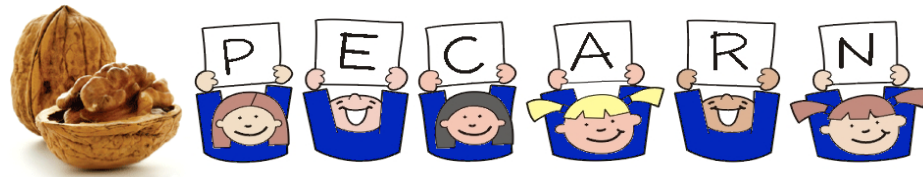


Fall 2011



In a nutshell

What's Inside?

- > PECARN History
- > Network Highlights
- > PECARN Timeline
- > New PECARN Nodes and Sites
- > Study Updates
- > Nodal Bios
- > PECARN Publications

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TEN YEARS OF PECARN PROGRESS AND INNOVATION

Submitted by Sally Jo Zuspan
 DCC Director

The Pediatric Emergency Care Applied Research Network (PECARN) is celebrating 10 years of innovative, progressive research in emergency medical services for children. The PECARN evolved from a desire to expand the quality and quantity of research in pediatric emergency care. In the past decade PECARN has established itself as the leader in pediatric emergency care research.

In June 2001, the Health Resources and Service's Administration (HRSA), Maternal and Child Health Bureau's (MCHB), Emergency Medical Services for Children (EMSC) Program awarded cooperative agreements to four research node centers to establish the infrastructure for PECARN. The PECARN was charged with conducting rigorous, high-priority, research in EMSC. The four research centers and respective sites totaled 26 PECARN hospitals. The Data Coordinating Center was added in 2002 as the fifth cooperative agreement.

The first project initiated by the PECARN was a descriptive study of network emergency department (ED) visits called the *PECARN Core Data Project (PCDP)*. This project collected and analyzed administrative data from electronic sources and medical records at all sites, demonstrating the ability of the network to collect and analyze large quantities of data electronically. The data provide information on the frequency of diagnoses seen within the PECARN. These data are routinely used for hypothesis generation and estimating accrual for new studies.

Data are collected annually totaling approximately 1,000,000 ED visits per year. Recently, census-related socioeconomic data have been linked to the PCDP datasets.

PECARN's first randomized controlled trial (RCT), enrolled nearly 600 subjects and evaluated oral dexamethasone vs. placebo for treatment of acute *bronchiolitis*. The manuscript was published in the *New England Journal of Medicine* in 2007. Another early project was a retrospective chart review to describe children eligible for a future study evaluating *hypothermia after pediatric cardiac arrest*. These data formed the foundation of the current *Therapeutic Hypothermia After Cardiac Arrest (THAPCA)* trial, funded by the National Heart Lung and Blood Institute (NHLBI) in 2009. The THAPCA trials are currently enrolling patients at over 30 PECARN and non-PECARN hospitals.

"HRSA recognizes the need to ensure evidence based treatments for children in an emergency setting and has provided funding and leadership for the PECARN. Over the past decade, PECARN has conducted research to find the best treatments for pediatric emergencies. Its success is due to the many investigators, research coordinators and staff who have lead and implemented studies across the country."

Mary Wakefield, Ph.D., R.N.
 HRSA Administrator

Continued on page 2



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Focus on Injury

Several early PECARN studies focused on pediatric injury. The *Cervical Spine Injury (CSI)* study was a case-control analysis that identified risk factors associated with CSI in children. This retrospective chart review studied 540 children with CSI and 2774 controls across 17 medical centers over 5 years. In 2004, EMSC funded the *Traumatic Brain Injury (TBI)* study. Twenty-five PECARN sites enrolled more than 43,000 subjects in this observational study aimed at developing a prediction rule to identify children at low risk for TBI after head trauma in whom CT scans might be unnecessary. The goal of this large, ambitious study was to appropriately reduce unnecessary CT scans (and associated radiation risk) in children at very low risk of clinically-important TBI. The study derived and validated two prediction rules; one for children 2 years and older and another for children younger than two. The prediction rules provide the necessary data to assist clinicians and families in CT decision making after head trauma. The manuscript was published in *The Lancet* in 2009. A similar study, funded by the CDC, aimed to identify low-risk indicators of *intra-abdominal injury* in children after blunt abdominal trauma. This study successfully enrolled over 12,000 children and was completed in early 2010. Like the TBI study, the goal of this research was to provide guidance to clinicians on obtaining CT scans in children after blunt abdominal trauma in order to reduce exposure to unnecessary radiation that carries a risk of malignancy later in life.

Recently, PECARN head injury research has taken a new direction. Brain injury in children causes substantial burden for parents and society and despite years of research, there is no effective treatment. The *Progesterone Yield* study is currently collecting data in preparation for a future trial evaluating the use of progesterone for emergent treatment of children with moderate to severe traumatic brain injuries.

Bringing Research Findings to the Bedside

One of the challenges in medical research is to seamlessly integrate research findings into daily patient care. Often, results from important research projects fail to find their way to clinicians caring for patients with the disease under study. The PECARN's challenge is to enhance the likelihood that research findings reach the clinician in emergency departments that care for children. The PECARN has taken a progressive step in this direction with efforts to "translate" research results into clinical practice. The *TBI Knowledge Translation* study focuses on implementing the PECARN TBI decision rules an integrated electronic health record-clinical decision support system. A seven-center prospective time series trial will assess CT use before and after implementation of the decision support that brings the prediction rule information directly to the clinician. The ultimate goal is to safely decrease the use of CT scans in children with minor head trauma. This 3 year study will enroll patients through

2013 and was funded by the American Recovery and Reinvestment Act-Office of the Secretary.

