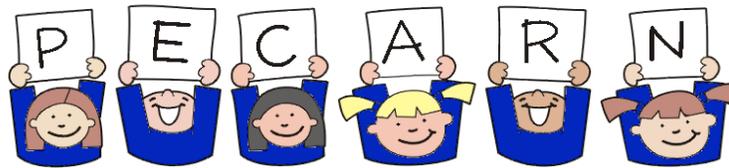


Fall
2009



In a nutshell

What's Inside?

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

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PECARN Study of Safety in the Pediatric Emergency Department

By Mikhail Berlyant, BBA
PEDNET Nodal Administrator



It is staggering that medical errors result in an estimated 44,000 to 98,000 deaths annually in the United States. The PECARN study “A Qualitative and Quantitative Evaluation of Patient Safety Issues in Pediatric Emergency Departments” has the long-term goal of decreasing medical errors by identifying and implementing best safety practices. An analysis of medical errors that do occur, using a combination of both qualitative and quantitative methodologies, is needed in order to understand and improve patient safety. To this end, the PECARN team of Drs. Kathy Lillis, James Chamberlain and Kathy Shaw was recently awarded a New York State Department of Health Grant that has two main aims:

Specific Aim 1. To classify and disseminate information from ongoing incident report monitoring, including actual and near-miss medication

errors that occurred in the emergency department (i.e. *qualitative* surveillance).



Specific Aim 2. To monitor medication error rates using systematic sampling and review of emergency department medical records. (i.e. *quantitative* surveillance). A robust PECARN-wide patient incident reporting (IR) system has been successfully developed by the investigators in order to meet objective 1. This IR system demonstrates that it is possible to create a multi-ED infrastructure that allows collection, transmission and analysis of IRs. The present grant will further examine the IRs collected from sites in New York State to identify patterns of errors. In or-

der to meet aim 2, trained nurse reviewers will assess de-identified medical records submitted to the CDMCC from the New York sites and determine the rate and type of medication errors. The three participating New York sites are the Women and Children’s Hospital of Buffalo, Children’s Hospital of New York-Presbyterian, and Jacobi Medical Center. The study nurse will determine if a medication error has occurred and classify errors into the following categories: wrong dose, wrong medication for indication, wrong medication for patient allergy, wrong medication based on chronic diseases, wrong patient and other errors. The results from this study will be used to develop and then implement safety intervention bundles at PECARN sites and measure the effectiveness of these interventions.

Mark your calendars

Upcoming PECARN Meetings: January 20-21, 2010 in San Francisco, CA; and April 13 - 14, 2010 in San Antonio, TX

Good Clinical Practice Tip:

Question: What is the difference between a protocol deviation and a protocol violation?

Answer: Neither the FDA nor the ICH GCP specifically defines the terms “protocol deviation” nor “protocol violation”, but sections 4.5.1-4.5.4 of the ICH GCP document, use the term “protocol deviation” to describe changes or noncompliance of the approved protocol. Because of the lack of a clear definition, sponsors and IRB standard operating procedures often determine how protocol deviations and violations are differentiated. As a general rule however, a protocol deviation is an incident involving noncompliance with the approved protocol, but an incident that **does not** have a significant effect on the subject’s rights, safety, welfare, or integrity of the resultant data. In contrast, a protocol violation is an incident where a noncompliance **does** affect the subject’s rights, safety, welfare, or the integrity of the data.

Note: For all PECARN studies we require that you report protocol deviations/violations to your IRB.

Source: Code of Federal Regulations, ICH Guidelines. Clinical Resources, LLC 2009



This GCP Tip is brought to you by Hai Le, BS of the CDMCC. He is one of our newest Clinical Research Coordinators.



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

www.pecarn.org



Also:

*PECARN Updates...
Helpful Resources ...
Current Research ...
... and MORE!*

New Jr. Faces to PECARN



After a lengthy pregnancy, which I must say he kept well concealed, Charlie Casper is the proud papa of a bouncing baby girl. He is not too sure about how to dress a girl, but he will learn. Please send best wishes to **Melody Casper** who will now have to defend herself against two older brothers.



*Ebony Parham is celebrating! Baby **Dariya** came **May 13th, 2009**. She is a beautiful 5lbs and 13oz baby girl. !*

Congratulations to all!

Kate Shreve and Aaron Jacobs are doing great after having their 9lbs 5ozs and 22 inches baby



boy, **Aden Alexander Shreve Jacobs, on Tuesday, August 18th**. Aden is doing really well. He's been studying non-Euclidean Geometry while Kate has started running her morning triathlons again. In other news, Aden is gaining weight, and has received a clean bill of health from his pediatrician (CNMC, of course). Gooooo CARN!

