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Advancing the Emergency Department Care of Very Young Children with Traumatic Brain Injury

Principal Investigator: Tara Rhine, MD, MS
Institution: Cincinnati Children's Hospital Medical Center

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Introduction

Thousands of infants and toddlers are evaluated in Ohio emergency departments (ED) each year for traumatic brain injury (TBI), although diagnosis can be difficult in this population. Emergency medicine clinicians often resort to computed tomography (CT) to rule out intracranial injury in young children, as diagnosis of TBI in this age group can be challenging because infants and toddlers cannot report their own symptoms. The Pediatric Emergency Care Applied Research Network (PECARN) created a clinical decision rule that has excellent sensitivity in identifying which children with mild TBI (i.e. have a Glasgow Coma Scale score of 14 or 15) are at “very low risk” for significant TBI (i.e. risk of <0.05%), and therefore do not need a head CT.¹ This rule also identifies those children for whom a period of clinical observation in the ED may be a safe and feasible alternative to obtaining an emergent head CT.¹⁻⁵ Despite this research, the observation period continues to be underutilized, especially in younger children (i.e. less than 5 years of age), likely due to a clinician’s or parent’s inability to identify the presence of TBI symptoms (e.g. headache, dizziness), leading to increased anxiety centered around not missing intracranial injury. There is a need for development of specific guidelines for well appearing children that do not fall into “very low risk” to further support decision making and to better define what exactly an observation period entails. The objective of this study was to improve the care for children, ages 0<5 years who have been identified as at risk (i.e. are not “very low risk”) based on the PECARN TBI rule, via development and implementation of an evidenced-based care pathway. We expected that through standardization of care during the observation period, including close reassessments and symptom management, we would decrease unnecessary hospital resource utilization (e.g. CT rates), improve the consistency with which evidenced-based and best care practices are provided (e.g. analgesia for pain), and improve parental understanding and satisfaction of the ED care their child received.

Executive Summary

This study was supported by the Ohio Department of Public Safety to investigate the nature and effects of emergency department (ED) care for young children, ages 0-4 years, “at risk” for a clinically important traumatic brain injury (ciTBI), per the PECARN neuroimaging decision rule. A ciTBI is defined as a TBI that causes death, the need for neurosurgery, an intubation >24 hours, or a hospitalization for ≥ 2 nights.¹ Research has shown that a period of clinical observation in the ED is a safe alternative to obtaining an emergent head CT for children in this risk category.^{2,3} Our research goal was to decrease head CT rates for this vulnerable population by offering a care pathway that standardized a clinical period of ED observation. We also sought to use this pathway to improve the provision of TBI best care practices (e.g. analgesia for pain), as well as parental understanding and satisfaction of ED care.

This study took place in a single Level 1 trauma accredited pediatric ED located in southern Ohio from December 2014 to December 2015. In the first six months of the study, the ED care for young children “at risk” for a ciTBI was observed and recorded. During this time we also successfully created a standardized care pathway based on prior literature and best care practices using a multi-disciplinary care team. The care pathway included hourly reassessments of vital signs, mental status, pain, and vomiting. The pathway also suggested the use of pain and/or anti-nausea medication if appropriate. This care pathway was then translated into a computerized order set within our electronic health record (EHR) for use in the ED. After the first six months of data collection was complete, this order set was made available for ED staff use and data was collected for an additional six months. To encourage evidenced-based care, it was linked to a TBI best practice alert (BPA) that was already present within our EHR.

Among the 104 study participants enrolled, 37 received a head CT, of which 21 (57%) were negative (i.e. normal). No children had ciTBI. There was not a significant difference among head CT rates for the 50 children enrolled prior to the order set becoming available in June 2015, relative to the 54 children enrolled after the order set’s implementation into our EHR. However, although not statistically significant, the negative CT rate did decrease after the order set implementation from 68% to 44% ($p=0.19$). There were no group differences among ED care practices pre and post order set

implementation, with less than 25% of children having a documented pain assessment, less than one-third (28%) receiving an analgesic medication, and only two-thirds (66%) of parents receiving our standardized patient information on the management and expected recovery of pediatric TBI. Parents were surveyed via phone 2-4 days after enrollment to assess parental satisfaction with ED communication and understanding of the care their child received. Satisfaction with communication in the ED was based on a Likert scale of 1-10, with 1 being “Not at all satisfied” and 10 being “Completely satisfied”. Eighty-four parents (81%) completed the survey, and although there was not a significant increase in parental satisfaction pre and post order set implementation, satisfaction remained very high throughout the study period, with an average \pm standard deviation of 8.9 ± 1.7 . Despite this high satisfaction, 25% of parents reported some degree of discomfort around the final decision to obtain or not obtain neuroimaging, and only half (51%) correctly identified that they had been observed in the ED for a specific period of time.

This study met significant study delays which compromised our ability to enroll the full 150 children (50 pre and 100 post care pathway), which was needed to detect a significant change in CT rates (the primary outcome). The institutional review board (IRB) raised concerns about actively influencing medical decision making that necessitated significant protocol changes. Based on the IRB’s recommendations, the care pathway did not automatically populate as a suggested order set if the child was eligible for observation, as identified by the PECARN TBI rule, but rather the ED staff was educated regarding the order set’s availability within the EHR. Due to these IRB and protocol revisions, the protocol was not approved until December 2014. To facilitate recruitment, we expanded eligibility from the initially proposed 0-2 years to 0-4 years of age. Also, our initially anticipated enrollment goals were based on past frequencies of TBI-related diagnoses; however, the vast majority of very young children with TBI fell into the “very low risk” stratification and were therefore ineligible for study enrollment. As a consequence, enrollment was challenging despite high participation rates (only 7 parents declined).

In summary, we found that among 104 children “at risk” for ciTBI, opting for a period of observation over emergent neuroimaging would not have missed any cases of ciTBI. Despite being a large academic pediatric center, we found a 36% CT rate for this population. Of the 37 children that received a CT, although 16 (43%) were technically “abnormal”, only 6 (16%) had intracranial injury, with the remaining 10 having isolated skull fractures. Our study also demonstrated that CT rates are not the only area of ED care in need of improvement, as pain evaluation/treatment was inconsistent for these children. Additionally, parents frequently demonstrated significant gaps in comfort and understanding of the ED care provided to their children. We were underpowered to detect a change in CT rates; however it is clear that continued education regarding the importance and safety of the observation pathway, as well as its availability as a standardized treatment option, is needed for it to become routinely implemented in our ED. Future work evaluating ED staff barriers to usage of the observation period would also help promote implementation. Once we have achieved those goals, we plan to disseminate our program regionally within Ohio and to other institutions that manage young TBI.