Translational Research: bedside to bench and back

PECARN is conducting an important translational research study that aims to bring findings from bench research to the bedside by defining host immune responses in the form of "biosignatures" using state-of-the-art RNA microarray technology. The investigators aim to redefine the reference standard for presence of infections in the very young febrile infants and essentially change the paradigm for diagnosis of infectious diseases. Investigators were initially funded by EMSC to gather blood samples from febrile children in PECARN EDs. Subsequently, the National Institute for Child Health and Human Development (NICHD) provided additional R01 funding to continue sample collection and develop bacterial and non-bacterial biosignatures. To date, over 2400 samples have been collected.



Randomized Trials: From ED into the hospital

Expert opinion recommends both diazepam and lorazepam as initial therapy for children in status epilepticus. However, unlike diazepam, lorazepam is only FDA-approved for treatment for seizures in patients over 18 years of age. Despite this fact, many experts support the use of lorazepam over diazepam in pediatric seizure care. Data to support firm recommendations for one medication over another are lacking. The purpose of the *Seizure* study is to determine the differences in efficacy and safety between these two commonly used benzodiazepines, as requested by the FDA under the Best Pharmaceuticals for Children Act, using the Exception from Informed Consent provided by the FDA. This double-blind randomized trial continues to enroll at 12 sites. Enrollment has been successful and is currently at 90% of final sample.

It is well known that children with sickle cell disease (SCD) are at risk for acute pain crises; however, no one knows why a pain crisis starts. Once a pain crisis starts, there are no treatments that have been shown to shorten the length or severity of the crisis.

Continued on page 3



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In an attempt to help alleviate suffering for children with sickle cell disease, the NICHD funded the *Magnesium in Sickle Cell Vasooclusive Crisis (MAGiC)* study in 2010. This randomized, blinded drug trial is currently enrolling children with acute pain crisis to evaluate the ability of magnesium to decrease length of hospital stay.

Prevention of complications of pediatric diabetes is another area being researched by the PECARN. The *Fluid Therapy and Cerebral Injury in Pediatric Diabetic Ketoacidosis (FLUID)* trial, also funded by NICHD, is currently enrolling patients at 10 PECARN sites to evaluate four fluid treatments for children with diabetic ketoacidosis (DKA). Current opinion is divided on the most effective fluid treatment for these children, and several different approaches can be found across the country. This study will compare fluid treatment using assessments for neurological injury with the goal of identifying the most ideal fluid management strategy for children with DKA.

Scientifically, the trial will also help to clarify the uncertain etiology of cerebral edema, the most dreaded complication of DKA. Recent data from the study investigators strongly support the notion that cerebral edema is a result of cerebral hypoperfusion/ischemia rather than from fluid shifts during resuscitation; results from this trial may cause a basic paradigm shift in our understanding and treatment of DKA.

Safety for Patients

Patient safety and reduction of medical errors is another focus of PECARN research. Since 2006, PECARN investigators have collaborated to organize several projects dedicated to assessing and reducing medical errors in emergency departments. PECARN investigators have collected over 22,000 incident reports from network sites and created a comprehensive medical error classification system. A second study retrospectively reviewed 3,000 ED charts to quantify medication error rates. The next step is to obtain funding to evaluate interventions and define best practices to reduce ED medical errors.

Quality in Pediatric Emergency Care

PECARN projects have also tackled the difficult issue of how to measure quality in pediatric emergency care systems. The *Diagnosis Grouping System (DGS)* project, initiated in 2004, developed a system to group pediatric emergency illness/injury diagnoses in a clinically relevant way and classify them based on severity. The diagnosis grouping and severity classification systems provide consistent tools to describe diagnoses and severity in ED populations. The tools are available on the PECARN website (www.pecarn.org/tools). Building on the DGS project, PECARN investigators were funded by EMSC to develop a quality of care “report card” as a means of measuring and improving pediatric emergency care. Children are particularly vulnerable when being cared for

inside emergency departments that primarily treat adults. But without a way to measure the quality of care received, it is difficult to affect change. The *Performance Measures* project, completed in 2010, developed a balanced set of measures that can be used to comprehensively evaluate pediatric emergency care. Similarly, the recently funded *PECARN Quality of Care* project is a retrospective chart review that will validate an existing tool used to measure quality of patient care for children in emergency departments. Ideally, this tool, once validated, could be used to evaluate care in EDs across the country. The performance measures grant allows hospital EDs to comprehensively understand the quality of care they provide to children by examining their performance across a broad range of care activities. The Quality of Care project examines quality at the individual visit level through chart review. Both of these efforts are important steps in being able to measure, and improve, the care of children in EMSC.

Another recently funded study addressing the intersection of electronic health record data and the quality of care is *Improving the Quality of Pediatric Emergency Care Using an Electronic Medical Record Registry and Clinician Feedback*. This study will establish a data registry from electronic health records of four PECARN sites to collect and report quality measures of emergency care provided to children. The project will establish measurable benchmarks and implement a clinician feedback intervention to improve performance.

