Spring 2011

What's Inside?

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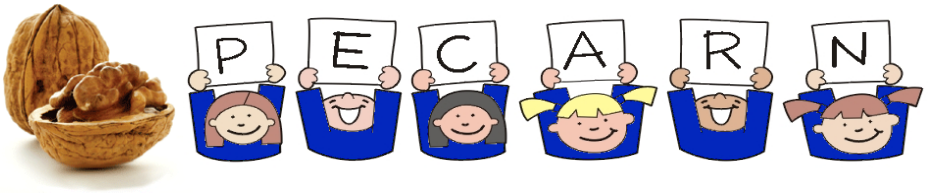

In a nutshell

New PECARN Site: Texas Children's Hospital (TCH)

Submitted by Mikhail Berlyant
PEDNET Nodal Administrator

We are excited to welcome Texas Children's Hospital (TCH) as a new PEDNET site. Founded in 1954, TCH in Houston is the largest free-standing children's hospital in the country and is a Baylor College of Medicine affiliate. TCH ranks highly in all 10 specialties in the U.S. News & World Report's list of America's Best Children's Hospitals. TCH is one entity in the TCH Integrated Delivery System, which includes a community-based pediatric practice network of over 150 pediatric and mid-level care providers (Texas Children's Pediatric Associates), TCH itself, and a health insurance plan (Texas Children's Health Plan).

The TCH emergency department has an annual volume of approximately 90,000 patient visits with more than 14,000 hospitalized. It has recently become a certified Level 1 Trauma Center for Pediatrics. Although the TCH catchment area includes southern and eastern Texas, Louisiana, and other neighboring states, its primary service population is a 13 county region in southeast Texas encompassing approximately 5 million residents.

The Section of Emergency Medicine at TCH has a strong research infrastructure led by Charles Macias, MD, MPH, who has more than 15 years of experience as a clinical investigator. Dr. Macias is a nationally recognized leader in quality improvement and has a long-standing commitment to multicenter research including as the Chairman of the Pediatric Emergency Medicine Collaborative Research Committee (PEM-CRC) of the American Academy of Pediatrics from 2004-2010. Dr. Macias and Dr. Andrea Cruz share the role of PECARN HEDA PI at TCH. Dr. Cruz is an accomplished junior investigator with subspecialty training and research expertise in both pediatric infectious diseases and emergency medicine. TCH has 13 funded PEM researchers and collaborative relationships with a number of centers and research initiatives at Baylor College of Medicine and its affiliates.

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Supported by Grant U03MC00008, Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services

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New PECARN Site: Texas Children's Hospital (TCH)

Dr. Macias is presently the Director of both the Center for Clinical Effectiveness (CCE) and the Evidence Based Outcome Center (EBOC) at Baylor College of Medicine and TCH. The CCE coordinates activities in health services research, informatics, educational outreach, patient safety support, policy and advocacy subgroups, and general support for Department of Pediatrics faculty who are engaged in quality improvement science. The EBOC develops and implements clinical guidelines that will translate to high quality, safe, and transparent patient care. To date, EBOC has assisted in the creation of 23 evidence-based guidelines. The entities targeted include common ED diagnoses such as asthma, bronchiolitis, gastroenteritis, rapid-sequence intubation, skin and soft tissue infections, and status epilepticus. Concurrently, the CCE has supported the translation of this work into knowledge translation and comparative effectiveness research.

Excuse Me, Do You Intend To Treat That Subject?

Submitted by Tomohiko Funai
Biostatistician at CDMCC

Occasionally, not always for the wrong reasons, a subject in a randomized controlled trial (RCT) may be given a wrong treatment, not follow the treatment instructions, fail to adhere to the prescribed protocol, or discontinue participation (perhaps due to death) caused by factors seemingly independent of the scope of the study. In such cases, our inclination is to exclude these subjects from the statistical analysis or to analyze them according to the treatment they received. In contrast, intention-to-treat (ITT) analysis, considered the best approach for unbiased comparisons between treatment groups, will not exclude such subjects nor consider them "reassigned".

