The PRIDENET Node joined the PECARN in late 2011 and worked hard to organize and begin enrolling in PECARN studies. Nodal sites now participate in 5 PECARN studies. To gauge sites’ performance, the first step was to develop meaningful performance metrics to track administrative and enrollment statistics for all studies. The node reviews these metrics monthly to assess study progress. The data are kept in an Excel spreadsheet with separate tabs for each study as well as a summary tab for overall enrollment (Fig. 1 on following page). Each site has a study specific table to track enrollment metrics and a separate table for tracking timelines for administrative activities (IRB submissions, project deadlines, etc.). The enrollment metrics are categorized as: Screened, Eligible, Approached, Enrolled, and Missed Eligible. This format filters the numbers in a step-wise manner that generates useful performance data. The screened category is the most broad, encompassing all patients that warrant further chart review to determine eligibility. After screening, eligibility is determined. A number of eligible patients presenting to a respective institution within a defined time frame can then be determined. Metrics are reviewed monthly while also keeping cumulative totals. Next, the approached category captures all eligible participants that were approached by a qualified member of the study team with the intent of enrollment. The enrolled category is a measurement of all the approached patients that were successfully enrolled as study participants. Enrolled is a broad term that facilitates generalization of one standard term applicable to a variety of study designs. In the clinical trials, this would be akin to the consented and randomized rates. Finally, the missed eligible column accounts for all patients who were eligible but not enrolled for a number of reasons, including being missed by the study team or refused participation, deemed inappropriate, etc. There is a final column for notes that allows the study coordinators to comment on special circumstances, especially in relation to missed eligible participants.

Through evaluation of the performance metrics, PRIDENET was able to identify a trend that hindered study enrollment. It became clear that failure to identify and enroll eligible participants by physicians, overnight, was a common issue. This is likely due to the fact that there is less research staff support at sites after 11 pm and that the doctors are busy with the demands of patient care. However, PRIDENET could not ignore this opportunity to boost enrollment. The node generated a system for better educating enrolling physicians by providing easier access to inclusion/exclusion criteria, in the form of laminated posters in each care team station, resident, and physician work room, as well as sending individualized reminder e-mails generated by the study PI, to physicians if an eligible patient is missed. Identifying this trend and formulating a plan to rectify the situation turned out to be beneficial on many levels. Not only did the increased information and communication with physicians help to bolster awareness and level of knowledge of the PECARN studies, but the initiative also helped facilitate collaboration between members of the PECARN study team and members of the hospitals’ health care team. The node observed an increased capture rate of eligible patients who were approached and enrolled into the study and a decrease in reports of missed eligible participants due to failure of physicians to enroll overnight, validating the success of the action plan.

This example is just one of many demonstrating that clearly defined metrics, real-time internal tracking of study performance, and performance evaluation, are effective tools to identifying trends in enrollment and potential areas for improvement. From the raw data it is easy to
Q: How should I document study staff training at my site?

A: The FDA’s regulations do not specify how to document training for site staff nor do they specify what training is required. The regulations hold the investigator responsible for the conduct of the study at their site. Therefore, the investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience. According to the ICH E6 GCP 4.1.5, the site should maintain a list of the study staff and at a minimum, the list should include:

- Description of the study related task
- Any training which individuals have received that qualifies them for the task
- Dates of the individuals’ involvement with the study

Study sponsors have discretion in determining what qualifications, training, and experience are needed for a particular trial. Therefore, they may request that your list include additional information.

The DCC assists investigators with study training materials. Moodle is a new DCC tool to help provide proper and consistent training for PECARN studies. Moodle provides documentation of completion of course material. See page 6 for more information.

Submitted by: Sara Mesley
EMSC Performance Measures Reassessment
On May 1, 2013, the Health Resources and Services Administration, Maternal and Child Health Bureau (MCHB) will begin conducting a re-assessment of the EMS for Children performance measures. Periodically Congress requests a report on the progress of the performance measures. Each state is required to participate in the re-assessment. The following measures will be reassessed from May 1, 2013-February 28, 2014.

Performance Measure 71: The percent of prehospital provider agencies in the state/territory that have on-line pediatric medical direction available from dispatch through patient transport to a definitive care facility

Performance Measure 72: The percent of prehospital provider agencies in the state/territory that have off-line pediatric medical direction available from dispatch through patient transport to a definitive care facility.

Performance Measure 73: The percent of patient care units in the state/territory that have essential pediatric equipment and supplies as outlined in national guidelines.