EMS Research

Emergency care for children occurs in the hospital, but also takes place outside the hospital at the scene of an illness or injury. The PECARN Emergency Medical Services (EMS) study developed partnerships with 22 EMS agencies geographically situated near PECARN sites and successfully collected electronic data surrounding pediatric care. Ultimately, 14 EMS agencies submitted data from over 500,000 pediatric EMS calls. These data will provide preliminary data for future EMS projects. The cervical spine injury study group built on these relationships by using qualitative methodology to identify barriers and motivators to participation in research among prehospital personnel. The ultimate goal of this work was to prepare for a study that limits immobilization for children at low risk for CSI. The manuscript has been accepted for publication.

Summary

Over the past decade, PECARN has made tremendous strides in researching diverse, important areas of pediatric emergency medicine. PECARN’s success is due to the vast experience, knowledge and passion of its investigators, the dedication and hard work of top notch research coordinators, and the infrastructure funding provided by HRSA/MCHB/EMSC. The network looks forward to continuing its leadership in the field and mentoring the next generation of researchers.



Completed and Ongoing PECARN Research

Study	Description	Funding Source	Dates
PECARN Core Data Project (PCDP)	Epidemiology and demographics of PECARN	Internal PECARN funding	2001-2012
Childhood Head Trauma (TBI)	Study of children with blunt head trauma to create prediction rule for emergency neuroimaging	HRSA/MCHB/EMSC R40 MC02461-01-00	\$1,945,416 2004-2006
Hypothermia for Pediatric Cardiac Arrest	Retrospective study to characterize patient population and facilitate planning of a future trial	NICHD R21HD044955-01 R34 HD050531	\$306,000 \$188,851 2003-2006 2006-2008
Creating a Diagnostic Grouping System for Child ED Visits	Categorizing ICD-9 diagnoses relevant to ED visits	HRSA/MCHB/EMSC H34 MC02457-01-00	\$600,000 2004-2007
The Effectiveness of Oral Dexamethasone for Acute Bronchiolitis	Oral dexamethasone vs. placebo for treatment of acute bronchiolitis.	R40MC04298-01-00	\$800,000 2003-2006
Predicting Cervical Spine Injury in Children (CSI)	Case-control study to identify clinical predictors of cervical spine injury	HRSA/MCHB/EMSC H34 MC03472-01-00	\$600,000 2005-2008
Lorazepam for Treatment of Pediatric Status Epilepticus	Pharmacokinetic study of lorazepam, and RCT of lorazepam vs. diazepam	NICHD HHSN275200403393C HHSN275201100017C	\$10,185,292 \$2,091,465 2004-2011 2011-2013
Mental Health Pilot Study	Retrospective study of pediatric patients with psychiatric complaints	Internal PECARN funding	2004-2006
Patient Safety in Pediatric Emergency Departments	Survey of ED staff; prospective collection of incident reports	Internal PECARN funding	2007-2011
Descriptive Study of EMS Pediatric Population	Descriptive survey of EMS agencies and patient populations in PECARN	Internal PECARN funding	2007-2011
A Clinical Decision Rule To Identify Children With Intra-Abdominal Injuries	Prospective cohort study of children with abdominal trauma to create a decision rule for emergency imaging	CDC (1 R49CE001002)	\$1,293,930 2007-2010
Defining Quality Performance Measures for Pediatric Emergency Care	Expert panel and data-derived effort to identify quality measures and a scorecard	HRSA/MCHB/EMSC H34MC08512	\$594,880 2007-2010
Therapeutic Hypothermia for Pediatric Cardiac Arrest (THAPCA)	RCT of hypothermia following cardiac arrest	NHLBI (U01 HL094345, U01 HL094339)	\$21,787,796 2009-2015
Role of Intra-abdominal Fat on the Sensitivity of CT IV to Visualize the Normal Appendix	Secondary study to evaluate role of fat in detecting a normal appendix	Internal PECARN funding	2009-2011
Evaluation of Patient Safety in Pediatric EDs	Retrospective chart review to evaluate medication errors in 3 hospitals	NY State Health Department R620427	\$262,272 2009-2010
Intravenous Magnesium for Sickle Cell Vaso-occlusive Crisis (MAGIC)	RCT of IV magnesium for treatment of acute painful crisis in sickle cell disease	NICHD 1R01HD062347-01	\$1,689,783 2010-2014
Health-related Quality of Life and Outcomes after IV Magnesium	A study to determine if HRQL of children with pain crisis is improved after treatment	NICHD 1R01HL103427-01A1	\$965,497 2011-2013
Fluid Therapy in Pediatric Diabetic Ketoacidosis (FLUID)	RCT of fluid regimens for DKA	NICHD 1R01HD062417-01	\$3,305,435 2010-2015
Progesterone for Traumatic Brain Injury in Children	Planning grant for RCT of progesterone for traumatic brain injury	EMSC TIG H34MC19353	\$599,757 2010-2012
Factors Associated with Quality of Care Delivered to Children in US EDs	Validation of implicit review instrument to assess quality of care for children in EDs	AHRQ 1R01HS019712-01	\$1,469,284 2010-2013
RNA Biosignatures in the Emergency Evaluation of Young Febrile Children	Evaluation of biosignatures to accurately discriminate between bacterial and non-bacterial infections	HRSA/MCHB/EMSC H34MC08509 NICHD 1R01HD062477-01A1	\$599,999 \$3,354,677 2007-2010 2010-2015
Implementation of PECARN TBI Prediction Rules Using Computerized Clinical Decision Support	A trial to determine if computerized decision support decreases CT use after head injury	MCHB S02MC19289	\$3,498,012 2010-2013
Development and Use of an Electronic Medical Record (EMR) Registry to Improve the Quality of Pediatric Emergency Care	Development and use of an EMR registry to improve the quality of pediatric emergency care	1R01HS020270-01A1	\$2,465,381 2011-2016



