

Winter 2011

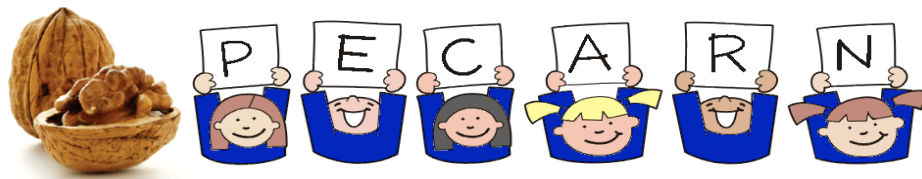
What's Inside?

- > Good Clinical Practice
Tip from the CDMCC
- > Federal Corner
- > Study Updates
- > Nodal News
- > New Faces to PECARN

Contact us:

P.O Box 581289
Salt Lake City, UT 84158
Phone (801) 581-6410
Fax (801) 581-8686

Or visit us online at:
www.pecarn.org



In a nutshell

Spotlight on Studies by Great Lakes

Investigators from the Great Lakes Node (GLEMSCRN) of PECARN have received funding to lead three important PECARN studies. Frank Moler, M.D., M.S., University of Michigan, Prashant Mahajan, M.D., M.P.H., M.B.A., HEDA Principal Investigator, Children's Hospital of Michigan/Wayne State University, and Rachel Stanley, M.D., M.H.S.A., GLEMSCRN Nodal Principal Investigator.

Study on body cooling study for pediatric cardiac arrest

Frank Moler, M.D., M.S. and J. Michael Dean, M.D., M.B.A. are leading a \$21 million, large-scale, multicenter study investigating the effectiveness of body cooling treatment in infants and children who have had cardiac arrest — the first such study of its kind.

Dr. Moler, scientific principal investigator, is a professor in the Department of Pediatrics and Communicable Diseases at the University of Michigan and a co-investigator in Great Lakes Node of PECARN. J. Michael Dean, M.D., M.B.A., principal investigator of the study's data coordinating center, is a professor of pediatrics, chief of the Division of Pediatric Critical Care Medicine at the University of Utah School of Medicine, and the PI for the PECARN Central Data Management Coordinating Center (CDMCC). Also known as the Therapeutic Hypothermia after

Pediatric Cardiac Arrest (THAPCA) trials, the work is being conducted over a six-year period in 34 clinical centers in the United States and Canada with funding from the National Heart, Lung, and Blood Institute (NHLBI).

Therapeutic hypothermia, or body cooling, has been successfully used in adults after cardiac arrest and in newborn infants after birth asphyxia, or lack of oxygen, to improve survival and outcomes. Until now, researchers had not studied on a large scale the impact of body cooling in infants or children who have had cardiac arrest.

The THAPCA trials begin to assess the effectiveness of therapeutic hypothermia in children, and should lead to evidence-based guidelines that will optimize both quality and survival rates. During body cooling treatment, participants lie on mattresses and are covered with blankets. Machines circulate water through the

blankets and mattresses to control the participants' body temperatures. Researchers do not yet know how body cooling will affect participants, since many factors can contribute to brain injury after cardiac arrest. However, they believe body cooling could provide several benefits, including less inflammation and cell death.

The THAPCA trials are being conducted in partnership between PECARN and the Collaborative Pediatric Critical Care Research Network, established in 2004 by the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD).



Continued on page 2...

Continued from page 1

Study to evaluate use of RNA Biosignatures to determine cause of fever in infants

Drs. Prashant Mahajan, Octavio Ramilo and Nathan Kuppermann are leading a study investigating the use of RNA biosignatures to distinguish between bacterial and viral infections in young infants with fevers evaluated in emergency departments. This could lead to more rapid and accurate diagnoses and treatment for serious bacterial infections such as bacteremia and meningitis. Prashant Mahajan, M.D., M.P.H., M.B.A., is the PECARN HEDA PI for Children's Hospital of Michigan/Wayne State University, Octavio Ramilo, MD, is chief of Infectious Diseases at Nationwide Children's Hospital and Nathan Kuppermann, M.D., M.P.H., is the nodal PI for the ACORN node of PECARN.