Investigators and Environment

Investigators

1. Dr. Tara Rhine, MD, MS (Principle Investigator) is an Assistant Professor and attending physician in the Division of Emergency Medicine. Dr. Rhine completed her fellowship in pediatric emergency medicine in 2013 at Cincinnati Children’s Hospital Medical Center (CCHMC) before joining as faculty. She also achieved an MS in Clinical and Translational Research from the University of Cincinnati in 2013. During fellowship, she successfully completed a prospective study using the Wii Balance Board as a novel way to quantify postural instability acutely following mild TBI in young athletes. Based on this work, she published two peer reviewed manuscripts, as well as won the “Best Fellow’s Emergency Medicine Platform Presentation” at the American Academy of Pediatrics National Conference. Dr. Rhine has obtained additional external funding and is continuing to publish and collaborate in the field of pediatric TBI research. In 2015, she was awarded a KL2 career development

grant to investigate the diagnostic and prognostic utility of serum biomarkers following TBI in young children. Her special research interest is understanding and improving the acute care and outcomes of TBI in very young children, and this proposal is consistent with this focus. She was involved in the study design, care pathway creation and implementation, data analyses, and publication writing.

2. Dr. Shari Wade, PhD (Co-Investigator) is the Director of Research and Tenured Professor in the Division of Physical Medicine and Rehabilitation at CCHMC. She is an experienced clinical scientist and international leader in developing interventions for pediatric TBI. She assisted in the study design, data analysis interpretation, and publication writing.

3. Dr. Lynn Babcock, MD, MS (Co-Investigator) is an Associate Professor and attending physician in the Division of Emergency Medicine at CCHMC. Her primary research focus is mild TBI, and she has developed procedures for recruitment, enrollment, and assessment of patients with TBI in the ED in her previous work. She was involved in the study design, care pathway creation and implementation, and publication writing.

4. Dr. Stephanie Kennebeck, MD (Co-Investigator) is an Associate Professor and attending physician in the Division of Emergency Medicine at CCHMC with a specialty in clinical information technology applications and family-centered care. She managed the development and implementation of the order set into our EHR.

5. Dr. Nanhua Zhang, PhD (Biostatistician) is an Assistant Professor in the Division of Biostatistics and Epidemiology at CCHMC. His statistical methodology research has covered missing data, causal inference, and joint modeling. He provided expert analysis to determine the amount of reduction of CT scans between the pre and post-intervention patients needed to detect a significant change, and he has been crucial in subsequent data analyses and interpretation.

Key Personnel

1. Caroline Reilly (Lead Clinical Research Coordinator) coordinated and ran staff training sessions, assisted with IRB maintenance, set up all necessary operational requirements for study conduct (participant packets, ED staff education, Clinical Research Coordinator training, etc.), conducted follow-up phone calls, entered study data, and tracked enrollment goals.

2. Kim Parker (Senior Analyst-Electronic Medical Record) works within CCHMC and closely collaborated with Drs. Rhine and Kennebeck in the development and implementation of the order set into our EHR.

3. Christy Turner-Hughes, RN (ED nurse) works within the CCHMC ED and was actively involved in the care pathway creation and implementation, as well as managed nursing staff education.

4. Olga Semenova (Application Specialist) is an employee of the Division of Emergency Medicine and created and managed data that was directly collected from our EHR for eligible study participants.

5. Melissa Armor (Data Coordinator) is an employee of the Division of Biostatistics at CCHMC and created and managed our study's REDCap database, which housed the majority of our study data.

6. Dr. James Leach, MD (Collaborator) is an Associate Professor and attending physician in the Division of Medical Imaging at CCHMC. He reviewed any neuroimaging of study participants if the clinical impressions were inconclusive or if additional clarification for study purposes was needed.

Environment

Cincinnati Children's Hospital Medical Center has over 90,000 visits each year to its ED. The Division of Emergency Medicine is a member of the PECARN network: the first federally-funded pediatric emergency medicine research network in the United States that conducts multi-institutional research. The Division of Emergency Medicine has a research infrastructure that is designed to assist investigators throughout all phases of the research process including a Research Manager, divisionally dedicated Clinical Research Coordinators, a Regulatory Coordinator, and a Financial Analyst.

Review of the Literature and Historical Perspectives

Challenges of Diagnosing Young TBI. Pediatric traumatic brain injury (TBI) imposes a major societal burden, affecting almost half a million children each year in the United States and accounting for hundreds of thousands of emergency department (ED) visits annually.⁶ Young children, ages 0-4 years, carry one of the highest risks for sustaining and dying from TBI among all pediatric age groups.^{1,7} Initial diagnosis and classification of TBI severity is typically determined by the clinically assigned Glasgow Coma Scale (GCS) score, which is of limited utility in very young children due to its reliance on expressive and receptive communication. Given the limitations of the GCS in very young children, clinicians often rely on neuroimaging using computed tomography (CT) to make the diagnosis of TBI in this vulnerable population. While the vast majority of head trauma in children is minor in nature (GCS scores of 14-15), clinicians obtain head CTs in about one-third of these children, but <10% will have intracranial injury on CT, and < 1% will require an acute neurosurgical intervention.¹ Head CTs are not benign and expose immature developing brains to the risk of radiation-associated malignancies,⁸ and they sometimes necessitate sedation in uncooperative young children which poses its own set of risks.⁹ ED clinicians must balance the competing risks of missing an intracranial injury versus radiation exposure, while remaining sensitive to parental anxieties.²

Clinical Observation is a Viable Alternative to Neuroimaging. The Pediatric Emergency Care Applied Research Network (PECARN) has created a clinical decision rule that has excellent sensitivity in identifying which children with mild TBI (i.e. have a GCS score of 14-15) are “very low risk” for significant TBI and do not need a head CT (i.e. risk for significant brain injury is <0.05%). The PECARN TBI rule incorporates patient’s symptoms, injury mechanism, and clinician assessment to provide an estimate of risk for a clinically important traumatic brain injury (ciTBI). A ciTBI is defined as death from TBI, need for neurosurgery, an intubation >24 hours, or a hospital admission ≥2 nights for the TBI.¹ This rule also identifies those children for whom clinical observation may be a safe and feasible alternative to obtaining a head CT.^{1,2,4,5,10} The observation period allows clinicians to selectively image only those children whose symptoms persist or worsen over time.^{2,10,11} Despite research demonstrating that a period of observation in the ED is both safe and can decrease CT imaging rates, this strategy has historically been underutilized with rates of application of about 15%.⁴ In part, this underutilization may be due to challenges communicating the potential radiation risk to anxious parents,¹² as well as the lack of standardization of this care option. Parents may also be anxious and unsure regarding standard ED return precautions (e.g. if the child had worsening headache or develops confusion) due to a very young child’s inability to communicate his or her symptoms. These challenges combined with the desire to not miss a significant injury can lead to parental requests for CT scans despite an unnecessary radiation exposure. This anxiety can also lead to inpatient admissions for observation and/or repeat ED evaluations even if a young child has normal neuroimaging, resulting in excessive medical costs and resource utilization.