The National Pediatric Readiness Project
The online Pediatric Readiness Assessment has opened in January for the first cohort of states. The assessment process of this national quality improvement initiative to ensure that all US emergency departments (EDs) have the resources to provide effective emergency care to children ends May 2013. In November 2012, EDs in Maryland, Minnesota, and Guam field tested the online assessment and currently have a combined response rate of over 80%. EMSC State Partnership Managers are coordinating the rollout of the assessment in each state. To find out when EDs in your state will participate in the online assessment, please visit the National Pediatric Readiness website at www.pediatricreadiness.org.

NRC Releases EMSC Targeted Issues Database
The EMS for Children (EMSC) National Resource Center (NRC) has released the EMSC Targeted Issue Database. The searchable database houses information for all Targeted Issue grants dating back to 1991 when the Health Resources and Services Administration's EMSC Program first funded Targeted Issue grants to states and accredited schools of medicine. The database can be accessed at: http://emscnrc.org/historicalgrants/.

Remembering Senator Daniel K. Inouye
Senator Daniel K. Inouye (D-HI), one of the fathers of the EMS for Children Program, passed away from respiratory failure December 17, 2012. The Senator, who was 88, advocated for the development of EMS programs that decrease disability and death in children and sponsored legislation that led to the establishment of the EMS for Children Program in 1984. Most recently, he sponsored the Wakefield Act, legislation to reauthorize the Program, in the 109th, 110th, and 111th Congresses. He remained a lifelong friend of the Program and champion for improving pediatric emergency care, receiving the "EMSC Champion for Children" award during the 2009 EMS for Children Program Meeting.

EMSC Targeted Issues Funding Opportunity
The Health Resources and Services Administration (HRSA) has released its funding opportunity announcement (FOA) for the Emergency Medical Services for Children (EMSC) Targeted Issue Demonstration Project. There are two categories of applications. The purpose of both categories is to improve pre-hospital pediatric research:

Category I: Emergency Medical Services (EMS) will demonstrate the ability of EMS systems to conduct pediatric pre-hospital research by establishing an EMS Research Node Center (E-RNC) for PECARN.

Category II: Traditional investigator-initiated ideas focused on promoting research and quality improvements in pediatric emergency care. Applications are due April 9, 2013. The full FOA is available at: http://www.grants.gov/search/search.do;jsessionid=pT62QnMJLD1tv0J1GKVQTSnXv9DmxYsJwSmhYMGDLc57MnbRNJkW!1043239538?oppId=214654&mode=VIEW/
MAGiC

All eight sites are actively enrolling and a total of 134 patients (64% of enrollment goal) have been enrolled as of January 2013! Routine site and pharmacy monitoring is underway and a second interim DSMB meeting is scheduled in late Spring. If enrollment at our current rate continues, we will finish this year. Thanks to all for their commitment to this study’s success!

PECARN REGISTRY

This project is to establish a data registry from electronic health records at four PECARN sites (CHOP, CCHMC, CNMC, Children’s Hospital Colorado) 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. The data dictionary for the project has been established and we anticipate data for 2012 to populate the Registry within the coming months.

IAI

We continue to analyze data and publish manuscripts from the IAI project. The main paper was published on-line on February 1 in Annals of Emergency Medicine. In addition, we have one manuscript accepted for publication (Interrater reliability of variables for a decision rule). One manuscript is being revised after initial review (Risk of IAI in children with normal abdominal CT scans). One manuscript (Use and Impact of Abdominal Ultrasonography) was just reviewed by GAPS and is being prepared for submission. Three more are close to circulation to collaborators. After that, we have four manuscripts and two more abstracts being prepared. We anticipate an additional 3 – 5 manuscripts prepared from this database.

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 Traumatic Brain Injury (TBI) prediction rules into clinical practice. We are in quarter two of the third year of the grant. We have continued data collection in the clinical trial using the EHR blunt head injury data collection tool and successfully implemented the CDS at four sites. Two of the sites will transition from vendor-specific CDS to web-services based CDS over the next month. With CDS implemented, we will assess if there is a change in the use of CT for children with minor blunt head injury.

Biosignatures Study

In its sixth year of enrollment, the Biosignatures study has now collected approximately 4,400 Biosignature samples and 1,700 PCT samples. Enrollment has been progressing at an impressive rate which is owed to the hard work of the 19 actively enrolling sites! The total enrollment goal is 4,800 with recruitment expected to continue through May 2013. Two papers are currently in progress.

