Into Practice: Lessons Learned and Future Directions

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AEM Consensus Conference
Emergency Department Diagnostic Imaging:
A Research Agenda to Optimize Diagnostic Imaging
May 12th, 2015
Disclosure

◆ No financial relationships or conflict of interests related to this talk
Background of a Story

- Change of research focus based on clinical events
- New environment: trauma, trauma, trauma
- I knew about clinical efficiencies, risk-stratification and radiation risk, but I wanted to know:
  - Who really needs a CT?
  - Once you figure it out, how do you change practice?
  - How to involve patients when the decision is unclear?
Objectives

- Briefly introduce the Pediatric Emergency Care Applied Research Network (PECARN), then...
- Review the PECARN Traumatic Brain Injury (TBI) Prediction Rules derivation / validation
- Describe how PECARN is translating the TBI Prediction Rules into practice
- Describe the principles of shared decision-making and patient-centered outcomes in research and its application to the PECARN TBI Prediction Rules
Pediatric Emergency Care Applied Research Network (PECARN)

Supported in full by Project #U03 MC00001-01 from the Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services.
Ongoing PECARN Research Development

- Patient safety and error reduction
- Quality of PEM care
- Evaluation of head trauma
- C-Spine immobilization
- Steroids in acute bronchiolitis
- The burden of mental illness and psychiatric emergencies in PED
- RCT of fluids for DKA
- Magnesium for sickle cell pain
- Therapeutic hypothermia in pediatric cardiopulmonary arrest
- Diagnostic categorization of illnesses and injuries in the PED
- Management of status epilepticus
- Evaluation of abdominal trauma
- Screening for alcohol abuse
- Probiotics for AGE
- Knowledge translation of TBI rules
- RNA transcription biosignatures to diagnose febrile infants
Case

- 8 month-old falls 2 feet from a carrier
- No LOC
- On exam, acting normally
- Small forehead hematoma, tender at site

What are you going to do?
Epidemiology of Pediatric Head Trauma

- Trauma the leading cause of death among children > 1 year
- Traumatic brain injury (TBI) the leading cause of death and disability due to trauma (> 70% of deaths)
- On an annual basis in the U.S., blunt head trauma in children results in:
  - 6,000 deaths
  - 60,000 hospitalizations
  - 620,000 ED visits (~50% evaluated with CT scans, use of CT increasing over the past decade, much variability in care)
Controversy over CT for Minor Blunt Head Trauma

Arguments for liberal use of CT:

- Preventable morbidity/mortality due to unrecognized TBIs
- Preverbal children difficult to eval.
- When indicated, benefit of CT greatly outweighs risk, however…
Controversy over CT for Minor Blunt Head Trauma

Arguments against liberal use of CT:

- Of the large number of children evaluated with CT after blunt head trauma, fewer than 10% have TBI
- Drawbacks of CT include transport outside the ED, pharmacological sedation, costs
- Most important (theoretical) risk: (lethal) malignancies

Imaging in pediatric blunt head trauma high priority for AAP, IOM, EMSC
Reducing CT Radiation Exposure

- Age and size-based radiation-reduction efforts ongoing (“ALARA” principle)
- Creation/validation of large CT imaging rules
- Slowing of new indications of CT, improved awareness of guidelines, increased use of ultrasound (Arasu JACR 2015)
- Feedback to physicians on test ordering, shared decision-making (Kanzaria Acad Emerg Med 2015)
- From a public-health view
  - ~300,000 CTs annually for pediatric head trauma
  - millions for all reasons
The PECARN Head Injury Study

**Goal**: to derive a clinical decision rule to accurately identify children at near zero risk of clinically important traumatic brain injury after blunt trauma with high accuracy and wide generalizability
Clinically-important TBI (ciTBI)

- Death from TBI
- Neurosurgical procedure
- Intubation for > 24 hours for head injury
- Positive CT in association with hospitalization > 2 nights
Results

57,030 eligible

54,161 GCS 14-15

Not enrolled

11,749 (21.7%)

Enrolled

42,412 (78.3%)

Validation

8,627

288 ciTBI (0.9%)