Defining the Best Evidence for an Observation Pathway. Despite observation being an acceptable management option for children with TBI, there are no guidelines outlining the steps for systematic observation. Reported durations of observation from time of injury to ED discharge are variable, ranging from one hour to eight hours,^{2,10} although a four hour time period from injury to ED discharge appears to provide an acceptable observation period.² Procedures during this time period have largely not been specified, but extrapolating from care guidelines for children with severe TBI,¹³ frequent reassessments of mental status and symptom burden are necessary. Underutilization of analgesics^{14,15} and antiemetics^{1,16,17} has been reported for the treatment of key TBI symptoms including pain (i.e. headache) and vomiting. It would be expected that CT rates would decrease among children at risk for ciTBI if they experienced symptomatic improvement during their period of observation. Additionally, improved communication during the observation period, including provision of standardized anticipatory guidance on the management and expected recovery of TBI, would allow parental discussion of their questions and concerns with the ED staff. One report found that if given information regarding the risks and benefits of

various TBI management options, 57% parents of head injured children in the ED preferred observation over an immediate CT.¹⁸

Translating the Rule into Clinical Practice. It has been shown that computer-based clinical decision support (CDS) and computerized physician order entry (CPOE) can influence clinician behavior, improve adherence to standardized best care practices, and improve the patient's perception of good care.^{19,20} Validated clinical decision rules have been incorporated into EHRs to provide real time CDS to clinicians via "Best Practice Alerts (BPA)" which, based on the chief complaint, automatically populate and ask a series of questions consistent with that decision rule. Thus, real time linkage between the BPA's risk assessment with evidenced-based CPOE could improve implementation of the observation period and decrease neuroimaging.

Current Status and Future Trends of the Topic, both Regionally and Nationally

Nationally, children 0 to 4 years of age have the highest rates for TBI-related ED visits of any age group, with thousands of infants and toddlers being evaluated in Ohio EDs each year. After the publication of the PECARN TBI rule in 2010, it was integrated as a BPA into the EHRs of several Ohio institutions, including CCHMC and Nationwide Children's Hospital. Questions addressing the presence of each of the PECARN risk factors appear, and once the questions have been answered, CDS is provided to the clinician as an assessment of the child's risk for ciTBI, in addition to suggested care options. For example, this child was not "very low risk" for ciTBI, so observation was a reasonable care option that the clinician could consider.

▼ Traumatic Brain Injury Risk Assessment: Child less than 2 years

RECOMMENDATION: Clinical observation in the ED is an acceptable strategy for many patients such as this, whose only risk factor from the PECARN prediction rule is severe mechanism of injury.

Risk Estimate: The risk of clinically important traumatic brain injury for this patient is approximately 0.2% (3/1226) based on the PECARN head injury study.

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

The age-specific PECARN rule findings documented are:

Loss of consciousness?:	No	10/05/12 1515 : THAM, ERIC
Acting normally per caregiver?:	Yes	10/05/12 1515 : THAM, ERIC
Mechanism of injury?:	Severe	10/05/12 1515 : THAM, ERIC
Total Glasgow Coma Scale score:	15	10/05/12 1515 : THAM, ERIC
Other signs of altered mental status?:	No	10/05/12 1515 : THAM, ERIC
Scalp hematoma?:	None	10/05/12 1511 : THAM, ERIC
Palpable skull fracture or unclear on the basis of swelling or distortion of the scalp?:	No	10/05/12 1515 : THAM, ERIC

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 to provide a revised risk assessment
▼ Click for more information

Implementation of an evidence-based order set into the EHR is a readily translatable care practice to many other hospitals, not only in Ohio, but across the country which could help decrease CT rates, especially in young children.

Financial Issues/Considerations

In addition to the Ohio Department of Public Safety grant, this project was supported by the CCHMC's Division of Emergency Medicine. Due to insufficient time and funds from the long delay of starting patient enrollment, data collection were stopped in December of 2015 despite suboptimal sample size in order to focus on data cleaning and analyses.

Educational and Training Issues/Considerations

Prior to initiation of the study, staff and parents surveys were reviewed and tested for content and readability by other ED staff members and their spouses without medical training. Study personnel provided education and training on the safety and importance of clinical observation and the functionality of the order set to divisional clinicians, nurses, research coordinators, and the pediatric residents who rotate within our ED. Analysis and dissemination of our work is ongoing, and we plan for additional peer-reviewed journal submissions by the end of this year. Our productivity to date:

A. Peer Reviewed Abstracts

- a. Reilly C, Rhine T. "Emergency Department Care of Young Children with Traumatic Brain Injury: What are We Doing and Do Parents Understand?" Poster presentation at Pediatric Trauma Society National Meeting. November 2015.
- b. Turner Hughes C, Rhine T. "Does Parental Satisfaction Equal Parental Understanding?" Pediatric Trauma Society National Meeting. *Under review*.

B. Peer Reviewed Manuscripts

- a. Reilly C, Wade SL, Rhine T. "Emergency Department Care of Young Children with Traumatic Brain Injury: What are We Doing and Do Parents Understand?" *Revised and under review*.
- b. Rhine T, Zhang N, Wade SL, Babcock L. "Emergency Department Care Practices for Very Young Children at Risk for Traumatic Brain Injury." *In progress*.

Legislative and Regulatory Issues/Considerations

There were no associated legislative issues or concerns for this study. There was a significant delay to the start of patient enrollment due to concerns put forth by our IRB, requiring the submission of multiple protocol revisions in order to clarify and revise the protocol in order to facilitate approval. The initial grant application proposed to have an opt-out format to encourage the use of the observation period's order set, by automatically populating if appropriate based on that's child's PECARN risk stratification. The IRB's concerns were that despite the observation period's demonstrated safety and the clinician's ability to opt-out/remove these orders, that this protocol would be actively influencing medical decision making. In order for IRB approval, changes were made so that the care pathway did not automatically populate as a suggested order set if the child was eligible for observation. Instead, the order set was made available in the EHR and educational efforts to inform ED staff of the order set's purpose and accessibility were made by study staff to encourage its use.

Data and Information Issues/Considerations

In addition to the delay in study enrollment initiation and protocol modification discussed in the prior section, enrollment itself was slower than anticipated. Our anticipated enrollment was based on TBI-related diagnosis coding, but we found the vast majority of our very young TBI population fell into the "very low risk" stratification and were therefore not eligible for the study. In an effort to maximize our recruitment, we expanded eligibility from the initially proposed 0-2 years to 0-4 years of age which went into effect in February 2015. A total of 114 children were approached for enrollment between December 2014 and December 2015: 107 were enrolled but 3 were withdrawn after being deemed ineligible after inclusion criteria were clarified, seven patients declined to participate due to time constraints, and 23 additional children were deemed "missed eligible" patients (i.e. they were in the ED during research coordinator work hours, but not approached for enrollment). There were no significant differences between the enrolled and missed eligible/declined groups with regards to age ($p=0.13$), gender ($p=0.21$), race ($p=0.18$), and ethnicity ($p=0.35$). Of the 104 enrolled patients, 84 (81%) of parents completed the follow-up phone survey. There were no significant differences between those children that did and did not complete the follow-up with regards to gender ($p=0.8$), race ($p=0.27$), and ethnicity ($p=0.75$). The children lost to follow-up were younger than those children that completed the follow-up ($p=0.001$).