Funding For K12 Program In Emergency Medicine

The National Heart, Lung, and Blood Institute (NHLBI), a part of the National Institutes of Health (NIH), is committed to optimizing the diagnosis and clinical management of patients with severe disease and trauma in the emergency department setting. In pursuit of that mission, the NHLBI funded six Institutional Training Awards in Emergency Medicine (EM) Clinical Research to support the establishment of multidisciplinary research training centers. The goal is to develop a cadre of emergency medicine clinician investigators capable of pioneering new and innovative research to improve the clinical care of patients with life-threatening cardiovascular, pulmonary, hematologic and traumatic disorders that are frequently seen in the emergency department.

The clinical training centers started on July 1, 2011 and will each be funded for five years. Training includes clinical research methodologies, statistics, and research ethics as well as comprehensive training in the unique procedures required to collect data in emergency care settings. Drs. Nathan Kuppermann and James Holmes

Jr., Department of Emergency Medicine, School of Medicine, The Regents of the University of California, Davis, Sacramento, CA direct the program “**Developing the Next Generation of Emergency Medicine Researchers (D.A.N.G.E.R.)**”.

This unique program will train five post-doctorate scholars from various disciplines for a 3-year period, with a special focus on participation and leadership in pediatric multicenter research via access to two pediatric EM research networks; the PECARN and the Western Emergency Services Translational Research Network (WESTRN), a consortium of emergency departments within Clinical and Translational Science Award (CTSA) centers. This program reflects the NHLBI’s commitment to the emergency medicine community, and its commitment to help prepare clinician-scientists for future careers in emergency medicine, pediatric emergency medicine research, academics, and leadership.

PECARN Timeline of Funding and Important Events

In 1993, the Institute of Medicine (IOM) published a report on Emergency Medical Services for Children and highlighted several issues associated with pediatric emergency care at the time. These areas of concern included: appropriate training and education among healthcare providers; appropriate supplies and equipment; pediatric-specific protocols and medical control; and strategies for categorization and regionalization.

Additionally, communication, planning, evaluation, and research were highlighted as activities needed to improve pediatric EMS in the future. As a result of these findings, the IOM made several recommendations for improving both pediatric emergency care and seven priority areas of associated research efforts. Fourteen years after its initial report, the IOM published *Emergency Care for Children: Growing Pains*,

highlighting successes since the 1993 report and issues still needing attention regarding pediatric emergency care.

The EMSC recommendations were updated for the Department of Health and Human Services to define a strategy for research organization and funding, including the following considerations: training investigators; standard pediatric-specific data elements in registries; development of multi-center research networks; involvement in the grant review and research advisory process; and improved research coordination through a dedicated institute. In this report, PECARN was cited as a model for conducting high priority research. Now in its 10th year, PECARN has published more than 30 papers and 60 abstracts and continues to make invaluable contributions to the field of pediatric emergency care.

Go to the next page for PECARN timeline.



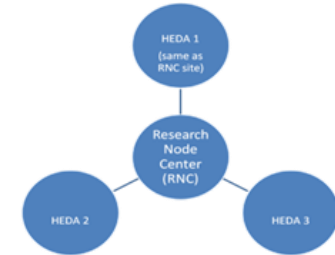
Funding and Important Events



1984—Congress authorizes the use of Federal funds to expand and improve emergency medical services for children in each state.



2007—The Institute of Medicine publishes *Emergency Care for Children: Growing Pains* and includes recommendations to address issues in pediatric emergency care research. In this report, PECARN is cited as a model for conducting high priority research.



September 2011—HRSA issues six competitive awards of up to \$630,000 to establish the new 6-node PECARN infrastructure with 18 HEDAs.



June 2001—HRSA awards cooperative agreements to four research node centers to establish the infrastructure for PECARN.



2002—HRSA issues an award for the Central Data Management and Coordinating Center (DCC) to support PECARN data functions.



September 2005—HRSA issues four competitive awards of up to \$700,000/year for three years to the four existing PECARN nodes.

September 2011—PECARN celebrates its 10th anniversary as the nation's leaders in pediatric emergency care research.



June 2003—PECARN publishes its first peer-reviewed paper in *Academic Emergency Medicine*.



July 2007—PECARN publishes the findings from its first RCT in the *New England Journal of Medicine*.