The Fluid Therapy and Cerebral Injury in Pediatric Diabetic Ketoacidosis (FLUID) study has a factorial design in which patients will be randomized to four groups that are defined by two rates of fluid administration (slow and rapid rehydration) and two levels of sodium content in the intravenous fluids (0.45% and 0.9% saline). The aim is to determine the effects of variations of these two factors in recovery. However, let's say there are, over the course of the trial, patients that are given the wrong rehydration rate or saline concentration after randomization. If these patients are excluded, the randomization is not preserved, and may introduce biases to the statistical analysis. For example, suppose patients who are less severe and would experience a good outcome, regardless of treatment, tend to be given slow rehydration when they are assigned to rapid. Analyzing patients by what they actually received would show that slow rehydration has better outcomes than rapid rehydration, even if slow rehydration is less effective.

Another RCT being implemented by PECARN, the Intravenous Magnesium for Sickle Cell Vasoocclusive Crisis (MAGiC) trial assigns research subjects to receive up to 6 intravenous infusions of either magnesium or placebo. Suppose we decide to include in the analysis only subjects who receive at least 3 study drug infusions. Now suppose IV magnesium has some strong side-effects, perhaps even leading to prolonged hospitalization, that cause infusions to be stopped. This makes it possible that many subjects with poor outcomes that should count against magnesium would be excluded from the analysis, biasing the results. In ITT analysis, none of the patients are excluded and patients are analyzed according to their assigned treatment groups, regardless of adherence to their assigned treatment.

Because of its ability to remove biases from the statistical analysis, the principle of ITT has become widely accepted as the standard for the analysis of RCTs. One thing to note when planning the ITT analysis is that all outcomes must be ascertained and included. This implies that it requires continued follow-up, even if a subject has discontinued their assigned treatment. In summary, by including all randomized subjects in the groups to which they were assigned, regardless of their eligibility, which treatment they actually received, or subsequent withdrawal from treatment or deviation from the protocol, ITT analysis is used as a tool to reduce bias and avoid false conclusions.

EMSC Federal Appropriations and Authorization Update

In April, the House of Representatives and Senate approved and the President signed into law H.R. 1473, the Department of Defense and Full-Year Continuing Appropriations Act. This measure funds federal agencies and programs for the remainder of fiscal year 2011.

Despite the passage of this bill, as of press time for this newsletter the final funding level for the EMSC Program has yet to be determined. While the bill does not identify any cuts specific to EMSC funding, it does apply an across-the-board 0.2% cut to all non-defense spending and a $1.2 billion reduction to the Health Resources and Services Administration's (HRSA) budget. It is up to HRSA to determine how to apply this reduction across its programs and operations.

EMSC Regional Activities

EMSC Program representatives from the Pacific Basin (American Samoa, the Commonwealth of Northern Marianas, Guam and Hawaii), federal representatives, and medical professionals met in Oahu, Hawaii, April 19-22. This is the second meeting that will focus on the region's challenges accessing pediatric specialty care and timely transport and transfer of severely ill and injured pediatric patients from the territories. Completion of a summary report describing the uniqueness of the territorial health systems, a white paper to facilitate education of hospital, state, territorial and national leaders on territorial challenges impacting pediatric care, as well as recommendations and strategies to facilitate better access to essential specialty services, inclusive of inter and intra island transfer processes are the planned end products of this activity.

NRC Pilots Newest Technology, the EMSC Online Community

The EMSC National Resource Center has piloted its newest social media application, the EMSC Online Community. The community serves as an interactive online portal providing grantees powerful ways to interact with each other in real time, electronically. PECARN research coordinators are using the community to publish, access, and share information about successes and challenges with recruiting and retaining patients for PECARN's DKA study. Through the use of community wikis, blogs, and forums, research coordinators can ask questions, post observations, discuss recruitment issues, and offer support and guidance to other members within the group. The community also allows members to upload and share documents and photos, and post events to a community calendar.

Dr. Elizabeth Edgerton Named Branch Chief for EMSC and Injury Prevention at HRSA

Elizabeth Edgerton, MD, MPH, joined HRSA as the new Branch Chief for EMSC and Injury Prevention within the Division of Child, Adolescent and Family Health, the Maternal and Child Health Bureau (MCHB) at HRSA. Dr. Edgerton is a previous EMSC Targeted Issues grantee and a recipient of the 2004 National Heroes Award for Outstanding EMSC Research Project. Most recently she served as an attending physician in the Emergency Medicine and Trauma Center at Children's National Medical Center in Washington, DC.