Derivation

33,785

88 ciTBI (1.0%)

2,869 GCS <14 or other exclusion
Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study


Summary
Background 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 (cTBI) 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 cTBI (death from traumatic brain injury, neurosurgery, intubation >24 h, or hospital admission ≥2 nights).
The PECARN TBI Rules (derived and validated)

*Children are at very low risk of clinically-important traumatic brain injury (TBI) if they meet all criteria in age-specific rule:*

**Children < 2 years**
1. Severe mechanism of injury
2. History of LOC ≥ 5 sec
3. GCS = 14 or other signs of altered mental status
4. Not acting normally per parent
5. Palpable skull fracture
6. Occipital/parietal/temporal scalp hematoma

**Children 2-18 years**
1. Severe mechanism of injury
2. History of LOC
3. GCS = 14 or other signs of altered mental status
4. History of vomiting
5. Severe headache in the ED
6. Signs of basilar skull fracture
Recommendations for children younger than 2

The Rule

GCS=14 or other signs of altered mental status†, or palpable skull fracture

Yes

13.9% of population
4.4% risk of ciTBI

CT recommended

No

Occipital or parietal or temporal scalp haematoma, or history of LOC ≥5 s, or severe mechanism of injury‡, or not acting normally per parent

Yes

32.9% of population
0.9% risk of ciTBI

CT not recommended

Observation versus CT on the basis of other clinical factors including:
- Physician experience
- Multiple versus isolated§ findings
- Worsening symptoms or signs after emergency department observation
- Age <3 months
- Parental preference

No

53.2% of population
<0.02% risk of ciTBI
Recommendations for children younger than 2

A

GCS=14 or other signs of altered mental status†, or palpable skull fracture

Yes

CT recommended

13.9% of population
4.4% risk of ciTBI

No

Suggestions

Occipital or parietal or temporal scalp haematoma, or history of LOC ≥5 s, or severe mechanism of injury‡, or not acting normally per parent

Yes

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0.9% risk of ciTBI

Observation versus CT on the basis of other clinical factors including:
- Physician experience
- Multiple versus isolated§ findings
- Worsening symptoms or signs after emergency department observation
- Age <3 months
- Parental preference

No

53.2% of population
<0.02% risk of ciTBI

CT not recommended¶
Recommendations for children 2 years and older

GCS=14 or other signs of altered mental status†, or signs of basilar skull fracture

Yes
- 14.0% of population
- 4.3% risk of ciTBI
- CT recommended

No
- 57.2% of population
- <0.05% risk of ciTBI
- CT not recommended

History of LOC, or history of vomiting, or severe mechanism of injury‡, or severe headache

Yes
- 28.8% of population
- 0.8% risk of ciTBI
- Observation versus CT on the basis of other clinical factors including:
  - Physician experience
  - Multiple versus isolated§ findings
  - Worsening symptoms or signs after emergency department observation
  - Parental preference

No
- The Rule
Recommendations for children 2 years and older

GCS=14 or other signs of altered mental status†, or signs of basilar skull fracture

- Yes
  - 14.0% of population
  - 4.3% risk of ciTBI
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  - History of LOC, or history of vomiting, or severe mechanism of injury‡, or severe headache

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  - 0.8% risk of ciTBI
  - Observation versus CT on the basis of other clinical factors including:
    - Physician experience
    - Multiple versus isolated§ findings
    - Worsening symptoms or signs after emergency department observation
    - Parental preference
  - CT not recommended

- No
  - 57.2% of population
  - <0.05% risk of ciTBI
  - CT not recommended

Suggestions
Do Children With Blunt Head Trauma and Normal Cranial Computed Tomography Scan Results Require Hospitalization for Neurologic Observation?