September 2008—HRSA issues four competitive awards of up to \$890,000/year for three years to the four existing PECARN nodes



GLEMSCRN Node

- University of Michigan, Ann Arbor, MI
- Children's Hospital of Michigan, Detroit, MI
- Nationwide Children's Hospital, Columbus, OH

HOMERUN Node

- Cincinnati Children's Hospital Medical Center, Cincinnati, OH
- St. Louis Children's Hospital, St. Louis, MO
- Children's Hospital of Wisconsin, Milwaukee, WI

PEM-NEWS Node

- Children's Hospital of New York, New York City, NY
- Children's Hospital Colorado, Denver, CO
- Texas Children's Hospital, Houston, TX

PRIDENET Node

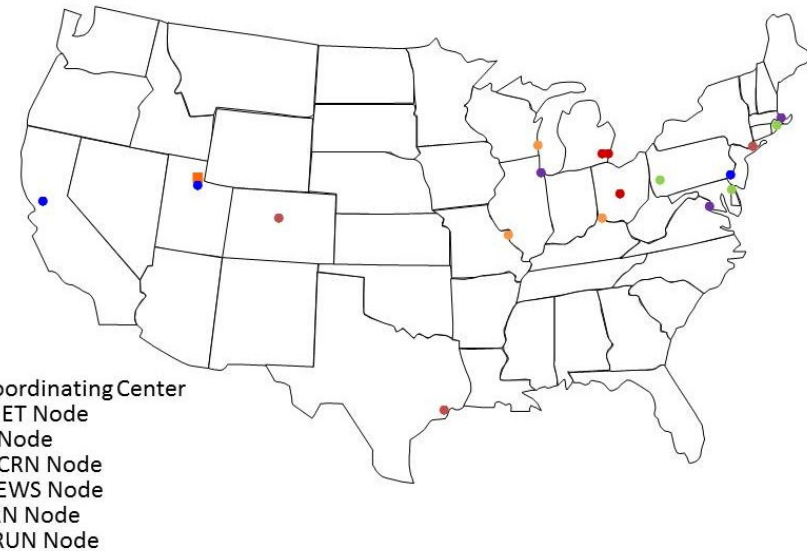
- Children's Hospital of Pittsburgh, Pittsburgh, PA
- Hasbro Children's Hospital, Providence, RI
- A.I. duPont Hospital for Children, Wilmington, DE

PRIME Node

- University of California, Davis, CA
- Children's Hospital of Philadelphia, Philadelphia, PA
- Primary Children's Medical Center, Salt Lake City, UT

WBCARN Node

- Children's National Medical Center, Washington, D.C.
- Children's Memorial Hospital Chicago, Chicago, IL
- The Children's Hospital Boston, Boston, MA



PECARN is supported by the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Emergency Medical Services for Children (EMSC) through the following grants:

DCC	U03MC00008	University of Utah
GLEMSCRN	U03MC00003	University of Michigan
HOMERUN	U03MC22684	Cincinnati Children's Hospital Medical Center
PEM-NEWS	U03MC00007	Columbia University Medical Center
PRIME	U03MC00001	University of California Davis Medical Center
PRIDENET	U03MC22685	Children's Hospital of Pittsburgh
WBCARN	U03MC00006	Children's National Medical Center



See PECARN History Article for an overview of PECARN studies

TBI-KT

The study entitled “Implementation of the PECARN Traumatic Brain Injury Prediction Rules for Children Using Computerized Clinical Decision Support (CCDS): An Interrupted Time Series Trial” is funded by the American Recovery and Reinvestment Act - Office of the Secretary (ARRA OS): Grant #S02MC19289-01-00. The overall goal of the study is to promote the appropriate use of cranial CT for children with blunt head trauma by creating a generalizable model to translate the PECARN TBI prediction rules into clinical practice. The study is progressing well. After completing focus groups and ED workflow evaluations, the electronic health record blunt head trauma data collection tool has been developed, usability testing has been performed, and the data collection system has been refined. In October 2011, the data collection will begin prior to implementation of the computerized clinical decision support (CCDS) to assess CT use for children with minor blunt head trauma. After the data collection, the CCDS will be implemented and CT use will be measured in order to assess the effectiveness of the intervention.

PECARN REGISTRY

This grant was recently awarded RO1 funding from AHRQ. This project will establish a data registry from electronic health records at four PECARN sites to collect and report quality measures of emergency care provided to children. Measurable benchmarks will be established and a clinician feedback intervention will be implemented to improve performance. The project will allow systematic and widespread collection and reporting of performance and outcomes and is critical to allow clinicians and emergency care stakeholders to improve care beyond the local level.

TBI

Data is being continuously analyzed and manuscripts are being published from the TBI project. Since the last update in April, one more manuscript is in press (*Isolated Mechanism of Injury and Risk of TBI*), and several others ready for review including: *IVH in Children with Head Trauma*, *Racial and Ethnic Disparities in CT use after Pediatric Head Trauma*, and *The Association of Scalp Hematomas and TBI*. Several more manuscripts are nearing completion. To maintain our presence and visibility at national meetings, two abstracts were accepted for presentation at the 2011 AAP meeting (*Sports-related TBI* and *Racial and Ethnic Disparities in CT use after Pediatric Head Trauma*). The latter abstract has been selected for a special press release by the AAP. This brings the total productivity of presented abstracts and published manuscripts to well over 20 for this project. All substudies should be submitted for publication by early 2012.



Conducting High Priority,
High-Quality Research in
Pediatric Emergency Care

PECARN CORE DATA PROJECT

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information about all ED patient visits from each participating hospitals within PECARN. The PCDP has data from 2002-2008 and has been instrumental in hypothesis generation and grant acquisition for PECARN. All locked PCDP Data for 2002 – 2008 are now available in the cubes. For preliminary analysis of PCDP data, PECARN can use the cubes or complete a data request form (found in the PCDP eRoom). The cubes can be accessed at <https://www.utahdcc.org/reportportal>. Contact Greg Chandler at greg.chandler@hsc.utah.edu to obtain or reset cube logins and passwords. For any questions, please contact Libby Alpern at alpern@email.chop.edu.