Fever is the third leading cause of emergency department (ED) visits and accounts for 15% of all ED visits in infants 60 days of age and younger. Despite the frequency of fever in young infants presenting to EDs, and the

importance of this topic to emergency medical services for children (EMSC), to date there is no single or combination of clinical parameters and laboratory tests that can uniformly distinguish infants with serious bacterial infections from those with uncomplicated and self-limiting viral or non-bacterial infections. Indeed, there have been no new technologies that have been routinely and successfully applied in the evaluation of these infants and novel, highly accurate tests are clearly needed.

In the current era, however, there are novel methods that may potentially offer higher fidelity in distinguishing among febrile infants with different types of infections. The most exciting advance pertains to a fundamental shift in the way we approach the diagnosis of different infectious diseases. Instead of attempting to detect the pathogens directly, it has become possible to detect the presence of infection by assessing the specific host response to different pathogens.

Advances in genomic sequencing and techniques for conducting high throughput deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) analysis have led to a better understanding of the host-pathogen response during infections. Thus, a novel approach to distinguish young febrile infants infected with bacterial pathogens from those infected with non-bacterial pathogens is to examine the host response to infection. Recent data indicate that different pathogens induce distinct transcriptional "biosignatures" in the RNA of blood leukocytes that can be reliably measured by microarray analysis.

The multi-site study is being conducted at some 20 children's hospitals, within the Pediatric Emergency Care Applied Research Network (PECARN) network.

Funding for the project is provided by the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development.

Study to look at progesterone's effect on children with traumatic brain injuries

Rachel Stanley, M.D., M.H.S.A., GLEMSCRN Nodal PI, has received a two-year grant to plan a randomized controlled study of progesterone to treat traumatic brain injuries in children. Stanley will lead the planning efforts for a future large safety and efficacy trial of progesterone for pediatric traumatic brain injury. Dr. Nathan Kuppermann, M.D., M.P.H., ACORN Nodal PI, will serve as the co-principal investigator on the study. Traumatic brain injury (TBI) is the leading cause of death from trauma, and of death in children. Despite the frequency of TBI (more than 1 million annual cases nationally), its impact on the health of children, and decades of research on the topic, no effective treatment exists for children with TBI. While previous single-center human studies have shown promising

results in adults, and a multi-center study on the use of progesterone for TBI in adults is currently underway in the Neurological Emergencies Treatment Trials Network, no previous studies have included children.

Progesterone is a potent neurosteroid that is naturally synthesized in the central nervous system. Animal studies have shown that early administration of progesterone after experimental TBI reduces cerebral edema, neuronal loss, and limits behavioral deficits in laboratory animals. Progesterone is an ideal candidate for treatment of TBI for several reasons. Progesterone enters the brain rapidly and reaches equilibrium with the plasma within an hour of administration. Progesterone also has a long history of safe use in men and women.

The planning project will establish the inclusion/exclusion criteria and outcomes for a future trial and will include an observational study at 15 PECARN sites to determine how many sites are necessary for a future interventional trial, as well as determining the timing of arrival of a legal guardian for consent purposes. The end product of this planning project will be a protocol for a large safety and efficacy trial of progesterone for pediatric TBI. This project is currently under way with an end date of the fall of 2012.

Funding for this project is provided by the Health Resources and Services Administration, Maternal and Child Health Bureau. The grant is an Emergency Medical Services for Children (EMSC) Targeted Issues Grant.

EMSC Federal Appropriations and Authorization Update

On Tuesday, December 21, both the U.S. House of Representatives and the U.S. Senate approved HR 3082, a fiscal year 2011 continuing appropriations act. For most existing Federal agencies, programs, and activities, this stop gap measure provides funding at the fiscal year 2010 level, through March 4, 2011. Specifically, the bill provides \$21.5 million per year for the EMSC Program during this period. The President signed the bill into law on Wednesday, December 22.

Congress will, however, return to the appropriations process next year, before the act expires on March 4, in order to provide funding for Federal programs from March 5 through the end of the fiscal year, on September 30.

The EMSC Program was reauthorized for five years (fiscal years 2010 to 2014) under the Patient Protection and Affordable Care Act, which was signed into law in March 2010.

