

In a nutshell

Knowledge Translation Research in PECARN: Lessons Learned from the Implementation of the PECARN Traumatic Brain Injury Knowledge Translation Study

By: Peter Dayan

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Imagine going in for a car repair on your 2014 sports car: the mechanic says he can fix it and does so with parts from a 2000 pick-up truck. Not acceptable. Unfortunately, it's quite common for patients not to receive the most up-to-date care. Why? As the amount of medical knowledge increases exponentially, it's nearly impossible to remain current. Furthermore, the latest evidence needs to be at the physician's fingertips at the time a medical decision must be made, without relying solely on memory. Knowledge translation research seeks to understand which interventions most effectively lead to using the best current evidence for individual patients and health systems.

Knowledge translation hinges upon having solid evidence on which to make recommendations to clinicians. PECARN has been successful in building a large evidence base and now has two ongoing knowledge translation studies, one entitled "Implementation of the PECARN Traumatic Brain Injury Prediction Rules Using Electronic Health Record-Based Clinical Decision Support" (shortened version is the TBI-Knowledge Translation study) and the second "PECARN Registry: Improving the Quality of Pediatric Emergency Care Using an Electronic Health Record Registry and Clinician Feedback". As would be appropriate for our times, both studies look to study if and how the electronic health record can be used as an effective tool to bring the best evidence to the bedside and best care to the patient.

In the TBI-Knowledge Translation study, we provide clinicians with specific information, based on our prior PECARN study, regarding the likelihood that a patient has an important brain injury after trauma and whether a cranial CT scan is needed or not. We hope that providing this information in the electronic health record (this is termed providing 'computerized clinical decision support' or CDS) will lead to more appropriate use of CT, particularly in order to minimize unnecessary CTs with the associated radiation risks.

We understood from prior medical literature that we would face substantial challenges to create successful CDS that would be accepted and easily implemented across multiple emergency departments. Therefore, to more fully understand the beliefs, needs and capabilities of the participating emergency departments, we visited all sites, during which

we conducted focus groups and in-depth interviews of medical staff, information technology leaders, and hospital administrators. Additionally, we conducted a detailed evaluation of the workflow in each emergency department, particularly how and when nurses and physicians used the electronic health record during patient visits.

The published article from this work summarizes multiple, potentially competing, needs and wishes of practitioners and organizations related to use of the electronic health record for knowledge translation.¹ There are other important lessons learned, however, that are not detailed in the manuscript, including the following:

1. When planning and preparing for such a study, site visits are important to insure site buy-in at all levels - all the stakeholders must be heard and be involved in the decision regarding what will (or won't) be allowed to change in the electronic health record and what might actually have the intended effect. The participation of nurses, emergency department administrators and hospital administrators, is particularly important.
2. For the lead study investigators, site visits more clearly identify the level of information technology infrastructure and support, crucial to the timely implementation of CDS and ongoing problem-solving. Additionally, site visits help investigators understand the degree to which emergency departments have IT 'autonomy'; the ability to make electronic health record changes with fewer levels of administrative oversight.
3. Additionally, if you've seen one emergency department, you only know one emergency department; they're all different. Although sites do have some overlap in how patients proceed from the time they walk in the door until the time of discharge, the workflow differs, particularly when it comes to use of the electronic health record. For example, we noted that sites differed on where, how, and by whom information was entered into the medical record, which necessitated site-specific adjustments in the CDS development. Workflow diagrams helped sites in the KT-TBI study decide how to implement the CDS at their sites.

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With the TBI-Knowledge Translation trial, which is assessing whether the CDS was effective now nearing completion, we have learned many lessons for future knowledge translation studies using the electronic health record, with many big and small-picture questions to consider. Some examples include:

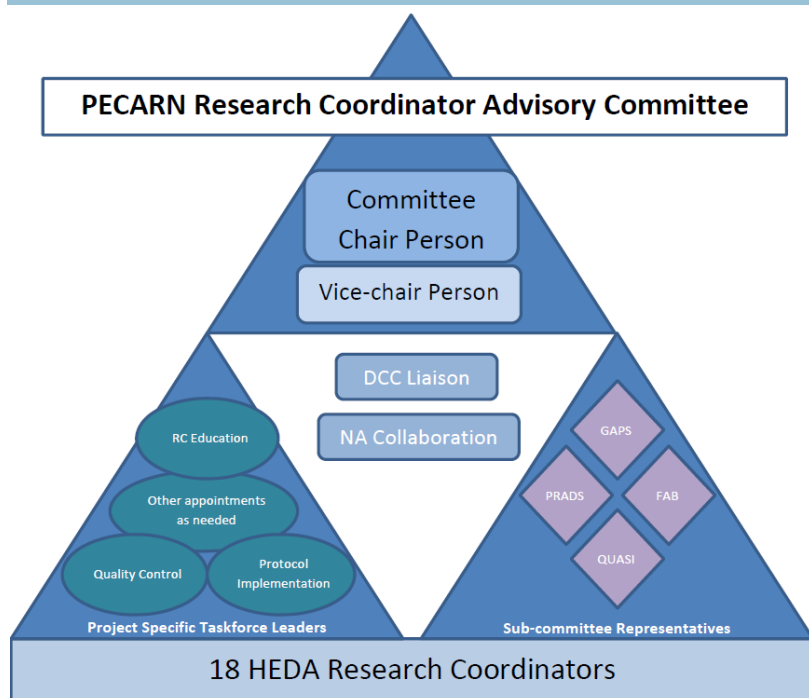
1. Collecting data in the electronic health record – we needed to have clinicians use checkboxes (i.e. clicking on a box in the computer) to provide information about the patient. This was required to provide patient-specific CDS at the time of decision-making. However, clinicians don't love checkboxes and don't love walking back and forth to and from the desktop computer – the key is to minimize the number of checkboxes and make the information the clinicians get back in the CDS something they want. Checkboxes potentially are more accepted by nurses. Also, computers should ideally be mobile (i.e. tablets).
2. CDS – we learned that a) developing CDS at one central site and then sending it (the computer code) to other sites is possible though still requires much work (such as testing the CDS accuracy) at each site; b) emergency department clinicians want specific recommendations (e.g. this patient doesn't need a head CT) but also want to maintain their decision-making autonomy, and c) finding the right place in the workflow for CDS to be seen and used before decision-making is challenging; we placed the CDS in multiple places in the electronic health record to try to capture the clinician's attention as early as possible.
3. IT teamwork – many aspects of this trial required strong input from information technology personnel at sites; their input was invaluable.