IAI

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in 2006. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Enrollment began in May 2007 and ended in January 2010. 12,044 patients were enrolled with a capture rate of 80.9%, including 762 patients with an IAI. Thanks to all for their hard work! Data cleaning is complete and the decision rule has been generated. Analysis and paper writing is ongoing. Initial results were presented in May and June 2011 at the PAS and SAEM meetings. Additional results will be presented at the upcoming PAS meeting.

EMS

An abstract for this project has been accepted for presentation at the National Association of EMS Physicians annual meeting. Data were reported for 521,239 runs from 14 partner EMS agencies covering the years 2004 to 2006. Data collection for this project is complete and manuscript writing is ongoing.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continues to enroll like gang busters! To date, the study has screened a total of 2060 subjects, 458 were eligible and 255 have been randomized. A total of 32 sites are enrolling and an additional 4 sites are coming on board. The participating sites have shown true commitment to the study and thanks to everyone for their hard work on the project.

IAF-APPENDIX

Congratulations to the study PI Madelyn Garcia, MD, MPH! The abstract was accepted as an Oral Presentation at the SAEM 2011 Annual Meeting. The IAF-Appendix Study aims to examine the role of intra-abdominal fat in CT imaging with IV contrast in visualizing the appendix and to determine if it is possible to predict which patients will have adequate intra-abdominal fat, and thus forgo oral contrast.

MAGiC

Thirty four patients have been enrolled to date with plans to add several new sites to boost enrollment. All sites continue to pre-consent, and several pre-consented patients have been subsequently enrolled. Thanks to the sites for their diligent screening efforts!



FLUID

FLUID, a prospective randomized clinical trial using a factorial design, will determine whether variations in the rate of administration and sodium content of rehydration fluids during pediatric DKA treatment are associated with differences in neurological outcomes. The NICHD-funded study will enroll 1,510 patients over five years at 10 PECARN centers. Drs. Nathan Kuppermann and Nicole Glaser, Study Principal Investigators, are excited that all ten sites are enrolling with 108 patients enrolled so far. Additionally, the study will compare neurocognitive function in children with diabetes who have experienced DKA to that of children with diabetes who have not experienced DKA. The "non-DKA" comparison group enrollment is getting started now with the lead site piloting and other sites currently submitting to their IRBs. Regular webinars for RCs and PIs are being held, and the study leadership is communicating on a weekly basis. The whole team is doing great, and steady progress is being made!



PATIENT SAFETY

Since July 2007, over 22,000 incident reports have been submitted in the DCC for the Patient Safety study. The first year of incident reporting data is being analyzed and various manuscripts are currently being written regarding falls, radiology errors, laboratory errors, and process variance errors. One manuscript on medication errors has been submitted to *Annals of Emergency Medicine*. A manuscript on the methodology of the study was submitted to *Academic Emergency Medicine* earlier this year. In addition, a grant was submitted to AHRQ in early October.

BIOSIGNATURES STUDY

Since the Biosignatures study started, sites have collected over 2,400 1ml Biosignatures samples, with over 710 having been collected just this year (January-September 2011). Since March, sites have collected over 375 PCT samples. Sites are currently enrolling at a rate of approximately 78 samples per month. The goal is to collect 1,000 Biosignatures samples by the end of 2011. In addition to collecting blood samples in febrile infants, a protocol amendment was recently released to conduct a retrospective review on the rate of Bacteremia and Serious Bacterial Infection (SBI) in infants 60 days of age and younger.

C-SPINE INJURY IN CHILDREN

Case-control analysis: The results of our primary analysis were published in *Annals of Emergency Medicine* this August. The manuscript for the utility of plain films in the diagnosis of CSI in children was accepted for publication in *Pediatric Emergency Care*. Drafts on three additional manuscripts are currently in progress addressing method of spinal immobilization in children less than 2 years old at risk for CSI, outcomes of children with CSI stabilized at outlying hospitals and SCIWORA. Six other manuscripts are in development: age stratification analysis, description of CSI patterns in children, inter-observer agreement, AARS, sports-related cervical spine injury and epidemiology of CSI in children.

EMS FOCUS GROUP

This aspect of the study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed to limit immobilization to children who are at non-negligible risk for C-spine injury. Focus groups and focused interviews with all echelons of EMS leadership were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, D.C. and Baltimore. All transcripts were reviewed and comments were categorized into topics such as qualities, beliefs, barriers, motivators and suggestions. The manuscript was accepted for publication in *Academic Emergency Medicine*. **Future Directions:** Study investigators with assistance of nodal leadership are reconsidering opportunities for collaboration to continue work aimed at refining, validating and implementing a Pediatric C-Spine Injury Risk Assessment Tool and to identify best imaging practices.

PROGESTERONE

In preparation for a future clinical trial, the Progesterone study is currently conducting a prospective yield study to pilot the inclusion/exclusion criteria, and determine study feasibility. Training sessions were held in late June and early July 2011 and all sites are currently enrolling. The study has enrolled a total of 103 patients thus far.