HRSA Anticipates Release of PECARN Grant Guidance

The grant guidance for the National Development Demonstration Projects (NDDP) or PECARN is anticipated to be released January 14, 2011. Six new cooperative agreement awards are planned at \$600,000 each year for four years. Each applicant will be expected to partner with two additional Hospital Emergency Department Affiliate (HEDA) sites in addition to their own site (for a total of three HEDA sites) to create a nodal structure that will participate in the PECARN. Applicants will have approximately 60 days from the January 2011 release date to submit an application. Successful applicants will be announced by August 1, 2011, and funding will start September 1, 2011. For more information about the grant competition, please contact Dr. Tasmeen Weik at tweik@hrsa.gov.

EMSC Webcast on PECARN's Pediatric Emergency Care Performance Measures Project

The HRSA MCHCOM EMSC webcast, "Using Performance Measures to Drive Improvement in Pediatric Emergency Care," led by Evaline Alessandrini, has been archived on the MCHCOM website. This webinar addressed the following issues:

- The importance of performance measurement in pediatric emergency care;
- Use of a consensus development process to define a balanced report card for pediatric emergency care;
- Integration of performance measurement into the electronic medical record;
- Examples of how measures have been used to improve pediatric emergency care;

The archived website is available at:

<http://webcast.hrsa.gov/postevents/archivedWebcastDetail.asp?aeid=534>

NRC Thanks You for Participating in the PECARN Evaluation

The EMSC National Resource Center (NRC) would like to thank everyone for completing the PECARN surveys this September. For the past year the NRC has worked with an external group of Stakeholders to develop the PECARN survey questions. The external working group is currently reviewing the respondent answers and a summary analysis will be communicated to the Network.

The NRC Welcomes Roshni Bhimani

Roshni Bhimani, MPH, recently joined the EMSC National Resource Center (NRC) as a new program coordinator working with PECARN and other research and education related projects. She received her Masters in Public Health from Johns Hopkins University and has an undergraduate degree in Biomedical Engineering from the Georgia Institute of Technology. Prior to joining the NRC, Roshni worked as an interventionist for Baltimore Healthy Eating Zones, a food consumption behavior program among Baltimore, MD youth, and as a healthcare consultant in Atlanta, GA. Roshni can be reached via email at rbhimani@cnmc.org or (202) 476-6880.

NRC Launches Website Redesign

The EMSC National Resource Center (NRC) has updated its [website](#) to make it more user-focused. Some of the changes visitors will see include:

- The new homepage features the NRC's most sought-out information: Current News, New Publications, and Upcoming Events.
- Each page provides direct access to the EMSC NRC Facebook, Twitter, and YouTube accounts.



Biosignatures Study

In 2010, sites collected ~822 1 ml samples and ~111 usable QNS samples for a grand total of ~933 samples. Sites are currently enrolling at a pace of approximately 68 samples per month. The study principal investigators have identified the samples with proven bacterial infections and proven viral infections collected during year two, sample analysis is underway and preliminary results will be presented at the January PECARN Steering Committee Meeting. The protocol has been amended to include the changes from the recently funded NIH grant titled 'RNA Biosignatures in the Emergency Evaluations of Febrile Infants' which will extend the sample collection for an additional two years. Under the new grant, sites will continue to collect samples to create the diagnostic biosignatures and will collect an additional sample to evaluate the newer screening test, procalcitonin. A training session is scheduled to take place in conjunction with the January 2011 PECARN Steering Committee Meeting in Miami, FL.

C-Spine Injury (CSI) in Children

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,774 controls. The main manuscript which presents the results of the case-control analysis was published in *Annals of Emergency Medicine*. Manuscripts are being written for 10 secondary analyses: age stratification analysis, description of CSI patterns in children, inter-observer agreement, AARS, utility of plain films in the diagnosis of CSI in children, method of spinal immobilization in children <2 years old at risk for cervical spine injury, CSI transport, SCIWORA, 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, DC and Baltimore. All transcripts were reviewed and comments were categorized into topics such as qualities, beliefs, barriers, motivators and suggestions. The manuscript was submitted to the *Annals of Emergency Medicine* and is under review.