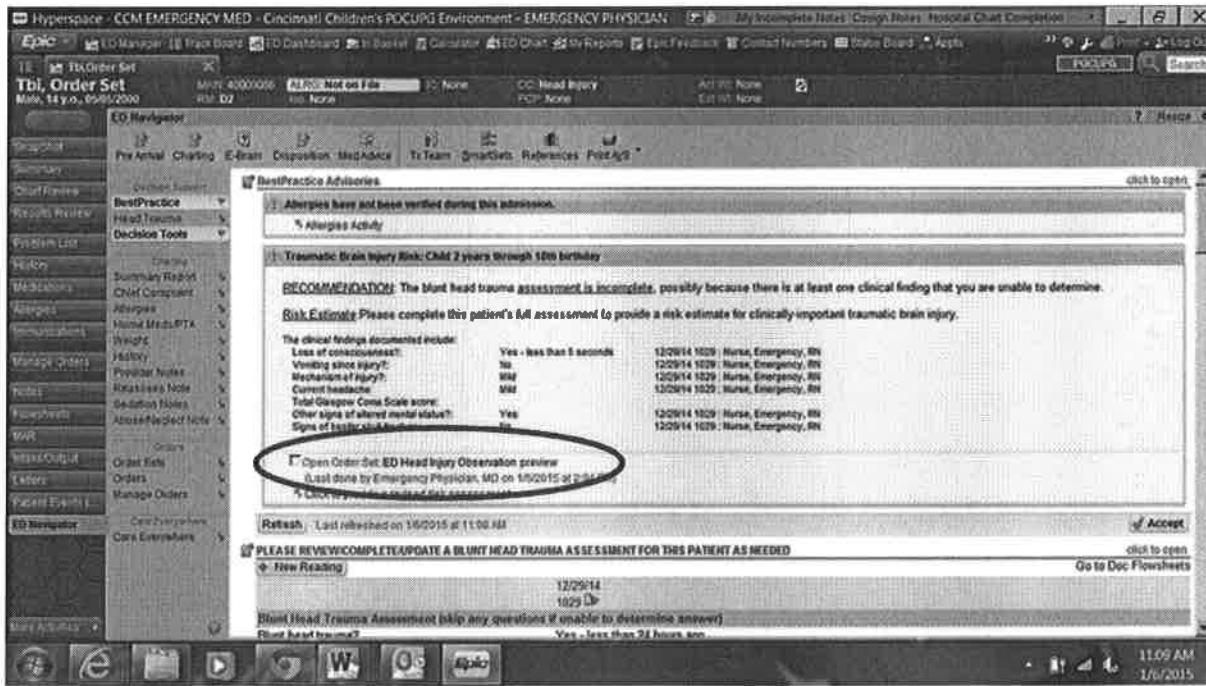
A Summary of the Researcher's Findings

Study Overview

This was a prospective quasi-experimental study that took place in a single pediatric ED within a Level 1 trauma accredited hospital located in southern Ohio. The goal of this study was to evaluate if an electronic order set created to standardize the care delivered during a period of ED observation following TBI could improve ED care by 1) decreasing unnecessary CT rates, 2) improving the quality and consistency of best care practices delivered, and 3) improving parental understanding and comfort with the care their child received. Children ages 0-4 years that were “at risk” for a cTBI per the PECARN TBI rule were enrolled from December 2014 - December 2015. At the time of study enrollment, the ED staff members who provided the bulk of the care for the study participant completed a survey about the care practices he/she provided for that patient. All study participants underwent routine clinical care as determined by the treating ED clinician. Various factors of ED care were observed and tracked by study staff in order to compare ED care practices during the six months before and after the order set became available for use by the ED staff. The parent or legal guardian of the enrolled child was contacted by phone after the ED visit to assess their understanding of the care that was provided in the ED and their comfort level with clinical decisions made in the ED.

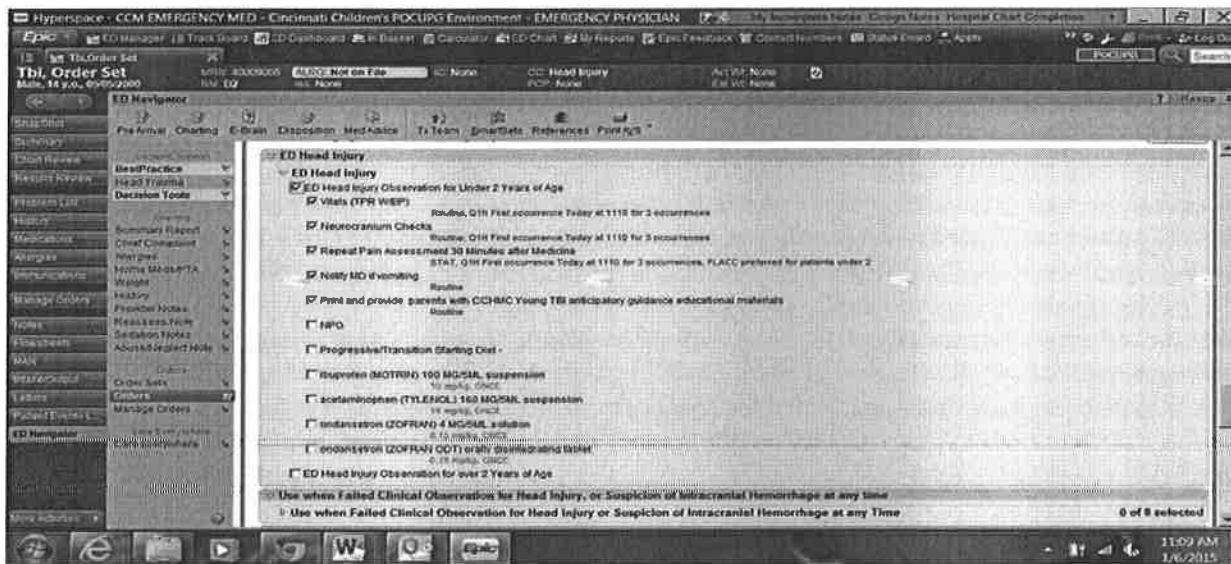
Observational Order Set Development

The purpose of the care pathway was to provide a structured management option if the clinician chose to observe a child with TBI in the ED. The care pathway was created based on prior literature and best care practices by the co-investigators, nursing staff, and divisional leadership. It was made into an order set to facilitate CPOE. A link to the order set was made available at the bottom of our TBI BPA so that after the clinician completed the BPA there was an option to open a link to the observation order set as shown below.