QUALITY OF CARE

The long-term objective of our study is to create a generalizable quality of care instrument that can be used to improve the quality of care provided to children in the ED. This will be accomplished by validating and applying a previously developed implicit review instrument that measures quality of care delivered to children in EDs. A study training session was held for Research Coordinators and Site PIs in Salt Lake City in July and the study officially started on 10/1/2011.

SEIZURE

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) continues to enroll at 10/11 participating sites. With a total of 274 overall patients enrolled (233 of which meet Modified Intention to Treat (MITT) criteria), we have now met approximately 89% of our projected enrollment numbers. Enrollment is anticipated through Spring 2012.



GLEMSCRN Node

Led by Rachel Stanley, MD, MHSA, of the University of Michigan, GLEMSCRN also includes Children's Hospital of Michigan (CHOM), and Nationwide Children's Hospital. Dr. Stanley has been involved in GLEMSCRN since its inception. Her research interests include traumatic brain injury (TBI) access to care and health services research. She leads the study *Progesterone*. Dr. Alexander Rogers is the PI at the U Mich. His research interests include procedural pain in the pediatric ED. Dr. Mahajan is the PI for CHOM. His research interests are access to care and evaluation of fever and mental health. Dr. Mahajan leads the *Biosignatures* project. Dr. Bema Bonsu is the PI at Nationwide. His research interests include acute infections and inflammatory conditions, sickle cell disease and surveillance tools in the ED for monitoring emerging infections and acts of bioterrorism.

HOMERUN Node

HOMERUN represents the three Midwestern cities, Cincinnati, Milwaukee, and St. Louis, all in baseball's National League Central Division. As previous HEDAs in the network, we were PIs of the EMSC-TIG grants - C-spine study (Leonard, Jaffe) and both Diagnostic Groupings and ED Performance Measures (Alessandrini) and now MAGIC (Brousseau). All sites have CTSA's and have committed resources to develop the next generation of EMSC researchers. HOMERUN's interests for future projects include Implementation / Knowledge Translation work, reducing imaging in abdominal pain (Brodzinski, Alessandrini), prospective work in C-Spine Injury (Leonard) and translational research in mild TBI (Babcock). Strengths across the node include research cores in proteomics and genomics, bioinformatics, imaging research and other research infrastructure.

PEM-NEWS Node

The **PEM-NEWS** node of PECARN consists of three high-volume, academic children's hospital HEDAs: The Morgan Stanley Children's Hospital of New York-Presbyterian (Columbia University College of Physicians & Surgeons), The Texas Children's Hospital (Baylor College of Medicine), and The Children's Hospital, Colorado (University of Colorado, Denver School of Medicine). The geographic, socio-economic, cultural and language diversity of PEM-NEWS sites provides substantial generalizability to study findings. Each has a strong history of sustained leadership in and successful completion of multicenter research within PECARN and the Pediatric Emergency Medicine Collaborative Research Committee of the AAP. The PEM-NEWS sites and lead investigators, Drs. Dayan, Kwok, Macias and Bajaj, together create a group of researchers with a particularly strong commitment to knowledge translation.

PRIDENET Node

The "**PRIDENET**" node, the **Pittsburgh, Rhode Island, Delaware NETwork**, with the Children's Hospital of Pittsburgh as the lead site, is the newest addition to PECARN. PRIDENET has an annual volume of 170,000 ED visits per year. The site PIs are Robert Hickey (P), Thomas Chun (RI) and Jonathan Bennett (DE). The investigators at these sites bring experience in research related to urinary tract infections, apparent life threatening events, acute otitis media, resuscitation, simulation training, traumatic brain injury, basic science research related to pathways of neuronal cell death, ED ultrasound, substance abuse, brief interventions for health behavior change (Dr. Chun is triple boarded in Pediatrics, Pediatric Emergency Medicine, and General Psychiatry), procedural sedation, intussusception and clinical prediction rules.

PRIME Node

We are the **Pediatric Research in Injuries and Medical Emergencies (PRIME)** node of PECARN, with Dr. Nathan Kuppermann as nodal PI. Our HEDAs include: The University of California, Davis (RNC) under the joint direction of Dr. Kuppermann and Leah Tzimenatos (HEDA PI), Children's Hospital of Philadelphia (Elizabeth Alpern, HEDA PI and nodal co-PI) and Primary Children's Medical Center at the University of Utah (Douglas Nelson, HEDA PI). Our core membership also includes: Walton Schalick, Ethics Consultant; Kathy Shaw, Epidemiology Core Leader; James Holmes, Trauma Consultant; and Emily Kim, Nodal Administrator. Our primary nodal objective is to perform high-quality research in pediatric trauma care, quality measures in PEM, infectious disease emergencies, knowledge translation, randomized controlled trials, and comparative effectiveness research.

WBCARN Node

The Washington-Boston-Chicago Applied Research Node (WBCARN) is made up of three Hospital Emergency Department Affiliates (HEDA): 1) Children's National Medical Center in Washington, D.C. (PI Kathleen Brown, MD), 2) Children's Hospital Boston (PI Lise Nigrovic, MD, MPH), and 3) Children's Memorial Hospital in Chicago, IL (PI Elizabeth Powell, MD, MPH). The Nodal PI is James Chamberlain, MD at Children's National. While WBCARN represents a new nodal structure in PECARN, each of its participating EDs and network PIs have been long-time active contributors to the network. The overall goal of the WBCARN is to improve the health of ill and injured children by contributing to generalizable knowledge gained through the conduct of rigorous, high-quality translational research and to contribute meaningfully to all (T1-T3) phases of translational research.