IAI

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Patient enrollment began in May 2007 and ended in January 2010. We enrolled 12,044 patients with a capture rate of 80.9%, including 762 patients with an IAI. Thanks to everyone for all their hard work over the past three years! Data cleaning is complete and the decision rule has been generated. Analysis and paper writing is on-going.

EMS

This study collected data for 521,239 runs from fourteen EMS agencies for the years of 2004-2006 through HEDA partnerships with the agencies. These fourteen submitted data sets consist of varying size, amount of missing data, and format. Twenty-two EMS agencies ultimately participated in the study, with eight unable to submit data. Data collection is complete and no future data collection will be done. Analysis and paper writing is on-going.

PECARN Core Data Project

All locked PCDP Data for 2002 – 2008 are now available in the cubes. For preliminary analysis of PCDP data, you can use the cubes or complete a data request form (found in the PCDP eRoom). The cubes can be accessed at <https://www.utahdccc.org/reportportal>. Contact Drew DeMarco at

andrew.demarco@hsc.utah.edu to obtain or reset your cube login and password.

For any questions, please contact Libby Alpern at alpern@email.chop.edu.

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 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 to get enrollment started in early 2011. In-person study training happened in September 2010, continued training is on-going, and sites are getting ready for enrollment.

Progesterone

The study executive committee will convene in Miami on January 18, 2011 to begin work on the clinical protocol for the future trial of progesterone for TBI. The committee will determine key elements of the protocol including:

Outcome measures, Inclusion/exclusion criteria, Progesterone dosing in children, Therapeutic window of progesterone, Therapeutic strategies in clinical management of TBI, Ethical, consent and regulatory issues and Biostatistical and trial design issues.

The next step will be to pilot the inclusion/exclusion criteria in prospective yield study. The yield study will be conducted from June through November 2011 in the participating clinical centers in PECARN to test accrual feasibility.

Patient Safety and New York State Patient Safety

The Patient Safety project continues to collect incident reports to determine the epidemiology of medical error reporting in EDs. We have collected over 16,000 incident reports since July 2007. A manuscript on medication events in a pediatric emergency research network has been submitted to *Pediatrics*. An additional manuscript on creating an infrastructure for safety event reporting in a multi-center pediatric ED network will be submitted soon.

The statistical analysis and manuscript preparation for the pilot study that took place in New York state is ongoing.

Thanks to the CDMCC and all other site investigators for the hard work to date!

will conduct an interrupted time series trial to test the effectiveness of the decision support intervention.

Performance Measures

Completed at the end of 2010, the performance measures study has generated a set of 60 performance measures, with a subset of 15 prioritized measures, that are sensitive to multiple domains of quality. These measures have been rated by EMSC stakeholders for face validity and credibility, assessed for data availability across PECARN hospitals and operational definitions have been delineated. These measures and a recent webcast describing the development process and use of measures at sites are available through the EMSC NRC. Remaining work includes the completion of manuscripts to further disseminate these products.

Seizure

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) is currently ongoing with 10 participating sites actively enrolling; including Baylor College of Medicine (Houston) who after completing their community consultation started enrolling at the beginning of November. Our Canadian sites (Alberta Children's Hospital (Calgary), Children's Hospital of Eastern Ontario /Ottawa) are awaiting the logistics of study drug shipment to be finalized and hope to be onboard to start enrolling soon. With a total of 222 patients enrolled, we have now met approximately 80% of our projected enrollment numbers.

MAGiC

The MAGiC study enrolled its first patient! We have had lots of great accomplishments since the last newsletter. Our protocol was DSMB approved and then reapproved with the ancillary study. The database development is complete; we had a successful training session in November and now almost every site is ready to rock and enroll. The first patient was a great learning experience and with the holidays ending, we hope to have many more great learning experiences.