If the clinician selected the Head Injury Observation order set, an example of what appeared is pictured below. The orders within the order set were modifiable, although defaulted to four hourly reassessments and suggested that the clinician order reassessments of vital signs, mental status, pain level, and ability to tolerate oral intake/presence of vomiting. Currently our institution assesses pain for this young population using the Face, Legs, Activity, Cry, Consolability (FLACC) behavioral pain assessment scale. Children

are scored from 0 to 2 based on none, some, or definite signs of pain in each of the five FLACC areas. A total FLACC score of 0 indicates no pain, 1-3 mild pain, 4-6 moderate pain, and 7-10 severe pain and discomfort.²¹ Medications for typical symptoms of headache and nausea/vomiting (i.e. acetaminophen, ibuprofen, and ondansetron) were also included in the order set, as well as a suggestion to print and provide parents with our standardized anticipatory guidance on the management and expected recovery of TBI.



Sample Selection

Children were consecutively screened for eligibility and approached for enrollment in the ED when trained research coordinators were present, approximately 8am-12am daily. This study involved children, ages 0-4 years, who presented to our ED within six hours of either witnessed blunt head trauma or unwitnessed trauma with signs/symptoms of head injury. Eligible children had a Pediatric Glasgow Coma Scale (GCS) of 14-15 in the ED and met the criteria as at risk (i.e. not “very low risk”) for ciTBI based on the PECARN neuroimaging decision rule. The risk categorization of ciTBI was determined at the time of initial ED evaluation using the ED clinician’s responses to the TBI BPA within our EHR. Once the questions were answered in the BPA, there was immediate electronic feedback regarding the child’s risk category. Children categorized as “very low risk” of ciTBI were ineligible for the study. Children were also excluded if they had any of the following: penetrating head trauma, head trauma judged by the ED care team as concerning for abuse, pre-existing neurologic impairment (e.g. seizure disorder, cerebrospinal fluid shunt), pre-existing cognitive disorder (developmental delay, mental retardation), bleeding disorder, receipt of neuroimaging at another medical facility prior to arrival, non-English speaking parents, lack of working phone number, or if their mechanism of injury was deemed “trivial”. A “trivial mechanism” was defined as: a minor mechanism of injury (defined as a ground-level fall or running into a stationary object) PLUS the child either had no signs/symptoms of head trauma or the only sign of head trauma was an isolated scalp injury.

Study Enrollment and Follow-up Procedures

Inclusion criteria were reviewed to determine eligibility and parental informed consent was obtained prior to study enrollment. Patient demographic information (e.g. age, race), injury variables (e.g. time of injury, mechanism of injury), and ED care factors (e.g. length of stay, if a CT was obtained) were ascertained from parents and the EHR. At time of enrollment, the clinician and the nurse who provided the bulk of the ED care for the study participant completed a survey about the care he/she provided for the

patient. This survey included questions about the care practices provided (e.g. medications, reassessments), factors that influenced the medical decision making, and what was discussed with the parents during the visit. Radiographic imaging, if obtained per clinical care, was interpreted by the clinical radiologist on duty at the time of ED presentation. Parents were contacted via phone for a follow-up survey at approximately 2-4 days after the initial ED visit. These surveys assessed parental satisfaction with ED communication and understanding of the care their child received. Parents were also asked how well they felt that their child had recovered since the injury and if there had been subsequent healthcare visits for the head injury. The EHR was also reviewed to assess for any return visits to our ED within four days of the initial injury, detailing any care practices provided and diagnoses associated with the return visit. If any clinical neuroimaging reads were inconclusive, additional clarification for study purposes was provided by our staff radiologist. Lastly, participants' medical charts were reviewed to determine if the child met criteria for a ciTBI per the PECARN neuroimaging rule: intubation >24 hours, admission to the hospital for ≥2 nights for care of the TBI, neurosurgical intervention, or death from the TBI.

Our study goal of enrolling 50 children before and 100 children after the order set implementation was based on the power to assess if there was a significant change in CT rates. As the order set was made available for ED staff use, clinician and nursing education about the importance, utility, and functionality of the care pathway was provided during staff meetings, shift huddles, educational flyers in ED staff areas, email reminders, and direct reminders by research coordinators in the ED to augment dissemination of knowledge.

Outcomes

The objective of our study was to improve the current ED management of young children, ages 0-4 years who were not at very low risk of ciTBI based on the PECARN decision rule, via implementation of a standardized observation care pathway that incorporates close reassessments and symptom management. Our primary aim was to increase the consistency with which evidenced-based care practices were implemented in the ED, thereby reducing unnecessary utilization of hospital resources (e.g. head CTs) and increasing the frequency for which best care practices are provided in the ED. Our secondary aim was to improve parental understanding and comfort with ED care. For our first aim, our primary outcome was head CT rates, although we also evaluated unnecessary hospital admissions (i.e. with a normal head CT), repeat ED evaluations (i.e. an repeat ED evaluation for the initial head injury without subsequent intervention/admission), and best care practices including 1) frequency of pain assessments (i.e. FLACC scores), 2) administration of common symptomatic treatments for TBI (acetaminophen, ibuprofen, and ondansetron), and 3) distribution of standardized patient information on the management and expected recovery of pediatric TBI. We also tracked ED length of stay (LOS), CT results (if applicable), and the occurrence of a ciTBI. For our secondary aim, parental understanding and satisfaction with ED care and communication were assessed via phone survey 2-4 days after enrollment. To assess parental understanding of ED care, parental survey responses were compared to the ED staff surveys regarding what care practices had been provided (e.g. observation, reassessments) and what had been discussed with the parents during the ED visit. Satisfaction with communication in the ED was scored on a Likert scale of 1-10, with 1 being "Not at all satisfied" and 10 being "Completely satisfied".

Statistical Analysis

Our proposed sample size goal of 50 pre and 100 post-intervention patients was based on a power calculation to detect a significant difference in CT rates for children at risk for ciTBI before and after the implementation of the order set. Basic descriptive statistics were computed for the individual factors, care practices, and outcomes of this cohort. Group comparisons were performed to assess if there was a difference between the LOS before and after the implementation of the order set. We examined differences between clinician and parent reports of what occurred and was discussed in the ED. We also compared parental comfort levels in the neuroimaging decision between those with children who did or

did not receive a CT. The survey data were analyzed using T-test and Mann-Whitney U test for continuous variables and Chi-square and Fisher's exact tests for categorical variables when appropriate, with $p<0.05$ denoting statistical significance.

Results

One hundred and seven patients were enrolled between December 2014 and December 2015. Fifty-one children were enrolled from December 1, 2014-June 15, 2015. One child was withdrawn after being noted to have been outside of the six hour post-injury eligibility window. An additional 56 children were enrolled after the order set was made available for use within the EHR in June 2015. Two participants were withdrawn after their study eligibility criteria was clarified with ED staff and subsequently deemed "very low risk" for ciTBI. Due to insufficient time and funds from the initial study start delay, data collection were stopped in December 31, 2015 despite the suboptimal sample size.

The majority of the entire study cohort was male (60%), white (70%), non-Hispanic (93%), and injured due to a fall (86%). There was no group difference between the first and second six month periods of enrollment with regards to individual and injury related characteristics (Table 1).