Pediatric Patient Safety Meeting:

In partnership with Duke University and the AAP, the EMSC National Resource Center convened a multidisciplinary panel of experts to discuss issues related to Pediatric Patient Safety. Representatives from federal agencies, academia, pharmacy organizations, industry, family representatives and physicians met in February to discuss recommendations to improve pediatric medication safety in the ED. Key recommendations included the creation of a steering committee, dissemination of a white paper with conference proceedings, standardizing pediatric dosing ranges and creating a more standardized CPOE system. A steering committee has been formed and continues to work to integrate the recommendations from the larger consensus meeting. PECARN was represented by Kathy Shaw and Jim Chamberlain.

Evidence Based Guidelines Meeting (EBG Meeting):

In consultation with The National Highway Transportation Safety Administration (NHTSA), the Emergency Medical Services for Children (EMSC) National Resource Center (NRC) seated a 14-member panel of experts to conduct the first test of the Evidence Based Guidelines (EBG) model by developing a pediatric prehospital non-traumatic seizure protocol. The protocol was presented to the National EMS Advisory Council (NEMSAC), the Federal Interagency Committee on EMS (FICEMS), and the Society for Academic Emergency Medicine meetings in May of 2009. Dr Peter Dayan from PECARN participated in the process.

Other Important EMSC Related Information:



The EMSC Bear has been named Benny the Bear-a-Medic. Thank you to all who participated in our Bear Naming Competition and congrats to Sarah House for the winning name!

Federal Interagency Committee on Emergency Medical Services (FICEMS) Update:

As part of the Federal Interagency Committee on EMS (FICEMS) Data and Research Committee's goal, to "ensure a comprehensive body of scientific evidence regarding the practice of prehospital EMS", the EMSC National Resource Center created a gap analysis of prehospital research scientific literature. This project summarizes EMS literature from the past 10 years and mapped it to priorities described in national research agendas. The gap analysis is meant to be used as a mechanism by funding agencies to identify funding priorities. It was reviewed and approved by the full FICEMS committee this summer and is available on the website at www.childrensnational.org/emsc.

Annual Program Meeting:

The 2009 EMSC Annual Program Meeting was held in June in Alexandria, VA. There were 250 EMSC grantees and speakers. Noted speakers included The Honorable David G. Reichart (WA-8th), Dr Mary Wakefield, HRSA Administrator, and Dr Calvin Sia, an early champion of EMSC. PECARN was featured in 3 breakout sessions with presentations from the Nodal and CDMCC PIs. Other EMSC grantees interacted with PECARN representatives and provided advice on increasing prehospital research within PECARN.

EMSC Appropriations and Reauthorization:

For Fiscal Year (FY) 2009, the Program is funded at \$20 million. For FY 2010 the US House of Representatives passed the FY 2010 Departments of Labor, Health and Human Services, and Education (Labor-HHS) appropriations bill, which includes \$21 million for EMSC. While the Senate Appropriations Committee has recommended \$22 million for the Program, the Senate has yet to consider its version of the FY 2010 Labor-HHS appropriations bill.

In January, Congressman Jim Matheson (D-UT) introduced HR 479, the Wakefield Act, to reauthorize the EMSC Program for five years, from FY 2010 through FY 2014. In March, the House of Representatives passed HR 479 by a vote of 390-6. In February, Senator Daniel Inouye (D-HI) introduced the Wakefield Act, S 408, in the Senate. Both bills authorize a funding level for the EMSC Program starting at \$25 million in FY 2010 and ending at approximately \$30.5 million in FY 2014. As an alternative means to advance the Wakefield Act in the Senate, the text of S 408 was incorporated into the Senate Health, Education, Labor and Pensions (HELP) Committee's version of health care reform legislation. Known as the Affordable Health Choices Act, this bill was approved by the committee in July. This is but one health care reform measure being considered by Congress, however, and is a long way from becoming law.

Welcome:

*The EMSC National Resource Center welcomes **Barbara Mitchell Swain, CMP** and **Tiffani Johnson, MD**.*

Ms. Mitchell Swain has been a successful meeting planner for over 20 years and has been an asset to the NRC. Her primary duties include planning and coordinating meetings, conferences and special events, including future PECARN meetings. To contact Barbara please email her at bswain@cnmc.org or 202-476-6861.