TBI

The TBI project continues to be productive in ongoing secondary analyses and manuscripts. All four abstracts submitted for the 2010 PAS/SAEM meetings were accepted and presented. One publication is in press at the *Journal of Pediatrics* (Risk of TBI in Patients with Coagulopathies), another one is "revise and reconsider" at *Annals of Emergency Medicine* (Clinical Outcomes after Negative CTs). We have another manuscript under consideration at *Pediatrics* (Clinical Observation before the Decision to Obtain a CT). We have approximately 5 manuscripts almost ready to submit to GAPS, and other analyses are almost complete. This brings the total to 17 completed and presented abstracts (none have been turned away!), on top of 4 published manuscripts (and several on the way). We are currently working on approximately 5-7 more TBI substudies/manuscripts. We hope to have all substudies submitted for publication over the next year, then it is on to other important TBI projects. We are in the middle of a funded knowledge translation project of the prediction rule (Peter Dayan PI), and a funded planning project for the use of progesterone for serious TBI (Rachel Stanley PI).

TBI-KT

The study entitled "Implementation of the PECARN Traumatic Brain Injury Prediction Rules for Children Using Computerized Clinical Decision Support: 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 rapidly. The rigorous development of the electronic data capture system and computerized clinical decision support are underway with focus groups, ED workflow evaluations, and key informant interviews ongoing. Subsequently, in years two and three, we

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials is one year old! We celebrated our one year enrollment anniversary on September 1, 2010! To date, the study has screened a total of 1080 subjects, 238 were eligible and 111 have been randomized.

Our second group of sites is in the process of submitting IRB's and contracts and we hope to have the first group on board before Christmas. We will have a total of 34 sites with the addition of this second group and we are very excited to start working with these new centers.

We are now up and running in OpenClinica and data entry is going very well considering the differences in the system and the quantity of data collected. A big thank you to all the sites as they have worked through this new system!

Thanks to everyone for their hard work and commitment to the THAPCA Trials.

Quality of Care

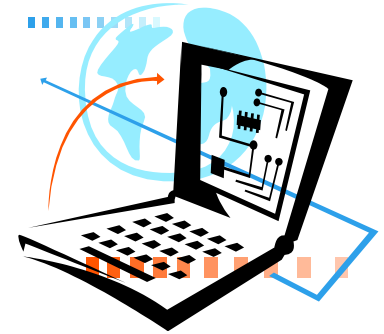
We are pleased to announce that we received funding from AHRQ for our project, titled "Factors Associated with Quality of Care Delivered to Children in US EDs." The project began on 9/30/2010 and will continue for 3 years. The overall objective is to validate a structured implicit review instrument that measures the quality of care provided to children presenting to EDs, and to identify factors (hospital, ED, physician, patient and presentation factors) associated with differences in quality of care among a diverse cohort of EDs and patients across the United States. We plan to review 600 pediatric patient records from 12 EDs in PECARN.



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

PECARN's TBI Rule Going Virtual!

By Rene Enriquez and J. Michael Dean



Remember the Traumatic Brain Injury (TBI) study? It is Going Virtual. Dr. Peter Dayan and colleagues are creating a Clinical Decision Support System (CDSS) that integrates with the hospital's electronic health record (EHR) to help implement the PECARN TBI prediction rule. The basic concept is to create a computer program (CDSS) that integrates data from the electronic medical record, checks and processes the data it receives, and returns a recommendation to the clinician regarding whether to CT. This recommendation will be implemented from the landmark PECARN Lancet paper.

What is a Clinical Decision Support System (CDSS)? A CDSS is a computer program that is capable of performing tasks that normally only trained and expert clinicians are able to perform. The goal of those developing decision support systems is to have a computer make or recommend decisions as close as possible to human experts. The ultimate types of CDSS are embedded in medical devices such as continuous insulin pumps, and these computer programs actually do not even ask clinicians to be involved in the individual decisions. For our project, the computer program will simply tell the clinician what the recommendation is, based on Dr. Nate Kuppermann's Lancet paper, and it will be up to the clinician to use their individual judgment about whether to order a CT scan or not. The hypothesis of the study is that the CDSS will improve the implementation and translation of the decision rule.

A CDSS generally consists of three components: 1) A database with

patient records, or at least a data entry screen to obtain the data needed to calculate a decision. 2) A knowledge base where a set of rules or protocols pertaining to a specific domain (e.g. TBI) exist. This is being developed by decision support experts who were identified for the KT project. 3) An inference engine that connects the database and the knowledge base. The inference engine is the piece that processes the data and makes the recommendation. The details of the inference engine are unimportant to this discussion.