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Table 1. Characteristics of Study Cohort

Characteristic	Total N=104	Pre- Implementation N=50	Post- Implementation N=54	Group Difference p-value*
Age in Years (mean \pm SD)	1.2 \pm 1.3	1.1 \pm 1.3	1.3 \pm 1.4	0.50
Male Gender (n, %)	62 (60)	34 (68)	28 (52)	0.11
Race				
White	73 (70)	37 (74)	36 (67)	0.73
Black	26 (25)	11 (22)	15 (28)	
Other	5 (5)	2 (4)	3 (5)	
Hispanic Ethnicity (n, %)	7 (0.1)	4 (0.1)	9 (0.2)	0.44
Mechanism (n, %)				
Fall from elevation	62 (60)	27 (54)	35 (65)	
Fall down stairs	15 (14)	10 (20)	5 (9)	
Fall to ground from standing height	12 (12)	4 (8)	8 (15)	0.17
Object struck head – accidental	11 (11)	8 (16)	3 (6)	
Walked/ran into stationary object	3 (3)	1 (2)	2 (4)	
Other wheeled transport	1 (1)	0 (0)	1 (2)	
PECARN Risk Factors (yes, %)				
Loss of Consciousness	15 (14)	7 (14)	8 (15)	0.21
Vomiting	31 (30)	12 (24)	19 (35)	0.23
Severity of Mechanism of Injury	104	50	54	0.31
Mild	37 (36)	21 (42)	16 (30)	
Neither mild nor severe	41 (39)	16 (32)	25 (46)	
Severe	25 (25)	13 (26)	13 (24)	
Headache	5 (5)	2 (4)	3 (6)	1
AMS per clinician	15 (14)	9 (18)	6 (11)	0.41
AMS per parent	16 (15)	8 (16)	8 (15)	1
Scalp Hematoma	104	50	54	0.49
Frontal	25 (24)	13 (26)	12 (22)	
All Other Locations	31 (30)	17 (34)	14 (26)	
None	48 (46)	20 (40)	28 (52)	
Concerns for skull fracture	2 (2)	2 (4)	0 (0)	0.23
Concerns for basilar skull fracture	0 (0)	0 (0)	0 (0)	1

Legend: AMS: altered mental status, SD: standard deviation, PECARN: Pediatric Emergency Care Academic Research Network

*Based on T-test or Fisher's exact test

Our primary aim was to increase the consistency with which evidenced-based care practices were implemented in the ED. Our outcomes pertaining to reducing unnecessary utilization of hospital resources (e.g. head CTs) are summarized in Table 2, and our outcomes pertaining to increasing the frequency of which best care practices are provided are summarized in Table 3. With regards to observation versus emergent neuroimaging, per clinician report, after the initial patient exam: 30 decided to obtain a CT, 59 decided to observe the child, and 15 did not obtain a head CT nor observe the child for a specific period of time. Although these proportions did not significantly change when compared by pre and post order set implementation ($p=0.1$), the proportion of children that were placed initially into a period of observation increased from 46% to 67%. In addition to the 30 children who underwent emergent neuroimaging, seven of the children who were initially observed subsequently received a head CT. Although overall rates of obtaining a head CT did not change during our study period and there was not a statistically significant decrease in unnecessary (i.e. negative) CTs, the latter did decrease from 68% to 44%. After taking into account cost and radiation exposure, this could be considered a clinically

significant group difference.

Two children returned to our ED within four days of the initial head injury, although the discharge diagnoses were leg laceration and fever and both were discharged home. Of the 12 children admitted to the inpatient unit, the majority (75%) were admitted for further monitoring after being found to have an abnormal head CT. The three other admitted children included a child with a normal head CT observed for pulmonary contusion symptoms, a child with a normal head CT observed for TBI and abdominal injury symptoms, and a child without a head CT admitted for management of a femur fracture.

Table 2. Neuroimaging and ED Disposition Outcomes for Young Children with Traumatic Brain Injury

Characteristic	Total N=104	Pre- Implementation N= 50	Post- Implementation N=54	Group Difference p-value*
Head CT (yes, %)	37 (36)	19 (38)	18 (33)	0.68
Unnecessary (i.e. Negative) Head CT (yes, %) ^e	21 (59)	13 (68)	8 (44)	0.19
ED Revisits (yes, %)	2 (2)	1 (2)	1 (2)	1
Inpatient Admission with Normal Head CT (yes, %)	2 (2)	1 (2)	1 (2)	1

Legend: CT: computed tomography; ED: emergency department

*Based on Fisher's exact test

^ePercentage based on proportion of all head CTs obtained

Sixteen children had abnormal head CTs (12 from the immediate CT group and 4 after a period of observation), and diagnoses included subarachnoid hemorrhage (n=2), skull fracture with extra-axial hemorrhage (n=4), isolated skull fracture (n=9), and orbital fracture/hematoma (n=1). The proportion of abnormal CTs increased from 32% to 56% after order set implementation, and although this change was not significant (p=0.19), it suggested that clinicians were becoming more judicious in the choice to obtain neuroimaging. No children enrolled in our study met criteria for ciTBI.

Regarding the provision of best care practices (Table 3), we found no group differences before and after the implementation of the order set. Additionally, LOS did increase, although not significantly, after the order set implementation (p=0.06).

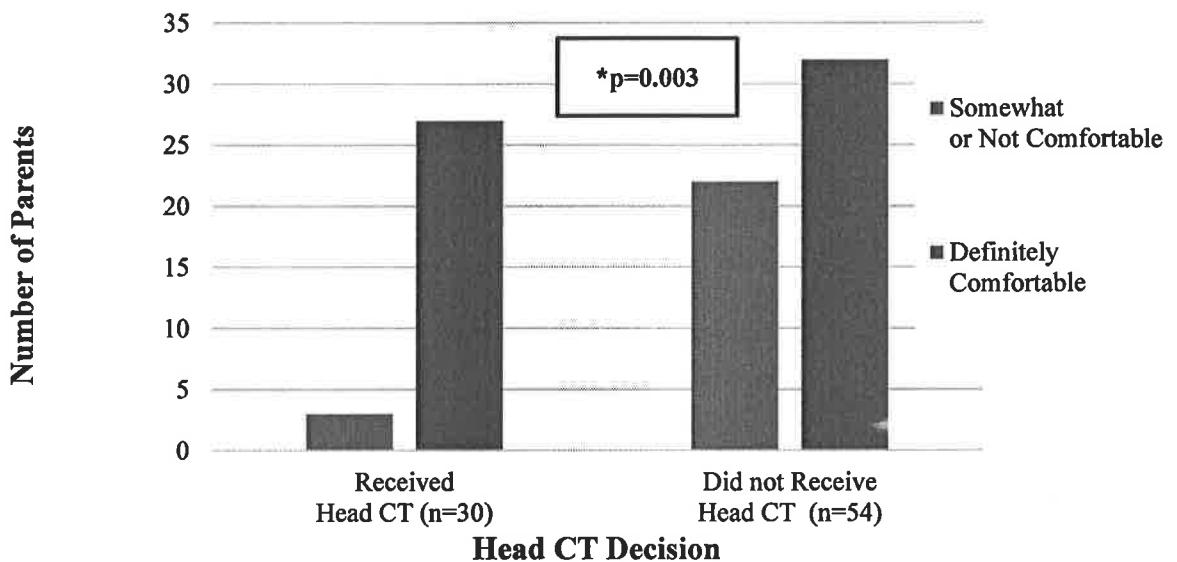
Table 3. ED Care Practices for Young Children with Traumatic Brain Injury