State Partnership Program Manager's Meeting

The EMSC Program will host a State Partnership Program Manager's meeting from May 2-4, 2011 in Annapolis, Maryland. The keynote address, "Fulfilling the Promise" will be given by Dia Gainor, EMS Director of Idaho. All presentations will be posted to the EMSC National Resource Center website www.childrensnational.org/emsc following the meeting.

EMSC EFIC Webcasts Archived on MCHCOM

If you were unable to view the EMSC webcasts, "Exception from Informed Consent: Lessons from a Consensus Conference," and "Exception from Informed Consent in Pediatric Trials," both have been archived and are available on www.mchcom.com.

NRC Begins EMSC Targeted Issues Archiving Project

The NRC has begun developing a historical account of all EMSC Targeted Issues (TI) work since the first grant was awarded in 1992. In-depth details about each project including manuscripts and subsequent projects born out of the original EMSC TI work will be highlighted on the website.

TBI

The TBI project continues to be productive with new manuscripts ongoing secondary analyses and manuscripts. Three manuscripts have recently been published or are in press, including: 1) Risk of TBI in Patients with Coagulopathies in the Journal of Pediatrics, 2) Clinical Observation before the Decision to Obtain a CT in Pediatrics, and 3) Clinical Outcomes after Negative CTs in Annals of Emergency Medicine. We have another manuscript being reviewed by GAPS, and several more are being prepared for GAPS submissions. In an effort to maintain our presence and visibility at national meetings, we have submitted two abstracts for consideration at the 2011 AAP meeting (Sports-related TBI and Racial/Ethic Disparities in CT use after Pediatric Head Trauma). This brings our total productivity of presented abstracts and published manuscripts to well over 20 for this project! We are currently working on several more TBI substudies/ manuscripts, and hope to have all substudies submitted for publication by 2012. Then the focus will shift to other important TBI projects. PECARN is in the middle of a funded knowledge translation project of the prediction rule, and a funded planning project for the use of progesterone for serious TBI (see those updates).

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 ongoing.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials is enrolling on schedule! To date, the study has screened a total of 1534 subjects, 322 were eligible and 161 have been randomized! Nearly all of the second group of sites are activated and now enrolling in the trial and we are in the process of adding a third group by the end of summer. We have a total of 30 sites enrolling and an additional 6 sites coming on board. We have new sites contact us weekly interested in participation so we anticipate even more sites by the end of 2011! The participating sites have shown true commitment to the study and we thank everyone for their hard work.

MAGiC

All four sites participating in the Intravenous Magnesium for Sickle Cell Vaso-occlusive Crisis (MAGiC) study are actively screening and enrolling patients. In mid-April, the study had screened approximately 60 patients, 28 were eligible, and 11 have been randomized. All four sites are actively pre-consenting patients in the Sickle Cell clinic, inpatient unit, and in the ED. A protocol amendment was approved by each site's IRB to include the Quality of Life ancillary study that is funded by the NHLBI. The ancillary study includes administering Quality of Life surveys to the patients enrolled, at four different time points, to assess the patient's health-related quality of life and short term outcomes.

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.

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. 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! Data cleaning is complete and the decision rule has been generated. Analysis and paper writing is ongoing. Initial results will be presented in May and June at the PAS and SAEM meetings.

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). 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. In the present year one, we have completed 11 focus groups and ED process evaluations in order to rigorously develop CCDS that fits into each ED's workflow. We are now developing the CCDS and preparing to initiate the interrupted time series trial to test the effectiveness of the CCDS intervention.

PECARN

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

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.utahdcc.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.

Biosignatures Study

Enrollment is off to a great start this year with over 350 1 ml biosignatures samples collected since January 1, 2011. Sites are currently enrolling at a pace of approximately 82 samples per month and we are on track to collect 1000 biosignatures samples in 2011! Most sites have received approval for the recent protocol amendment which includes the changes from the grant titled 'RNA Biosignatures in the Emergency Evaluations of Febrile Infants'. The grant extends the sample collection period for the Biosignatures study for an additional two years. Under the new grant, sites will continue to collect samples to create the diagnostic Biosignatures and will also collect an additional sample to evaluate the new screening test, procalcitonin. Currently, over 50 PCT samples have been collected. We are also in the process of migrating all study data from TrialDB to a new database called OpenClinica. We anticipate that the data migration will be completed and OpenClinica will be live by the end of May 2011. During this migration period sites will continue to enroll patients.