ASSESS

Project ASSESS is off to a great start! Sites have been finalizing their consent/assent documents and submitting to their IRBs. The ASSESS training is scheduled for April 2nd in Providence, RI with enrollment beginning shortly after.

EMS

The Prehospital Infrastructure Project has completed its main analysis and manuscript. The manuscript was submitted to Prehospital Emergency Care for publication consideration.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials Out-of-Hospital (OH) trial has been closed because the enrollment target has been met! This is an amazing milestone which couldn’t have been met without everyone’s time and commitment. The final enrollment number for the OH Trial was 295 subjects. The In-Hospital Trial continues to enroll as the enrollment target has not yet been met. To date the study has screened a total of 4130 subjects; 914 were eligible and 485 have been enrolled, of which 190 were IH cases. The participating sites have shown true commitment to the study and we thank everyone for their work on the project!

TBI

We continue to analyze data and publish manuscripts from the TBI project. We have published 10 manuscripts from this study and currently have three manuscripts under review at journals (the Association of Scalp Hematomas and TBI; Risks of Sedation for Children Undergoing CT; and Non-traumatic Findings on CT in Children with Minor Head Trauma). Two others are getting ready to be submitted to GAPS (Practice Variation of CT Use; Isolated Vomiting and TBI), and 6 more are close to circulation to collaborators. We have approximately 5 more manuscripts being prepared. This will eventually bring the total productivity of manuscripts for this project to well over 20! The TBI Public Use Dataset has been released.

IAF-Appendix

This study’s aim was to determine how the adequacy of intra-abdominal fat impacted the ability of radiologists to detect a normal appendix on CT scan. The study is completed and a manuscript is under review for publication.
PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information on all ED visits from each participating hospital within PECARN. These data have been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2011. The PCDP Demographic Reports have been generated to reflect 2002 – 2011 data and can be found in the Report Manager tool https://rm.utahdcc.org/reports. Beginning April 1, 2013, these reports will be available through the DCC SharePoint site at https://sp.utahdcc.org. PCDP data from 2002 – 2012 are currently available in the cubes which can be accessed at https://www.utahdcc.org/reportportal. Information about using the cubes, is available in the eRoom in the PCDP eRoom. If you need help with access, please contact Sara Mesley at the DCC. For preliminary analysis of PCDP data, PECARN members can use the cubes or complete a data request form that can be found in the PCDP eRoom. Data submission for 2012 will be accepted via XML or CSV. The MOO, with updated data submission instructions, is available in the PCDP eRoom. April 15, 2013 is the deadline for data submission from all sites for 2012 data. For any questions, please contact Libby Alpern at alpern@email.chop.edu.

Progestrone

In preparation for a future clinical trial, the Progestrone study has completed a prospective yield study to pilot the inclusion/exclusion criteria, as well as test accrual feasibility. We enrolled 295 patients at 16 sites. We presented a poster at the National Neurotrauma Society annual meeting in July 2012, and the manuscript is being prepared. Concurrently, there is ongoing work at two laboratories (AT Emory University and Boston Children’s) involving preclinical testing of progesterone in juvenile rats and mice. The preclinical work and the prospective yield study are important to inform a future large grant application for a clinical trial of Progestrone for head-injured children.

Seizure

The Lorazepam study is completed. Many thanks to site investigators and research coordinators for lots of long hours enrolling over 300 patients. Data have been cleaned and most analyses have been performed. Public disclosure activities will be ongoing through May 31, 2013 at all sites that enrolled patients into this trial, per EFIC Guidelines. Results of the clinical trial will be presented at the PECARN Steering Committee in March.

Quality of Care

The long term objective of the study is to create a generalizable instrument to measure quality of ED care that can be used to improve the quality of care provided to children in the ED. We will accomplish this by applying and further validating a previously developed implicit review instrument that measures quality of care delivered to children in EDs. Data collection at the performance sites is now complete. Physician reviewers are conducting quality assessments and assigning scores, of which 99% have been completed. A Nurse Researcher has started the review process for the Gausche-Hill instrument for the purpose of validating the quality of care instrument. The review process will be completed by spring 2013.

Patient Safety

Manuscript writing is ongoing in the Patient Safety and NYS Patient Safety studies. Progress is being made on writing manuscripts involving diagnostic errors, falls, laboratory errors, process variance errors, radiology errors, and the NYS Patient Safety data. An abstract on near-miss and unsafe conditions was submitted to PAS this year. A paper on medication events (Reported medication events in a paediatric emergency research network: sharing to improve patient safety) was published in “Emergency Medicine Journal”, while a manuscript on the infrastructure of the study (Creating an infrastructure for safety event reporting and analysis in a multi-center pediatric emergency department network) will soon be published in “Pediatric Emergency Care”.