Care practice	Total N=104	Pre- Implementation n=50	Post- Implementation n=54	Group Difference p-value*
Pain Assessment (yes, %)	24 (23)	13 (26)	11 (20)	0.64
Analgesic (yes, %)	29 (28)	13 (26)	15 (28)	0.83
Acetaminophen	21	12	9	
Ibuprofen	4	0	4	
Both	3	1	2	
Antiemetic (yes, %)	10 (10)	3 (6)	7 (13)	0.32
Written TBI Anticipatory Guidance (yes, %)	69 (66)	34 (68)	35 (65)	0.84
ED Length of Stay in Hours (mean \pm SD)	2.9 \pm 1.8	2.6 \pm 1.3	3.3 \pm 2.1	0.06

Legend: ED: emergency department; TBI: traumatic brain injury; SD: standard deviation

*Based on T-test or Fisher's exact test

For our secondary aim, to improve parental understanding and comfort with care, parents were contacted after their ED visit, of which 84 (81%) completed the phone follow-up. All 84 parents felt that their child had recovered from their head injury. Thirteen parents reported a repeat medical evaluation since the initial injury. One was the ED re-evaluation for fever noted above, nine were with the primary care doctor due the ED clinician instructing them to follow-up, one child had an already scheduled well child check-up with their primary care doctor, and one child followed up with the CCHMC head injury clinic due to the ED clinician instructing them to do so. Of those that completed the follow-up survey, 30 endorsed their child had a CT and 54 said their child did not have a head CT. It should be noted that one of the parents that said their child received a CT only had a skull x-ray performed. This child was kept in the head CT group for analysis due to the fact that the parent answered all of the survey questions as if their child received a head CT. Figure 1 illustrates Fisher's exact test analysis comparing the proportion of parents comfortable with whether their child did or did not receive a head CT. Parents' comfort ratings were dichotomized as "Somewhat or Not Comfortable" versus "Definitely Comfortable". The decision to dichotomize was based on the reasoning that if a parent was only "somewhat" comfortable with the medical care their child received in an ED, this was suboptimal and therefore more suitably grouped with those who were "not" comfortable. Parents of children that did not receive a CT were more likely to report being uncomfortable with this decision versus those with children that did receive a CT ($p=0.003$). The basis of discomfort varied among the 22 parents who were partially ($n=14$) or not at all ($n=8$) comfortable with the fact their child did not receive a CT. Eleven parents stated they were nervous and wanted a CT to definitively rule out injury given their child's young age and small size. Similarly, two were concerned due to their child's size and mechanism (i.e. a fall from elevation), four parents stated they were confused about why they did not get a CT and/or had unanswered questions about the decision, and five felt their child had significant TBI signs/symptoms that warranted a CT (loss of consciousness, dizziness, altered mental status and scalp swelling). However, most parents stated that despite their anxiety, they ultimately trusted the clinician's decision to not order imaging after an explanation was given. The risk of exposing a very young child to radiation was cited as the source of discomfort among two of the three parents who were not completely comfortable with the fact their child received a CT. The third parent thought the process of the CT was scary and that she was unable to comfort her child inside the scanner. One of the parents that stated they were "Definitely Comfortable" with getting a head CT was the parent of the child that only received a skull x-ray.

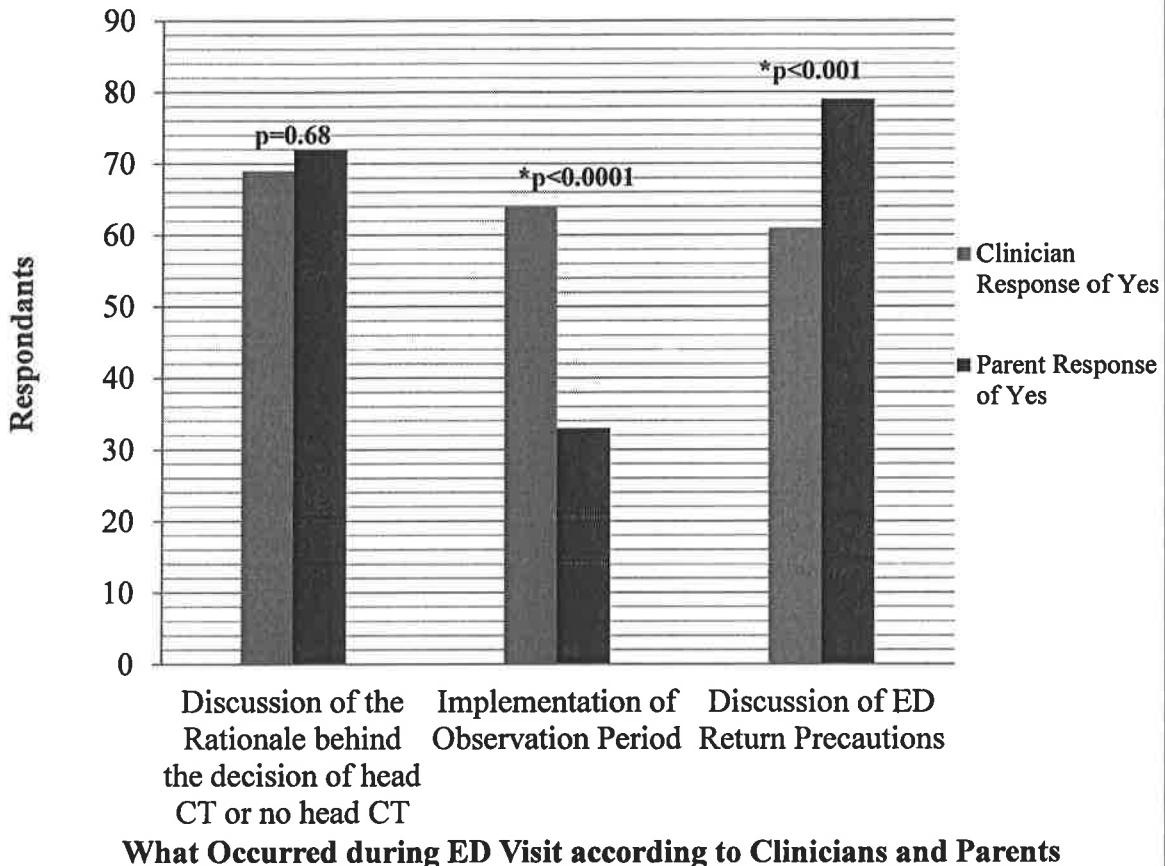
Figure 1. Parental Comfort with Head CT Decision (n =84)