James F. Holmes, MD, MPH, Dominic A. Borgialli, DO, MPH, Frances M. Nadel, MD, MSCE, Kimberly S. Quayle, MD, Neil Schambam, MD, Art Cooper, MD, Jeff E. Schunk, MD, Michelle L. Miskin, MS, Shireen M. Atabaki, MD, MPH, John D. Hoyle, MD, Peter S. Dayan, MD, MSc, Nathan Kuppermann, MD, MPH, and the TBI Study Group for the Pediatric Emergency Care Applied Research Network*

From the Department of Emergency Medicine, University of California, Davis School of Medicine, Sacramento, CA (Holmes); the Department of Emergency Medicine, University of Michigan School of Medicine and Hurley Medical Center, Flint, MI (Borgialli); the Department of Pediatrics, University of Pennsylvania School of Medicine, Philadelphia, PA (Nadel); the Department of Pediatrics, Washington University School of Medicine, St. Louis, MO (Quayle); the Departments of Emergency Medicine and Pediatrics, Newark Beth Israel Medical Center, Newark, NJ (Schambam); the Department of Surgery, Columbia University Medical Center at Harlem Hospital, New York, NY (Cooper); the Department of Pediatrics, University of Utah, Salt Lake City, UT (Schunk) and PECARN Central Data Management and Coordinating Center, University of Utah, Salt Lake City, UT (Miskin); the Departments of Pediatrics and Emergency Medicine, The George Washington University School of Medicine, Washington, DC (Atabaki); the Department of Emergency Medicine, Michigan State University School of Medicine/Helen DeVos Children’s Hospital, Grand Rapids, MI (Hoyle); the Department of Pediatrics, Columbia University College of Physicians and Surgeons, New York, NY (Dayan); and the Departments of Emergency Medicine and Pediatrics, University of California, Davis School of Medicine, Sacramento, CA (Kuppermann).
The Effect of Observation on Cranial Computed Tomography Utilization for Children After Blunt Head Trauma


Division of Emergency Medicine, Children's Hospital Boston, Harvard Medical School, Boston, Massachusetts; Department of Pediatrics, Primary Children's Medical Center, Salt Lake City, Utah; University of Utah School of Medicine, Salt Lake, Utah; Silver Spring Emergency Physicians, Holy Cross Hospital, Silver Spring, Maryland; Department of Surgery, Harlem Hospital Medical Center and Department of Pediatrics, Morgan Stanley Children's Hospital of New York—Presbyterian, Columbia University College of Physicians and Surgeons, New York, New York; Departments of Pediatrics and Emergency Medicine, Children's National Medical Center, George Washington University School of Medicine, Washington, DC; Division of Emergency Medicine, Helen DeVos Children's Hospital, Michigan State University School of Medicine, Grand Rapids, Michigan; Department of Emergency Medicine and Departments of Emergency Medicine and Pediatrics, Davis Medical Center, University of California, Davis School of Medicine, Davis, California

Key Words: traumatic brain injury, computed tomography, clinical observation

What's Known on This Subject: Emergency-department observation of children with minor blunt head trauma for symptom progression before making a decision regarding computed tomography may decrease computed tomography use. The actual impact of this strategy on computed tomography use and clinical outcomes, however, is unknown.

What This Study Adds: Clinicians currently observe some children with head trauma before deciding whether to obtain a cranial computed tomography scan. Patients who were observed had a significantly lower rate of overall cranial computed tomography use after adjusting for markers of head injury severity.

Abstract

Objective: Children with minor blunt head trauma often are observed in the emergency department before a decision is made regarding computed tomography use. We studied the impact of this clinical strategy on computed tomography use and outcomes.
Isolated Clinical Findings

**Online First**

Prevalence of Clinically Important Traumatic Brain Injuries in Children With Minor Blunt Head Trauma and Isolated Severe Injury Mechanisms

Lise E. Nigrin, MD, MPH; Lois K. Lee, MD, MPH; John Hoyle, MD; Rachel M. Stanley, MD; Marc H. Gorelick, MD; Michelle Miskin, MS; Shireen Atebaki, MD; Peter S. Dayan, MD, MSc; James F. Holmes, MD, MPH; Nathan Kuppermann, MD, MPH; for the Traumatic Brain Injury (TBI) Working Group of the Pediatric Emergency Care Applied Research Network (PECARN)

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**Pediatrics/Original Research**

Risk of Traumatic Brain Injuries in Children Younger than 24 Months With Isolated Scalp Hematomas