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DATA COORDINATING CENTER

The Central Data Management and Coordinating Center (CDMCC) has officially changed its name to Data Coordinating Center (DCC). Mike Dean, the Principal Investigator, and Sally Jo Zuspan, RN, MSN, the Program Director, lead the DCC in its responsibilities to implement PECARN-wide standards for data collection. Our goal is to ensure uniformity and quality of the data, and monitor the safety and timely progress of PECARN studies. The DCC includes four Project Managers, Heather Gramse, Marci Fjelstad, Hai Le and Marie Kay. Each one is the main point of contact for PECARN sites and is assigned to manage studies for the study investigator team. The DCC works with many statisticians and data managers who all contribute to PECARN studies.



MARIE T. KAY, BA, CCRC, recently joined the CDMCC as a Project Manager. In 2004, she earned her degree in Psychology and Anthropology from UW Madison where her research career began. She spent an exciting 3 years researching primates in both the lab and the rainforest eventually paving her way into human research. For the past 4 years, she has coordinated clinical trials in numerous therapeutic areas from pediatrics to geriatrics. For fun, she loves to rock climb, ski, and spend time with her family and friends. Marie is delighted to join the PECARN team.

GLEMSCRN Node



KATIE MARHEFKA joined the staff at Nationwide Children's Hospital in May, 2011. She graduated with a BS in Biological Sciences from Ohio University and an MPH from The Ohio State University. Katie grew up in Columbus, Ohio and enjoys cheering on the Buckeyes. She enjoys spending time with her family, friends and her black lab Tobi.



SUSAN GAILEY joined the staff of Nationwide Children's Hospital Emergency Medicine in January 2011. She has been a Research Coordinator for five years and recently obtained her CCRC certification. She is originally from Cleveland and graduated from the Ohio State University. She enjoys traveling, white water rafting, and camping.



RAHSHELL STEPHENS is a new Research Coordinator at the University of Michigan Hospital. She obtained her M.S. in Clinical Research Administration from Eastern Michigan University. Rahshell enjoys traveling, and spending time with her poodle Basil. She is excited to be a part of PECARN, and looks forward to learning with such a great team.

HOMERUN Node



RICHARD RUDDY, MD, is the new Nodal Principal Investigator for the HOMERUN node. His clinical research focus is respiratory illness and improvement science / knowledge translation in EMSC. He is director of the Division of Emergency Medicine at Cincinnati Children's Hospital Medical Center and Professor of Pediatrics at the University of Cincinnati College of Medicine.



MELANIE HOUNCHELL, BA, CCRC, is the new Nodal Administrator for the HOMERUN node. Ms. Houchell has served as the Clinical Research Manager for the Division of EM since 2005. She has 13 years of experience in Clinical Research and has been ACRP certified since 2002. She coordinated over forty multi-center clinical trials. Ms. Houchell has been active in the PECARN network since 2005, having overseen 8 PECARN studies. Ms. Houchell was a member of the Feasibility and Budget Subcommittee from 2007-2009.



PRIME Node



Britta Ameel, MFA, began as a student in the Academic Associate Program and shifted from temporary research assistant work to full-time clinical research coordinator as of this past June. She coordinates DKA, Seizure, and Progesterone studies and is currently applying to medical school for fall of 2012. She's married and has a MFA in creative writing from the University of Michigan. She's a poet and non-fiction writer and

PRIDENET Node



ROBERT HICKEY, MD, FAAP, FAHA, is the Principal Investigator for the PRIDENET node. He is an Associate Professor of Pediatrics at the University of Pittsburgh and serves on numerous committees within the American Heart Association including work related to the development of the PALS curriculum.



THOMAS H. CHUN, M.D., M.P.H., FAAP, is the Principal Investigator of the Rhode Island HEDA Site and an Associate Professor in the Departments of Emergency Medicine and Pediatrics at the Alpert Medical School of Brown University. He is a Fellow of the American Academy of Pediatrics and a member of their Committee on Pediatric Emergency Medicine.



JONATHAN BENNETT, MD, is the Principal investigator for the A.I. duPont Hospital for Children HEDA site in Delaware. He is an Associate Professor of Pediatrics, Jefferson Medical College.

Good Clinical Practice Tip

Q: What is "protected health information", or "PHI"?

A: Health information is defined as any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual. Health information is individually identifiable, and thus is considered to be PHI if there is any reasonable basis to believe that the information can be used to identify an individual.

Source: *Good Clinical Practice: A Question & Answer Reference Guide May 2006*

Submitted by **Hai Le, BS**
PECARN Project Manager

CONGRATULATIONS!

The **PRIME** node would like to congratulate our nodal PI, Dr. Nathan Kuppermann, on his receipt of the 2011 ACEP Award for Outstanding Contribution in Research. This award is given to one person each year. We are also proud to announce that both UC Davis (Drs. Kuppermann and Holmes, PIs) and U Penn (in collaboration with CHOP) are recipients of the K12 Research Career Development awards in Emergency Medicine. Finally, we offer our congratulations to Libby Alpern, who received funding from the Agency for Healthcare Research and Quality for her PECARN Registry project.



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PECARN Newsletter online at:

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