Legend: CT: Computed tomography

*Based on Fischer's Exact test, denotes a statistically significant ($p<0.05$) group difference

Figure 2 shows a comparison of clinician versus parent report regarding what happened or what was discussed during the child's ED visit, including discussion of the rationale for ordering (or not ordering) a head CT, whether there was a period of observation in the ED, and whether or not there was discussion about ED return precautions. We found significant group differences between parent and clinician report of the occurrence of the ED observation period ($p<0.0001$) and discussion of ED return precautions ($p<0.001$). Sixty-four clinicians reported observing the child in the ED, although only 47 reported that they discussed the rationale of the observation with the parent. Of the 64 children observed, only 33 parents reported that this occurred, although of these 33 parents, 32 (97%) could correctly articulate the purpose of the observation period, with only one parent stating they were unsure of its purpose. Given the degree of discomfort with the neuroimaging decision, as illustrated in Figure 1, it was surprising that 72 (86%) parents endorsed that the decision to obtain neuroimaging was explicitly discussed with them.

Figure 2. Comparison of Clinician and Parental Perceptions of Emergency Department Care Provided (n=168)



Legend: ED: emergency department; CT: Computed tomography

*Based on Fischer's Exact test, denotes a statistically significant ($p<0.05$) group difference

The average \pm SD overall parent satisfaction score for the communication in the ED was 8.9 ± 1.7 . Using the Mann-Whitney U test, there was not a difference in parental satisfaction between those parents that did or did not receive a head CT: 9 ± 1.9 versus 8.9 ± 1.5 , respectively ($p=0.51$).

Conclusions

These findings suggest that, despite the PECARN neuroimaging rule, ED clinicians at single academic center continue to have a high rate of CTs and underutilize the observation period in young children at risk for ciTBI. While this study was underpowered to detect a change in overall CT rates, it did show trends of improvement in the implementation of the observational care pathway, with an increase in the use of the observation period per clinician report and a decrease in the negative CT rate of 24%. Our findings demonstrated additional areas of ED care in need of improvement, with just 25% of children

receiving pain assessments and/or treatment and only 50% of parents being aware that they were intentionally kept in the ED for a period of observation. Additionally, the discomfort around the decision to obtain neuroimaging was not fully ameliorated despite parents acknowledging that this was discussed with them in the ED, underscoring the need for improved communication.

Recommendations

Future work characterizing the barriers to implementing a period of observation as well as providing optimal communication to parents in the ED is needed to advance the quality of ED care and improve parental understanding and comfort with care, respectively. Additional work refining how to stratify a child's risk for TBI would further reduce unnecessary CT rates and clinician anxiety around foregoing emergent neuroimaging.

References

1. Kuppermann N, Holmes JF, Dayan PS, et al. Identification of children at very low risk of clinically-important brain injuries after head trauma: a prospective cohort study. *The Lancet*. 2009;374(9696):1160-1170.
2. Schonfeld D, Fitz BM, Nigrovic LE. Effect of the duration of emergency department observation on computed tomography use in children with minor blunt head trauma. *Annals of emergency medicine*. 2013;62(6):597-603.
3. Nigrovic LE, Schunk JE, Foerster A, et al. The effect of observation on cranial computed tomography utilization for children after blunt head trauma. *Pediatrics*. 2011;127(6):1067-1073.
4. Nigrovic LE, Stack AM, Mannix RC, et al. Quality Improvement Effort to Reduce Cranial CTs for Children With Minor Blunt Head Trauma. *Pediatrics*. 2015;136(1):e227-233.
5. Schonfeld D, Bressan S, Da Dalt L, Henien MN, Winnett JA, Nigrovic LE. Pediatric emergency care applied research network head injury clinical prediction rules are reliable in practice. *Postgrad Med J*. 2015;91(1081):634-638.
6. Faul M, Xu L, Wald MW, Coronado VG. Traumatic Brain Injury in the United States: Emergency Department Visits, Hospitalizations, and Deaths 2002-2006. 2010; http://www.cdc.gov/traumaticbraininjury/pdf/blue_book.pdf.
7. 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(5):983-993.
8. Pearce MS, Salotti JA, Little MP, et al. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet*. 2012;380(9840):499-505.
9. Hennelly KE, Mannix R, Nigrovic LE, et al. Pediatric traumatic brain injury and radiation risks: a clinical decision analysis. *J Pediatr*. 2013;162(2):392-397.
10. Nigrovic LE, Schunk JE, Foerster A, et al. The effect of observation on cranial computed tomography utilization for children after blunt head trauma. *Pediatrics*. 2011;127(6):1067-1073.
11. Osmond MH, Klassen TP, Wells GA, et al. CATCH: a clinical decision rule for the use of computed tomography in children with minor head injury. *Canadian Medical Association Journal*. 2010;182(4):341-348.
12. Boutis K, Cogollo W, Fischer J, Freedman SB, David GB, Thomas KE. Parental knowledge of potential cancer risks from exposure to computed tomography. *Pediatrics*. 2013;132(2):305-311.
13. Kochanek PM, Carney N, Adelson PD, et al. Guidelines for the acute medical management of severe traumatic brain injury in infants, children, and adolescents--second edition. *Pediatric critical care medicine : a journal of the Society of Critical Care Medicine and the World Federation of Pediatric Intensive and Critical Care Societies*. 2012;13 Suppl 1:S1-82.
14. Babcock L, Byczkowski T, Wade SL, Ho M, Mookerjee S, Bazarian JJ. Predicting postconcussion syndrome after mild traumatic brain injury in children and adolescents who present to the emergency department. *JAMA pediatrics*. 2013;167(2):156-161.
15. Blume HK, Vavilala MS, Jaffe KM, et al. Headache after pediatric traumatic brain injury: a cohort study. *Pediatrics*. 2012;129(1):e31-39.
16. Colvin JD, Thurm C, Pate BM, Newland JG, Hall M, Meehan WP. Diagnosis and acute management of patients with concussion at children's hospitals. *Arch Dis Child*. 2013;98(12):934-938.
17. Dayan PS, Holmes JF, Atabaki S, et al. Association of traumatic brain injuries with vomiting in children with blunt head trauma. *Annals of emergency medicine*. 2014;63(6):657-665.

18. Karpas A, Finkelstein M, Reid S. Which management strategy do parents prefer for their head-injured child: immediate computed tomography scan or observation? *Pediatric emergency care*. 2013;29(1):30-35.
19. Lobach D, Sanders GD, Bright TJ, et al. Enabling health care decisionmaking through clinical decision support and knowledge management. 2012.
20. Graumlich JF, Novotny NL, Nace GS, Aldag JC. Patient and physician perceptions after software-assisted hospital discharge: Cluster randomized trial. *Journal of hospital medicine*. 2009;4(6):356-363.
21. Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: a behavioral scale for scoring postoperative pain in young children. *Pediatr Nurs*. 1997;23(3):293-297.