Dr. Tiffani Johnson earned her medical degree from the University of Medicine and Dentistry – Robert Wood Johnson Medical School. She recently completed her pediatric residency training at CNMC in the Community Health Track. Tiffani will be helping the NRC to develop the next generation of performance measures for State Partnership grants and leading projects related to pediatric disaster preparedness. To contact Tiffani please email her at tjohnso@cnmc.org or 202-476-6850.

Biosignatures Study

Sites have been busy enrolling and have collected over 600 samples. Our goal is to collect 1050 samples in year 2, so please continue enrolling! Enrollment for year 2 will continue through December 2009. Some changes will be made to the study procedures in year 3 and amendment materials will be disseminated in November. A training session will be held in conjunction with the January PECARN Steering Committee Meeting in San Francisco. Year 3 enrollment will begin shortly following the training session.

C-Spine Injury (CSI) in Children

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,774 controls. Abstracts were presented at the 2009 PAS and SAEM meetings: Predicting C-Spine Injury (CSI) in Children: a case-control analysis, Age-related Differences in Risk Factors Associated with CSI in Children and Inter-observer agreement for Clinical Findings in Children at Risk of CSI. Two secondary analyses were accepted for AAP: Presentation for Utility of Plain Films in the Diagnosis of CSI in Children, and a poster for Spine Immobilization Among Children Less than 2. Abstracts are being written for submission to 2010 PAS and SAEM meetings: EMS care and CSI outcomes; AARS: Incidence, Associated Mechanisms, Associated Clinical findings; and Sports-related CSI: A Description of Mechanism and Injury Patterns. The main manuscript which presents the results of the case-control analysis is currently in draft form and is under review.

C-Spine 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. We are currently reviewing these categorizations and writing the manuscript.



IAI

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The study will enroll 13,000 children with blunt torso trauma, including over 800 with IAI. 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. As of August 17, we have enrolled 10,350 patients with a capture rate of 81.2%. This includes 650 patients with IAI. Final site monitoring visits have been completed over the summer. In addition, the CDMCC continues to generate queries to ensure top data quality. Patient enrollment is expected to continue through the end of January 2010. Please remind your site physicians to enroll all eligible patients as we head into the final months of the study.

IAF Appendix Study

The Intra-abdominal Fat and Appendix Visualization study has received IRB approval from its lead site Rochester, as well as CDMCC. The protocol is finalized and has been distributed to participating sites for IRB approval. The study will have a total of 16 participating sites and 24 radiologists. Data collection will begin in October.

Patient Safety and New York State Patient Safety

Eighteen sites are continuing to collect incident reports for classification into the categorization scheme developed by the study PIs as part of phase 1B of the Patient Safety study. A pilot study has been approved and funded by the New York State Department of Health. The objectives are to; 1) classify and disseminate information from ongoing ED incident report monitoring; and 2) to monitor medication error rates using systematic sampling and review of ED medical records. Three sites from PEDNET are participating in the pilot study.

PECARN Core Data Project

All locked PCDP Data for 2002 – 2008 are now available in the cubes. Please plan for 2009 data to be submitted to the CDMCC by April 1, 2010. We will be happy to help in any way to streamline the submission process. Reports for data validity checks will be generated after data submission. Please review your site's report in a timely fashion. Planning and quick review this year helped us get to completion much quicker this year – thanks!

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 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.

Performance Measures

Having winnowed the initial list of over 300 nominated performance measures down to 55 over the past year and a half, work continues to create operational definitions for the remaining measures. External stakeholders will be surveyed in the coming months to assess the face validity of these measures and the feasibility of collecting measure related data in current EMR systems.

Pre-hospital Infrastructure

Thanks to all the hard work we have collected data for 521,239 runs from fourteen EMS agencies for the years of 2004-2006. Data submission ended in 2009 and work has continued on preparing the data for analysis. These fourteen submitted data sets consist of varying size, degree of missing-ness, and format. Twenty-two EMS agencies ultimately participated in the study, with eight unable to submit data.

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. We have enrolled a total of 122 patients (51% of the study goal) and we have recruited 5 additional sites that joined the study this summer. There is active engagement with the Data Safety Monitoring Board and an Ethics Advisory Board because of the use of the Exception from Informed Consent for Emergency Research. A 25% enrollment safety analysis revealed no problems and a 50% analysis is imminent. We are transitioning to a new Data Coordinating Center (Emmes, Rockville, MD).