Peter S. Dayan, MD, MSc; James F. Holmes, MD, MPH; Sara Schusterman, MD; Jeffrey Schunk, MD; Richard Lichenstein, MD; Lilian A. Froenbach, MD; John Hoyle Jr, MD; Shireen Atebaki, MD, MPH; Michelle Miskin, MS; David Weiner, MD; Sally A. Zapata, RN, MSN; Nathan Kuppermann, MD, MPH; for the Traumatic Brain Injury Study Group of the Pediatric Emergency Care Applied Research Network (PECARN)*

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**Pediatrics/Original Research**

Association of Traumatic Brain Injuries With Vomiting in Children With Blunt Head Trauma

Peter S. Dayan, MD, MSc; James F. Holmes, MD, MPH; Shireen Atebaki, MD, MPH; John Hoyle Jr, MD; Michael G. Tunik, MD; Richard Lichenstein, MD; Elizabeth Alpert, MD, MSc; Michelle Miskin, MS; Nathan Kuppermann, MD, MPH; for the Traumatic Brain Injury Study Group of the Pediatric Emergency Care Applied Research Network (PECARN)*

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**Original Investigation**

Isolated Loss of Consciousness in Children With Minor Blunt Head Trauma

Lois K. Lee, MD, MPH; David Monroes, MD; Michael C. Bockman, MD; Todd F. Glass, MD; Prashant V. Mhaisi, MD, MPH; Misha, Arthur Cooper, MD; Rachel M. Stanley, MD, MPH; Michelle Miskin, MS; Peter S. Dayan, MD, MSc; James F. Holmes, MD, MPH; Nathan Kuppermann, MD, MPH; for the Traumatic Brain Injury (TBI) Working Group of the Pediatric Emergency Care Applied Research Network (PECARN)

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**Pediatrics/Original Research**

Headache in Traumatic Brain Injuries From Blunt Head Trauma

Peter S. Dayan, MD, MSc; James F. Holmes, MD, MPH; John Hoyle Jr, MD; Shireen Atebaki, MD, MPH; Michael G. Tunik, MD; Richard Lichenstein, MD; Michelle Miskin, MS; Nathan Kuppermann, MD, MPH; for the Pediatric Emergency Care Applied Research Network (PECARN)
How to get clinicians to use the prediction rules?
Knowledge Translation

“Knowledge translation (KT) is the effective and timely incorporation of evidence-based information into the practices of health professionals in such a way as to effect optimal health care outcomes and maximize the potential of the health system.”

(Modified from the Canadian Institutes for Health Research definition)

Need definitive, validated evidence that is ripe for translation
- Not all data should be translated
- Attend break-out Group 5!
The research-to-practice pipeline. New research, of varying soundness, is added to the expanding pool and enters practice both directly or is reviewed, summarised, and systematised (delay) before entering practice, with leakage occurring at each of several stages between awareness and patient outcome. Different knowledge translation disciplines focus on different parts of the pipeline (1-4).

Glasziou and Haynes, 2005
Pediatric Head Trauma
CT Decision Guide
Children 2 years and older

- GCS < 15
- Signs of basilar skull fracture
- AMS (agitation, somnolence, slow response, repetitive questions)

**YES TO ANY**

- Vomiting
- LOC
- Severe headache
- Severe mechanism of injury
  - Fall > 5 ft
  - MVA w/ejection, rollover, or fatality
  - Bike/ped vs. vehicle w/o helmet
  - Struck by high-impact object

**Intermediate Risk – 0.8%**
Observation vs. CT using shared decision-making

Clinical factors used to guide decision-making:
- Multiple vs. isolated factors
- Worsening findings during observation (AMS, headache, vomiting)
- Physician experience
- Parental preference

**Low Risk – < 0.05%**

CT not indicated, Observe

*ci-TBI: risk of clinically important TBI needing acute intervention, based on PECARN validated prediction rules

Pediatric Head Trauma
CT Decision Guide
Children younger than 2 years

- GCS < 15
- Palpable skull fracture
- AMS (agitation, somnolence, slow response, repetitive questioning)