Patient Safety and New York State Patient Safety

Throughout the Patient Safety study over 18,000 incident reports have been submitted to the CDMCC since July 2007. Nine reviewers have finished categorization of the first year of incident reporting data. From their review, it was found that laboratory errors were the most common, followed by medication errors and process variance errors. Multiple manuscripts are in progress including one on the methodology of the study and another on medication error rates. Data analysis is ongoing for the pilot study that took place in New York state, where over 3200 ED charts were reviewed by a study nurse and incident reports from the participating sites were reviewed. A grant submission to AHRQ is planned to be submitted this Fall.

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 seven sites are enrolling with nineteen patients enrolled so far. The two additional sites should be enrolling by the end of May. In the meantime, we are holding regular webinars for RCs and PIs, and the study leadership is communicating on a weekly basis. The whole team is great, and we are ready to go!

Quality of Care

The Quality of Care study received funding from AHRQ. The overall objective of the study is to validate a structured implicit review instrument that measures the quality of care provided to children presenting to EDs, and to identify factors (i.e. hospital, ED, physician, patient and presentation factors) associated with differences in quality of care among diverse cohort of EDs and patients across the United States. The study plans to review 600 pediatric patient records from 13 EDs in PECARN. Currently, the Principal Investigators are working with the CDMCC to finalize study details, and enrollment is expected to begin summer 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 participating sites. Our Canadian sites (Alberta Children's Hospital (Calgary), Children's Hospital of Eastern Ontario (Ottawa) have completed all site preparations and training and are preparing to start enrolling soon. With a total of 251 patients enrolled, we have now met approximately 88% of our projected enrollment numbers.

Progesterone

In preparation for a future clinical trial, the Progesterone study will initiate a prospective yield study to pilot the inclusion/exclusion criteria. The yield study will be conducted from approximately June through November 2011 in the participating centers in PECARN to test accrual feasibility. The finalized study protocol has been released to the participating sites and is awaiting IRB approval. Study enrollment and training is anticipated to begin in June.

C-Spine Injury in Children

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,774 controls. Manuscript for utility of plain films in the diagnosis of CSI is undergoing peer review. We have working drafts on three additional manuscripts: method of spinal immobilization in children <2 years old at risk for cervical spine injury, CSI transport 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. We will be presenting the protocol for prospective refinement and validation of a prediction tool at the Spring PECARN Steering Committee meeting.

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 interviews 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 is undergoing peer review for resubmission.

Performance Measures

While the formal study period for this project has officially ended, dissemination and publication of the work continues. The first manuscript has been accepted for publication and we expect to see it in the Academic Emergency Medicine in the coming months. Two abstracts have been submitted for the upcoming AAP meeting and work has begun on the 5 additional planned manuscripts. We are also working with CHCA on piloting the data capture of a select number of measures out of the PHIS database. This work might help inform future data collection requirements for the database.

NEXT PECARN MEETING:

November 2011 Bethesda, MD
Nov 2: Pre-meetings
Nov 3-4: Steering Committee meeting

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

www.pecarn.org

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ACORN

The ACORN node would like to extend sincere congratulations to **Marc Gorelick**, who became the CEO of the Children's Specialty Group, and the Senior Associate Dean for Clinical Affairs at Medical College/Children's Hospital of Wisconsin as of March 1. David Brousseau is now Associate Section Chief for Pediatric Emergency Medicine and will take over for Dr. Gorelick as the PECARN HEDA PI at MCW.

CARN

Congratulations to **Britni Barnes**, **Julie Jennings, Ebony Parham**, and **Bobbe Thomas** for passing the Society of Clinical Research Associates (SoCRA) exam and are now certified clinical research professionals (CCRP)!

Gooooo CARN!

Good Clinical Practice Tip

Q: How should the Informed Consent process be documented?

A: We all know that the Informed Consent documents must be signed by the study participant/ parent, dated, timed, signed by the investigator and/or consenter and stored with study records. But since Informed Consent is a process, how should we document the ongoing conversations, discussions, and information exchange that makes up this process? The document is the basis for the start of the a meaningful exchange between investigator and study participant, rather than the end point. The process begins when a potential research subject is initially contacted and documentation of this conversation should be included in study records. Each conversation that occurs with the participant about the study should be documented in the study record. The CDMCC has provided a template to help sites document this process for PECARN studies that require consent.