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 DKA patients and 400 non-DKA patients over five years at 13 PECARN centers. We have enrolled 425 DKA patients to date. All new sites are currently enrolling and doing a great job! We have also enrolled 57 "non-DKA" comparison patients – children with type 1 diabetes who have never had DKA. Our “Methods” manuscript was recently accepted for publication in Pediatric Diabetes. We have also recently submitted an ancillary study grant application to the NIH to investigate cerebral hemodynamics in children with DKA. A second ancillary study, investigating biomarkers of cerebral injury, is in the protocol-writing phase. The study is going well, the team is great, and we are anticipating ongoing enrollment.

C-Spine Injury (CSI) in Children

Case-control analysis: We published the primary analysis in Annals of Emergency Medicine. The manuscripts for the utility of plain films in the diagnosis of CSI in children and for the method of spinal immobilization in children less than 2 years old at risk for CSI were published in Pediatric Emergency Care. Seven other manuscripts are in progress.

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. The manuscript was published in the February 2012 issue of Academic Emergency Medicine.

Future Directions: An R21 was submitted to the NICHD to fund a HOMERUN pilot aimed at prospectively refining, validating and implementing a Pediatric C-Spine Injury Risk Assessment Tool in the pre-hospital and ED settings. The grant scored at the 14th percentile and either will be funded or undergo revision.
The Research Coordinator Advisory (RCA) Committee continues its efforts to provide meaningful collaborative experiences in which RCs contribute to the mission of PECARN. We have a saying, coined by Duke Wagner of MCW, “We don’t want more to do, but smarter ways to do things better”. We recognize how busy the RCs are and appreciate that they participate in additional projects in order to develop ways to do things better. Some of the projects that we are currently pursuing include:

- Compilation and publication of the RC poster data presented at the November meeting, led by Kammy Jacobsen (UofU)
- Standardization of terminology for performance metrics, led by Duke Wagner (MCW)
- Developing best practices for study implementation; a collaborative effort with the QUASI committee, led by Melissa Metheney (Nationwide)
- The PECARN Research Coordinators Blog, led by Clare Levijoki (UMich)

We also have reviewed some of the new protocols being developed within the network and have been pleased to provide the RC perspective on implementation. Feedback from investigators indicates that this is a valuable process and helps to identify problems that can be addressed before IRB or grant applications are submitted. If you have a project or protocol that you would like RC collaboration with, please contact the committee chair, Kammy Jacobsen kammy.jacobsen@hsc.utah.edu

DCC Corner

Moodle is an online interactive course management system for PECARN studies. Moodle allows users to access recorded presentations, quizzes and videos to learn or review study information. We have designed Moodle modules to be brief; each lesson will be about 10-15 minutes in length. Thus, research staff can access Moodle and orient to a study on their own schedule. Moodle also provides a training certificate after successful completion of the course or module. The DCC will include Moodle course completion as a pre-requisite prior to study start-up. Ideally, making training courses more accessible to participating clinicians and research coordinators will help train staff and shorten study start-up time.

We have uploaded several presentations for the PECARN FLUID Trial into Moodle for your review. Presentations will be uploaded into Moodle for the upcoming ASSESS study so that training will be available for those unable to attend the physical training. Moodle became accessible to all PECARN FLUID members on February 15 at https://elearning.utahdcc.org/course/view.php?id=21. Log into the Moodle system using your eRoom account information. More information will be available from the DCC project managers in the coming months.

NEW and Improved

DCC Study Reports

The Data Coordinating Center has improved the way we make network and study-specific reports available to sites. The old system, Report Manager, will be replaced shortly with a new, more user friendly reporting system. This system will allow Research Coordinators, Nodal Administrators, Principal Investigators, and others to access PECARN study reports at any time using the DCC Reporting website. Total enrollment numbers, demographic reports and other useful information will now be available through this website: https://sp.utahdcc.org/.