Consider the CDSS a tool box that can help clinicians make decisions (most often by reminding them of what a guideline would recommend), remind them of certain tasks, and in extreme cases save a patient's life. For example, a CDSS can be used to manage a glucose protocol and remind the clinician to continue insulin if a glucose value exceeded a certain parameter. Another example is alerting the clinician that a prescribed medication has not been given or that the prescribed medication can cause an adverse event if combined with current medication. The most extreme situation might involve a device shut off during certain types of

malfunction.

Today, many clinicians still perceive CDSS applications with hesitation, a fact that can be an obstacle to the implementation of these systems. One key attribute of a CDSS is whether it is a closed loop system or an open loop system. When it is open loop, as in the Dayan project, the CDSS is simply giving guidance to the clinician, and the clinician still must use clinical judgment about the decision for the individual patient.

Other decision support tools are being developed at the Data Coordinating Center in Utah for potential use in the critical care setting, including tools for management of insulin for hyperglycemia in the ICU, management of vasoactive drips in septic shock, management of ICP elevation with hypertonic saline, and management of pediatric mechanical ventilation. These tools are being developed with a common template so that additional domains, including the pediatric emergency care setting, may also be amenable to similar decision support tools.

However, the key is to develop systems that are tailored to the clinicians' needs. If this is done, the systems will become attractive and implementable. The KT project directed by Dr. Dayan is hopefully the first of many future informatics projects that will be conducted within PECARN.



Research Coordinator of the Year Award

Beginning last year, PECARN instituted a formal process for recognizing some of the most important members of PECARN; the site research coordinators (RCs). Without the hard work of the RCs, PECARN could not function. To honor their commitment to the success of our network, PECARN introduced the first annual PECARN Research Coordinator of the Year Award in January 2010.



This year the same process was conducted in search of the 2011 Research Coordinator of the year. Investigators were asked to nominate a coordinator who demonstrated the following qualities:

- An RC who contributes to the network, node or site
- An RC whom you admire and respect and who is respected and admired by their colleagues
- An RC who has overcome obstacles to help you/the network/site/node
- An RC who has had numerous accomplishments that you'd like to recognize



After many nominations, and much deliberation, this award was presented to **Kammy Jacobsen**, Research Coordinator at Primary Children's in Salt Lake City Utah.

Kammy Jacobsen was nominated by Doug Nelson, MD HEDA PI at the University of Utah for PECARN Research Coordinator of the Year. Kammy has many outstanding qualities, among which are professionalism, dedication and leadership.

Kammy is an invaluable contributor to our department and to the network. She has been working with PECARN since April, 2004 and she really deserves recognition for all that she's given us.



Next PECARN meeting:

May 2011 Alexandria, VA

May 17: Pre-meetings

May 18-19: Steering Committee meeting



See *THIS* Edition of the
PECARN Newsletter online at:

www.pecarn.org

Also:

PECARN Updates...

... Helpful Resources

Current Research ...

... and MORE!



ACORN**PECARN Grantee Nathan Kuppermann Elected to IOM**

Nathan Kuppermann, MD, MPH, nodal principal investigator for the Pediatric Emergency Care Applied Research Network (PECARN), has been elected as a member of the Institute of Medicine (IOM). New IOM members were announced during IOM's 40th Annual Meeting held in Washington, DC. Election to the IOM is considered one of the highest honors in the fields of health and medicine and recognizes individuals who have demonstrated outstanding professional achievement and commitment to service. Congratulations on this exemplary honor Dr. Kuppermann!

GLEMSCRN

Melissa Metheney, BS, RN, CCRC, graduated with honors with her RN degree from Chamberlain College of Nursing on October 24, 2010. She became board certified on November 26th after passing the NCLEX National Licensure Exam and is very excited to incorporate nursing into her search position at Nationwide Children's Hospital.

**PEDNET**

We welcome the Texas Children's Hospital (TCH), Houston. The Section of Emergency Medicine of the Department of Pediatrics at Baylor College of Medicine has a strong research infrastructure led by Charles Macias, MD, MPH, who is the Chief of Academic Services and Research Director for the Section of Emergency Medicine, Director of the Evidence Based Outcomes Center at TCH and the Director of Center for Clinical Effectiveness at Baylor College of Medicine. Dr. Macias will share the HEDA PI role with Dr. Andrea Cruz, MD, MPH who is Associate Research Director of the Section of Emergency Medicine.