**YES TO ANY**

- Scalp hematoma (excluding frontal)
- LOC > 5 seconds
- Not acting normally per parent
- Severe mechanism of injury
  - Fall > 3 ft
  - MVA w/ejection, rollover, or fatality
  - Bike/ped vs. vehicle w/o helmet
  - Struck by high-impact object

**Intermediate Risk – 0.9%**
Observation vs. CT using shared decision-making

Clinical factors used to guide decision-making:
- Multiple vs. isolated factors
- Worsening findings during observation (AMS, headache, vomiting)
- Physician experience
- Parental preference
- < 3 months old

**Low Risk – < 0.02%**
CT not indicated, Observe

*ci-TBI: risk of clinically important TBI needing acute intervention, based on PECARN validated prediction rules
Clinical decision support more successful when:

- Automatic provision of support in workflow
- Recommendations given rather than risks
- Support given at the time and location of decision-making
- Support is computer based

Kawamoto, BMJ, 2005
Challenges to Knowledge Translation using Computerized Algorithms

The human brain

Shankar Vedantam (author of “The Hidden Brain” and NPR social science correspondent) and Berkeley Dietvorst (Wharton doctoral student)

• Even though algorithms typically outperform humans, we are distrustful of algorithms
• People fail to use algorithms even when they see it outperform humans
• Humans fear machines (“algorithmic aversion”)

NPR Radio, February 3, 2015
Translating Research into Practice

*What PECARN is doing...*
Implementation of the PECARN Traumatic Brain Injury Prediction Rules Using Electronic Health Record-Based Clinical Decision Support:
An Interrupted Time Series Trial

Funded by the American Recovery and Reinvestment Act – Office of the Secretary: Grant #S02MC19289-01-00

PI – Peter Dayan, MD, MSc
Specific Aims

1. To develop and pilot test a computer-based data collection and recommendation system to implement the PECARN TBI prediction rules.

2. To assess whether this system decreases the number of (unnecessary) head CTs in the ED in children at very low risk of important brain injuries.
Methods

Computer-Based Decision Support Development and Pilot

- Perform focus groups
- Perform ED work flow assessments
- Develop EHR blunt head injury template
- Develop CDS
- Pilot testing
### Blunt Head Trauma Assessment

#### Blunt Head Trauma Assessment (skip any question if unable to determine answer)

<table>
<thead>
<tr>
<th>Blunt head trauma?</th>
<th>No</th>
<th>Yes - less than 24 hours ago</th>
<th>Yes - more than 24 hours ago</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of consciousness?</td>
<td>No</td>
<td>Yes - less than 5 seconds</td>
<td>Yes - 5 seconds up to one minute</td>
</tr>
<tr>
<td>Vomiting since injury?</td>
<td>No</td>
<td>Once</td>
<td>Twice</td>
</tr>
<tr>
<td>Acting normally per caregiver?</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Severe mechanism of injury?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Current headache?</td>
<td>No</td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Other signs of altered mental status?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Temporal, parietal, or occipital scalp hematoma?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### Other signs of altered mental status?

- Agitation
- Somnolence
- Repetitive questioning
- Slow response to verbal communication

#### GCS

<table>
<thead>
<tr>
<th>Eye Opening</th>
<th>4 3 2 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Verbal Response</td>
<td>5 4 3 2 1</td>
</tr>
<tr>
<td>Motor Response</td>
<td>6 5 4 3 2 1</td>
</tr>
<tr>
<td>Total GCS</td>
<td></td>
</tr>
</tbody>
</table>
Methods – design
Interrupted Time Series Trial with Concurrent Controls

Month of Trial
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29

Pre-intervention phase
Intervention implemented
Intervention maintained (post-intervention phase)
Main Comparisons: Pre to post int.

Intervention Group Measurement (receives CDS)
Baseline rate of CT use

Post-intervention rate of CT use

Control Group Measurement (standard of care)
Rate of CT use measured throughout the study period
Case

- 8 month-old falls 2 feet from a carrier
- No LOC
- On exam, acting normally
- Small forehead hematoma, tender at site

What are you going to do?
Traumatic Brain Injury Risk: Child less than 2 years

**RECOMMENDATION:** A head CT is not recommended for this patient based on the absence of any of the PECARN prediction rule variables.