This new reporting system offers advantages over Report Manager. Reports can be easily accessed using your DCC username and password. This system also allows study reports and study data to be exported into various formats. As this service is further developed, sites can use the data to assist with nodal performance metrics and monitoring. PECARN reports will ‘go live’ on April 1, 2013. More information will be coming via email to notify you when these reports are ready.
As always, the PRIDENET Node is happy to announce that it is alive and well. We are very excited for the imminent launch of the ASSESS study and hope to see many of you at training in April! Thank you to the DCC and Hasbro for all of your time and effort in the development of this protocol. The node has hired a new Research Coordinator at Children’s Hospital of Pittsburgh of UPMC. Amy Russell, RN was previously a nurse in the ED at Children’s of UPMC before joining the PECARN family. She is enjoying her new job and very much looking forward to meeting everyone in March!

WBCARN

Samira Shahzeidi, CCRP, Research Coordinator for the MAGiC Study, based at Children’s National Medical Center, has been accepted into medical school and will be leaving WBCARN in July 2013. Congratulations, Samira, and thank you for all of your wonderful work!

PRIME

The PRIME node extends congratulations to Natasha Kwendakwema (CRC, Univ of Utah), who was accepted into medical school and is moving to Connecticut this summer. Congratulations are also in order for Cindy Chang (CRC, UC Davis) who was accepted into medical school at Ohio State University. We would also like to make long-overdue introductions to Justine Cortez (CRC, UCD) and Cindy Chang (CRC, UCD) who joined our team a year ago (pictured together). Justine loves to cook and craft, and is an excellent balloon arranger. Justine plans to teach English in Korea before ultimately enrolling in nursing school. Cindy enjoys photography and painting, and gives generously of her time to a local homeless shelter. She will leave for medical school this summer. We would like to introduce Lane Hollister (CRC, UCD), who recently joined our team after having worked as an ER Scribe at San Francisco General Hospital. Lane loves to surf and ski, and never misses 60 Minutes. Steve Yakscoe re-joined the team at CHOP this past year. Steve earned a BS in Chemistry from the University of Pittsburgh in 2009. He joined CHOP as a Research Coordinator in the fall of 2009 but then took a yearlong position as a military contractor at Camp Lemonnier in Djibouti City, Djibouti. Steve returned to CHOP in September 2012. His interests include ancestral health, rugby, traveling, and reading. Welcome!

New Faces to PECARN

HOMERUN

Please welcome Nicole McClanahan as a Co-Nodal Administrator of HOMERUN. Nicole graduated with a BA in Psychology and minor in Neuroscience from Northern Kentucky University. She married her high-school sweetheart, Matt, in 2009. Nicole joined the Division of Emergency Medicine in 2007. Her key areas of interest and experience are injury prevention, randomized drug trials, and head injury research.

GLEMSCRN

Kim Pham is a new Research Associate at the University of Michigan Hospital, joining the staff in November 2012. She graduated with a BS in Neuroscience from the University of Michigan and hopes to pursue a career in Public Health. In her spare time, Kim enjoys running, yoga, exploring Ann Arbor, and cheering on the Wolverines– Go Blue!
Owen Francis is a DCC Statistician. He began working as a statistical analyst for the DCC in June. He is working on the MAGIC and ASSESS studies. Owen recently graduated from Brigham Young University with an M.S. in Statistics.

Sara Mesley joined the DCC in January as a project manager. She has worked for the University of Utah for the past 5 years coordinating clinical trials. During her work hours, she tackles the PCDP, FLUID, and Registry projects. Sara enjoys biking, skiing, hiking, camping and volunteers with local animal shelters.

Andi Thomas has been with the University of Utah in general admin since 2011, this year she will be joining the PECARN team as administrative support. Andi is currently finishing her Clinical Medical Assistant certification. She is originally from Alaska, enjoys baking, snowboarding and until recently played roller derby.

Kent Page, MStat, began providing statistical support for PECARN in April 2012. For nearly four years prior to that, he was a statistician for the National EMS for Children Data Analysis Resource Center (NEDARC). Kent also supports CPCCRN and THAPCA studies. Kent enjoys running and cycling and being a father of two little girls.

Missy Ringwood, BS, joined the PECARN team in October 2012 as a Clinical Data Manager for FLUID and non-DKA. She has worked in data management for 14 years in the pharmaceutical industry. She is a mother of two boys, ages 12 and 8 and enjoys skiing, boating, hiking and gardening.

Although not an official member of the PECARN staff, this little guy does hang out outside the DCC windows wishing he could help analyze data.

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**Scientific Grant Writing Workshop**

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This is a valuable 2-1/2 day workshop for those who want to improve their skills, receive professional guidance on rigorous research-oriented grant writing, and to learn to:

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