TBI

The TBI project continues to forge ahead. Ten TBI abstracts were presented at the 2008 and 2009 PAS, SAEM, and AAP meetings, and several more are being prepared for the 2010 PAS/SAEM meetings. Many manuscripts are currently being drafted. The **BIG** news is that the main Prediction Rule manuscript has been published in *The Lancet*, one of the highest impact factor journals in the world and is available at Lancet Online as of September 19th! We anticipate completing approximately 10 manuscripts regarding TBI sub-studies over the next year, and continuing to submit 3-4 abstracts per meeting at the important national EM and Pediatric meetings over the next 1-2 years until all sub-studies have been presented (we are getting there!). Next TBI projects: 1) knowledge translation of the prediction rule, and 2) progesterone for serious TBI!

Site Monitoring Visits

Submitted by Marci Fjelstad

All IAI sites had a third and final site monitoring visit during June and July. These visits focused on source documentation and data entry verification, as well as checking on regulatory documentation.



June: NWCH, BOST, DEVO, CHOP, CINC, CHON, CNMC, UMAR, MICH, UCDA, PCMC, WASH, MCWI

July: CHOM, HWRD, ROCH, CHOB, HRLY, BELL, JACO



You're the only Bee in our Bonnet!

From CHOM: "We had a triumphant celebration after entering roughly 120 Abdominal Trauma folders recently. We left our office (some queries remained unresolved) on Friday afternoon wearing our beatific Utah bonnets with a slight sugar high from the chocolate dipped Utah shaped RiceCrispie treats. From work we hit the Mexican town neighborhood of Detroit where we were ushered in the back way a la "Goodfellas" to El Zocalo restaurant. The entire time, wearing the bonnets.

The bonnets really did exceed all of our expectations (who knew they had neck flaps?), so much so that we may withhold data entry again so we can get the matching dresses...

I'm not even sorry for the ulcers caused to Marci or demanding a ransom of bonnets!"



Kim Remski (left) and Courtney Cartrette (right) from Children's Hospital of Michigan, in their "Utah Bonnets"





New PECARN site: The Children's Hospital of Denver

By Deb York, MPH

We are excited to welcome The Children's Hospital Denver as the new PEDNET site. Founded in 1908, The Children's Hospital of Denver (TCH) resides in Aurora, a suburb of Denver, Colorado. TCH is a clinical affiliate of the University of Colorado Denver School of Medicine's Department of Pediatrics. For the past decade it has consistently ranked among the top ten children's hospitals nationwide. TCH is the only tertiary care pediatric hospital in Colorado and the only dedicated Level 1 pediatric trauma center serving the 7-state Rocky Mountain region

(Colorado, Montana, New Mexico, North Dakota, South Dakota, Utah and Wyoming). TCH serves as the hub for a growing network of pediatric healthcare services, comprised of the Aurora site and 13 other Network of Care locations throughout Colorado, including 2 other emergency care sites, 3 urgent care sites and 9 specialty care clinics. The emergency and trauma care center at TCH has an annual volume of 55,000 visits for children and adolescents aged 21 years and under. The HEDA PI for TCH is Lalit Bajaj, MD, MPH. Lalit is an Associate

Professor of Pediatrics and the Research Director for the Section of Emergency Medicine. He is also the Director of Evidence Based Practice for TCH, overseeing the development of clinical care guidelines, their integration into the electronic medical record, and outcomes analyses on adherence to the guidelines.



NodalNews

ACORN

ACORN would like to welcome Joey Mechak, a new member of the CHOP team. Joey recently completed his undergraduate work in Biology at Villanova University, where he was also a member of the varsity swim team. He is currently completing his post-bac work at UPenn and hopes to enter medical school in fall of 2010.

We would also like to congratulate Jim and Cindy Holmes on the birth of their second daughter, Audrey Holmes, in August.

CDMCC

Congratulations to Angie Webster (formerly Marchant) who married Jack Webster on June 1, 2009.

PEDNET:

We'd like to welcome Sara Deakyne, our new PEDNET research coordinator at the The Children's Hospital of Denver. Sara recently graduated from the Colorado School of Public Health with a Master's in Public Health focusing on Epidemiology. She has been involved with clinical research for approximately 4.5 years, coordinating a variety of multi-center, industry sponsored and local research projects. Welcome Sara.

GLEMSCRN

Frank Moler, MD (University of Michigan) received the 2009 EMSC National Heroes Award for Outstanding Research Project. Dr. Moler was commended for his pilot and feasibility studies of therapeutic hypothermia recently conducted in PECARN, which have two publications currently in press.