**Risk Estimate:** The risk of **clinically-important traumatic brain injury** for patients less than 2 years is < 1/5000

*Importantly, the PECARN rules were based on attending initial evaluations (not based on subsequent evaluations over time).*

The age-specific PECARN rule findings documented are:

- Loss of consciousness?: No
- Acting normally per caregiver?: Yes
- Mechanism of injury?: Mild
- Total Glasgow Coma Scale score: 15
- Other signs of altered mental status?: No
- Scalp hematoma?: None
- Palpable skull fracture or unclear on the basis of swelling or distortion of the scalp?: No

If the above clinical findings are incorrect, please revise.

**Note:** The PECARN prediction rules do not apply to patients with: bleeding diatheses, ventricular (e.g. “VP”) shunts, known brain tumors, or pre-existing neurological disorders complicating your clinical assessment.

[Click here to view the PECARN prediction rule manuscript (Lancet)](#)

[Click to provide a revised risk assessment](#)
What about sharing decision-making with patients/parents/guardians when the decision is not clear?
The Head CT Choice Trial

Funded by a grant from the Patient Centered Outcomes Research Initiative (PCORI)

PI – Erik Hess, MD, MSc

(break-out Group 3!)
Overview

◆ What is shared decision making?
◆ Why shared decision making?
◆ Why in pediatric minor head trauma?
What is Shared Decision Making?

- Educating patients (parents) such that they are empowered to apply their values and preferences to management decisions

- *Inviting* patients (parents) to participate in decision making *to the extent that they desire*

- Coming to a consensus on the best management approach, such that *risk-informed parental preferences* are taken into consideration
What Shared Decision Making is Not

- Handing over the decision to the patient (parent) regardless of your professional opinion

- Primarily an effort to manage legal risk: it’s not about the clinician, it’s about the patient
Why Do Shared Decision Making?

- Respect for autonomy
- Opportunity to rapidly develop rapport, educate and meaningfully connect
Paternalistic

Shared Decision Making
Why Pediatric Head Trauma?
Recommendations for children younger than 2

A

GCS=14 or other signs of altered mental status†, or palpable skull fracture

Yes
CT recommended

13.9% of population
4.4% risk of ciTBI

No

Occipital or parietal or temporal scalp haematoma, or history of LOC ≥ 5 s, or severe mechanism of injury‡, or not acting normally per parent

Yes
Observation versus CT on the basis of other clinical factors including:
- Physician experience
- Multiple versus isolated§ findings
- Worsening symptoms or signs after emergency department observation
- Age < 3 months
- Parental preference

32.9% of population
0.9% risk of ciTBI

No
53.2% of population
< 0.02% risk of ciTBI

CT not recommended¶
Recommendations for children 2 years and older

B

GCS=14 or other signs of altered mental status†, or signs of basilar skull fracture

No

History of LOC, or history of vomiting, or severe mechanism of injury‡, or severe headache

No

57.2% of population <0.05% risk of ciTBI

CT not recommended¶

Yes

14.0% of population 4.3% risk of ciTBI

CT recommended

Yes

28.8% of population 0.8% risk of ciTBI

Observation versus CT on the basis of other clinical factors including:
- Physician experience
- Multiple versus isolated symptoms findings
- Worsening symptoms or signs after emergency department observation
- Parental preference

¶

CT not recommended

†

GCS

‡

LOC

§

Symptoms
Head CT Choice Trial

Hypothesis: Use of Head CT Choice will

• Significantly increase parents’ knowledge, engagement, and satisfaction

• Safely decrease the rate of CT and 7-day healthcare utilization
Conclusion

- Limiting inappropriate imaging a priority in EM
- Requires generating/validating definitive evidence
- Requires dissemination and implementation at the point of patient care, with minimal interruption
- Shared decision-making appropriate when the decision is not clear
- *Much work to be done on many topics…*