The ED at TCH has a strong history of successful participation and leadership in multicenter research and partners heavily with the Houston Fire Department for collaborative work in pre-hospital care and research.

TCH is a large, tertiary care center which consistently ranks as one of the top ten pediatric hospitals in the country. The emergency department cares for more than eighty thousand patients annually and has recently become a certified Level 1 Trauma Center for Pediatrics. The ED and hospital have a large referral area, receiving transfers from surrounding states including New Mexico, Oklahoma, Arkansas and Louisiana.

CDMCC

Congratulations to Kym Call who was married on August 6th, 2010 to her sweetheart Thomas. The happy couple are expecting a baby boy in May.

Congratulations to Marci Fjelstad and her boyfriend Ben who welcomed the arrival of their newest family member, a neon tree lizard named Go-Go.

**HCUP Training Workshop for EMSC Grantees**

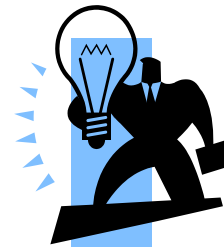
On May 16, 2011, The Agency for HealthCare Research and Quality (AHRQ) will conduct a full day, intermediate-level workshop designed specifically for EMSC Targeted Issues and PECARN research investigators.

This workshop will be held at the Rockville, Maryland AHRQ training room with research staff who will work with workshop attendees on select research questions using the AHRQ Nationwide Inpatient Sampling (NIS), the Nationwide Emergency Department Samplings (NEDS), KIDS' Inpatient Database (KID), and the State Inpatient Databases (SID). This is a great opportunity to use the different databases and ask technical questions to knowledgeable AHRQ research staff.

Registration on the EMSC National Resource Center website will open January 31, 2011. **Space is limited and registration will be on a first come first serve basis so please do not wait to register.**



Good Clinical Practice Tip:



Q: Are consent documents required to include a space for the assent of children?

A: No. The basic requirement of 21 CFR 50.20 is that the legally effective informed consent of the subject or the subject's legally authorized representative must be obtained *before* enrollment. Parents, legal guardians and/or others may have the ability to give permission to enroll children in research, depending on applicable state and local law of the jurisdiction in which the research is conducted. However the FDA specifically states, "Although there is no requirement that the informed consent document contain a space for assent by children, many investigators and IRBs consider it standard practice to obtain the agreement of older children who can understand the circumstances before enrolling them in research." IRBs generally require investigators to obtain the permission of one or both of the parents or guardians (as appropriate) and the assent of children who possess the maturity and intellectual and emotional ability to comprehend the concepts involved. Some IRBs require two documents, a fully detailed explanation for parents and older children to read and sign, and a shorter, simpler one for younger children.

Source: Mathieu, M.P. (2010). *Good Clinical Practice: A Question & Answer Reference Guide*. Needham, MA: Barnett Educational Services.

Submitted by **Heather Gramse, BS, CCRP**
CDMCC Project Manager

New Faces to PECARN

CARN



CARI MUNRO, BSN, RN, CPN -RESEARCH NURSE EDUCATOR

Based at CNMC, Cari Munro recently joined CARN in the role of Nursing Educator, responsible for training nurses in the ED and inpatient units on PECARN protocols. When she is not working clinically in the emergency department, Cari is traveling the world, most recently in Haiti and Egypt, providing medical support for relief organizations such as the American Red Cross, Habitat for Humanity and Operation Smile. In addition to nursing, Cari has a broad background in community outreach as a birthing doula and as a teacher in Indonesia and South Korea. Welcome, Cari!



JOHANNA MCKENNA, BSN, RN, CPN-RESEARCH NURSE EDUCATOR

Johanna McKenna recently joined CARN in the role of Nursing Educator, responsible for training nurses in the ED and inpatient units on PECARN protocols. Johanna is a senior nurse with over 32 years of nursing at CNMC, 17 of these based in the emergency department. Her prior research and projects have focused on improving triage practices (reducing ED throughput times; implementing electronic queues to improve patient flow and confidentiality) as well as implementing health promotion tools in the emergency department waiting room. Welcome, Johanna!