CDMCC Selects OpenClinica for EDC in PECARN Studies

By Rene Enriquez, BS, IT/Data Resource Manager

Announcement

Starting next year the Central Data Management Coordinating Center (CDMCC) will use OpenClinica to support new studies that will be conducted by the Pediatric Emergency Care Applied Research Network (PECARN). CDMCC selected OpenClinica in part to streamline and enhance the data management and data collection needs of the network. OpenClinica also enables CDMCC to continue providing quality services using a flexible, robust, open source solution.



What is OpenClinica?

OpenClinica is open source, web-based clinical trials software for electronic data capture (EDC) and clinical data management. It facilitates data collection via electronic case report forms (eCRFs), and provides tools for data management and productive monitoring of research studies. OpenClinica supports leading CDISC standards and is designed to be compliant with industry and government regulations and guidelines such as 21 CFR Part 11, GCP, and HIPAA.

OpenClinica is professionally supported by Akaza Research and has a worldwide open source community of over 6,000 users and developers.

What is Next?

CDMCC is currently preparing for the upcoming release of OpenClinica 3.0. This upcoming release adds some key functional capabilities, and takes a step further to streamline data entry and workflows.

This is another exciting milestone for the CDMCC. The use of a robust, open source system to support a national research infrastructure is an exciting endeavor. CDMCC is counting on all PECARN members to help make this transition a success.

OpenClinica Key Features

- Organization of clinical research by study protocol and site, each with its own set of authorized users, subjects, study event definitions, and CRFs.
- Dynamic generation of web-based CRFs for electronic data capture via user-defined clinical parameters and validation logic specified in portable Excel templates.
- Extensive interfaces for data query and retrieval across subjects, time, and clinical parameters.
- Compliance with regulatory guidelines such as 21 CFR Part 11.
- A robust and scalable open source technology infrastructure.

For a complete list of features and a self-directed demo go to: <http://www.openclinica.org>

Children's Hospital of Michigan

Kim Remski graduated in December 2008 from the University of Michigan-Ann Arbor. She has a B.S. degree in Brain, Behavior, and Cognitive Science and plans to attend medical school in the next few years. Kim lives in Royal Oak, MI with her older sister and friend. She is a huge Detroit Red Wings fan and still bleeds maize and blue for her Michigan football team, despite the blunders of the 2008 season.

Courtney Cartrette graduated from Eastern Michigan University with a Bachelor's degree in biology with a minor in chemistry. She lives in Lincoln Park, MI with her roommate and the love of her life, her Yorkie, Tito, also known as "Tiny Dog." Courtney is a huge Pistons fan and loves cheesy reality T.V. In her free time she volunteers for the American Cancer Society.



Courtney (left) & Kim (Right)



Congratulations to Mr. and Mrs. Phillip Villanueva on their recent marriage!

Nationwide Children's

Melissa Metheny is a Certified Clinical Research Coordinator at Nationwide Children's Hospital. She has a BS in biology and is returning to the Emergency Medicine department after being away for 10 years. She has spent the last 5 years as the CRC working on several nationwide collaboratives in the Inflammatory Bowel Disease Center. Melissa is very excited to join PECARN and the GLEMSCRN team and is looking forward to working with everyone! Outside of work she is a full-time nursing student, loves to work on home improvement projects, and help with party/wedding planning.



Central Data Management & Coordinating Center



Alecia Peterson joined the Clinical Data Management team six months ago and has been providing data management support for both CPCCRN and PECARN networks. Currently, her focus has been the Patient Safety database. Being a native Utahn, she enjoys anything outdoors (hiking, biking, trail running) with her family and regularly practices yoga. Alecia's 7 pound Persian cat, Sticky, rules her world.



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



Michelle Miskin is a CDMCC Statistician. She began working as a statistical analyst for the CDMCC in May. She is working on the IAI Study and the TBI Study. Michelle recently graduated from Brigham Young University with an M.S. in Statistics. She and her husband are originally from Utah and are living near Salt Lake City.

Hai Le is a recent graduate of the University of Utah with a BS in Psychology and Anthropology. Prior to PECARN, he was a Research Coordinator for a diabetes research project through the University's Psychology department for three years. He is currently working on the IAF- Appendix project, as well as some aspects of the IAI study. He enjoys spending his time reading and being with his beautiful wife of two years.



Danielle Caswell is a Clinical Data Manager for the CDMCC. She is currently working on IAI, TBI, and IAF for PECARN. She graduated from Brigham Young University-Idaho with a B.S. in Health Science. Danielle grew up living by the beach, which she misses - but loves living by the mountains for camping and snowboarding. She enjoys spending time with her family.