Submitted by Marci Fjelstad, MPH, MBA, CCRP
CDMCC Project Manager

Scientific Grant Writing Workshop
August 24-26, 2011
Chicago, IL

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

- Write the specific aims
- Outline the significance, innovation, and the approach section
- Write your biographical sketch
- Plan your budget

At this workshop, attendees will work on each section of their research grant proposal, receive continual feedback from experienced grant writers, and leave with a well-defined draft.

Visit **www.nedarc.org** for online registration.

New Faces to PECARN

CDMCC

Zoljargal "Zola" Nkansah, BS, is the PECARN executive secretary at the CDMCC. Originally from Mongolia, Zola graduated from Brigham Young University-Hawaii in 2007 with a BS degree in International Business Management. She aspires to dedicate her career in the healthcare industry and has taken several pre-nursing classes at the University of Utah. She speaks English, Mongolian and Russian. As a newlywed, Zola enjoys cooking, cleaning and picking up after her husband.

Rebecca Kelly, BS, joined the PECARN in April 2011 as a Clinical Data Associate. She studied Health Education at Western Oregon University, graduating in 2009. While attending college, she worked as a MA in Gastroenterology, Cardiology and Urgent Care. She took a year off after graduating to care for her new daughter, Bristol. She is excited for the new experience working in research, branching outside of her clinical experience.

Jerry Butler, MAS, is a new biostatistician at the CDMCC. Jerry earned his MAS degree in Biostatistics at The Ohio State University in 2006. He has worked as a statistician in the financial services industry for the past 4 years where he worked on experimental designs and the development of statistical models. Jerry looks forward to applying his skills in clinical and public health research and is excited to be a part of the PECARN team.

Bradley C. Baird MS, M Stat., has recently joined the Biosignatures Study as a biostatistician. Brad has recently moved to the Department of Pediatrics at the University of Utah Health Sciences Center having previously worked for Internal Medicine for eight years performing research on kidney dialysis and transplant outcomes. He received his Master of Statistics from the University of Utah and an MS in Information Systems from the University of Arizona. Brad also teaches Statistics at a local college in the evenings. He enjoys sports, family outings and playing golf.

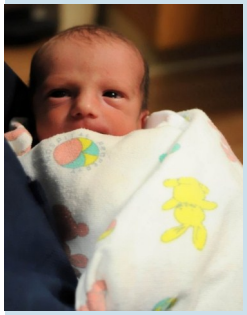
Casey Evans, BS, has worked as a clinical data manager at the University of Utah Central Data Management and Coordinating Center since September 2010. Before joining the data center, he was a data manager at Myriad Pharmaceuticals for three years, where he worked mostly with oncology studies. Casey graduated from the University of Utah with a BS in behavioral science and health in August 2006. Casey enjoys basketball, golf, crossfit, running, and spending time with family and friends.

PEDNET

Sarah Warnock is a new Research Coordinator with Children's Hospital of New York Columbia University Medical Center. Originally from Texas, Sarah studied anthropology, psychology and pre-medicine at the University of Texas and the American University of Beirut. Since joining Children's Hospital of New York-Columbia University Medical Center in 2009 she has worked in the Department of Pediatric Emergency Medicine and has served as the Pediatric Emergency Medicine Fellowship Coordinator for Columbia University. She is also a freelance photojournalist and medical photographer .

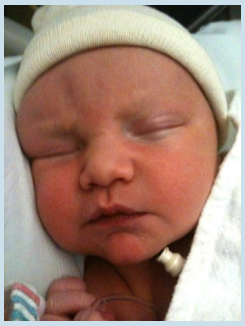
New Jr. Faces to PECARN

Tom and Tasmeen Singh Weik are pleased to announce that their twin boys, Rohan Alexander Weik and Krishen Robert Weik are born on March 14, 2011.



Krishen was born 4 lbs. 15 oz. and 18 in.

Rohan was born 6 lbs. 6 oz. and 18.5 in.



Kym Call had her baby boy. He was born 8 lbs. 9 oz.

Congratulations!