DEVON SHOOK, BS-CLINICAL RESEARCH COORDINATOR

Devon Shook joined Children's National Medical Center as a research coordinator in September, 2010. As a former graduate student of neuroscience at Georgetown University, Devon is excited to be part of the clinical research team at Children's National. He enjoys outdoor activities like snowboarding and diving as well as pretending he can speak French with any skill. His favorite parts of PECARN are all the wonderful kids and his amazing research team. Gooooo CARN! Welcome, Devon!

GLEMSCRN



Jenna Barhorst, BS, has worked as a research assistant at Nationwide Children's Hospital (NCH) since 2008. Before joining the Emergency Department in September 2010, she consented for a Duchenne's Muscular Dystrophy study sponsored by the Center for Gene Therapy at NCH. Jenna graduated from The Ohio State University with a BS in biology in June 2010. She is happily continuing her education there as a graduate student pursuing a doctorate degree in Physical Therapy. Jenna enjoys reading, boating, and spending time with family and friends.



Jennifer Morgenstern, BS, has worked as a research assistant at Nationwide Children's Hospital since 2009. Jen graduated with a BS in Health Sciences from The Ohio State University in 2009 and is currently attending graduate school to become a Women's Health Nurse Practitioner. Before joining the Emergency Department in August 2010, Jen previously worked at NCH on a study consenting to have newborns tested for Duchenne's Muscular Dystrophy. Outside of class, she enjoys being involved in student organizations.

PEDNET



Grant Jones is the new Traumatic Brain Injury-Knowledge Translation Study Coordinator at Columbia University. Originally from Oklahoma, Grant studied zoology and pre-medical studies as undergraduate coursework. Additionally, he received his Masters of Science degree from the College of Physicians and Surgeons (P&S). Grant aspires to be a physician with a career in academic medicine and focus in a pediatric surgical subspecialty.



Charles G Macias MD, MPH is a co-HEDA PI for the latest HEDA for PEDNET: Texas Children's Hospital/Baylor College of Medicine. He has a long history of research design, implementation and administration experience. He is the past Chairman of the Pediatric Emergency Medicine Collaborative Research Committee, and thus has participated in many multi-center research studies. His personal research interests are in quality of care improvement strategies, often focused on applications through respiratory disease management.

Despite having lived in a variety of different cities throughout his life, he has been in Houston for the last 15 years, acclimating to balmy summers but relishing mild winters.



Andrea Cruz MD, MPH is one of the co-site PIs at Texas Children's Hospital. She is originally from Miami, Florida, and completed undergraduate studies at Harvard and medical school at Vanderbilt. Upon graduation, she moved to Houston for Pediatric Residency and fellowships in Pediatric Emergency Medicine and Pediatric Infectious Diseases at Baylor College of Medicine, where she is now an Assistant Professor of Pediatrics. She also recently completed a Masters of Public Health in epidemiology and global health at the University of Texas.

She enjoys hiking, biking, softball, and reading and is a die-hard Miami Hurricanes fan.

Elena Reynoso is the new HEDA Research Coordinator at the Children's Hospital of New York, Columbia University Medical Center. Elena, a native New Yorker, completed her medical degree in the Dominican Republic. She aspires to specialize in Pediatric Emergency Medicine, once she completes her board exams and acquires her MPH. Currently she has immersed herself in the research field and enjoys training and volunteering with international organizations. On her free time she enjoys quality time with her daughter, reading, dancing, singing and sports. Elena is thrilled to be a part of the PECARN research team.

New Jr. Faces to PECARN

CDMCC



Cody and Kimberly Olsen welcomed Laney Olsen on September 3, 2010. She was 7 lbs. 13oz and 20 inches tall. Everyone is happy and healthy.

ACORN



Brooke Lerner is pleased to announce that her new daughter, Olivia Asmara Lookman, arrived on Dec. 2, 2010. She was 7 lbs. 7 oz. and 19 inches tall. Everyone is happy and healthy.

Congratulations to the new arrivals!