Obviously, there are many more lessons learned from the TBI-Knowledge Translation study. We look forward to completing the study, sharing its results and continuing to study the best ways to bring evidence to the bedside. Patients shouldn't have to wait to have the latest evidence brought to their care.

References

1. Sheehan B, Nigrovic LE, Dayan PS, et al. for the PECARN. Informing the design of clinical decision support services for evaluation of children with minor blunt head trauma in the emergency department: A sociotechnical analysis. *J Biomed Inform.* 2013 Oct;46(5):905-13.

The Research Coordinator (RC) Advisory Committee



The RC Advisory Committee is committed to identifying "best practices" within the network and to sharing our findings widely. By sharing best practices, we have improved Network operations as well as study protocols. We have developed and formalized a structure that will help ensure management of future research studies. The organizational chart (to the left) gives a representation of the committee's structure. New elections for the committee chair and vice-chair positions will take place during the February Steering Committee. The addition of the vice-chair position will allow for workload distribution and ensure timely follow through. Further support of the committee is provided by DCC liaison, Melissa Metheney, who works to support the administrative activities of the committee and overcome logistical obstacles. A collaborative relationship with the Nodal Administrators is in place to support the committee and encourage site participation. We identified RC representatives to serve as members of each PECARN sub-committee. RC leaders will be assigned as needed to organize workgroups for project-specific tasks. These workgroups aim to tackle issues related to RC Education, Quality Control, Protocol Implementation, or other "hot

topics" as designated by the committee chair. Finally, a Hospital Emergency Department Affiliate (HEDA) RC from each site is appointed formally to the committee. While all RCs in the network are encouraged to participate in committee meetings, polls, and phone calls, the HEDA RC serves as a specific contact and voting member, similar to the HEDA PI, thereby ensuring that "committee" decisions are representative of all RCs within the network.

EMSC Program Meeting, Jul 29-Aug 1, 2014

Exciting plans are underway for the 2014 EMSC Program Meeting, which will take place July 29 to August 1, at the Renaissance Arlington Capital View Hotel in Arlington, VA. The theme for this year's meeting is "Emergency Medical Services for Children: Then, Now, Imagine." As the federal EMSC Program celebrates its 30th

anniversary, attendees will have ample opportunities to honor the past, experience the present, and visualize the future of EMSC through plenary and breakout sessions. Online registration for the meeting will go live on March 3. More information on content and logistics will be available soon.



NICHD Activities Shared with PECARN Network

Valerie Malhomes, PhD, branch chief of the Eunice Kennedy Shriver, National Institute of Child Health and Human Development's (NICHD) Pediatric Trauma and Critical Illness Branch (PTCIB), spoke to the PECARN Network during the December virtual meeting about collaborative opportunities. PTCIB's focus on the development and support of research and training in pediatric trauma, injury, and critical illness represents an opportunity to forge partnerships with the PECARN nodes in the development and implementation of best practices in pediatric emergency care.

IOM Releases Concussion Report

In October 2013, the Institute of Medicine (IOM) published Sports-Related Concussions in Youth: Improving the Science, Changing the Culture. The report, which was partially funded by HRSA, highlights the gaps in knowledge on the extent of concussions in youth, including how to diagnose, manage, and prevent concussions, as well as the short and long-term consequences of concussions and repetitive head impacts that do not result in concussive symptoms. The recent approval of the concussion-related concepts at the October PECARN meeting illustrates the Network's commitment to being on the cutting edge of relevant pediatric research. The report can be downloaded from the IOM website at <http://www.iom.edu/Reports/2013/Sports-Related-Concussions-in-Youth-Improving-the-Science-Changing-the-Culture.aspx>.

Trauma Research and Practice: EMSC Targeted Issues Grant Toolkit Available

Randall Burd, MD, former Targeted Issues (TI) recipient and trauma surgeon, recently released the Pediatric Trauma Resuscitation Checklist Toolkit as a part of the 2010 TI project "Reducing Errors in Pediatric Trauma Resuscitation Using a Checklist." This toolkit is designed to help hospitals create a trauma resuscitation checklist that address the unique needs of each institution. Dr. Burd has authored more than 40 publications, many of which are related to pediatrics and trauma. His most recent publication, "Improving ATLS Performance in Simulated Pediatric Trauma Resuscitation Using a Checklist," was published in the October 2013 issue of *Annals of Surgery*.

For a complete list of TI project descriptions and products, please access the EMSC National Resource Center website at <http://www.childrensnational.org/emsc>. Once here, click on "Grant Programs" then "Targeted Issues."

Culture of Safety Strategy Document Aims to Improve EMS Delivery

The American College of Emergency Physicians (ACEP) recently released the National EMS Culture of Safety Strategy document. This report is the product of a 36-month cooperative agreement between ACEP and the National Highway Traffic Safety Administration (NHTSA), with support from HRSA's EMSC Program. The primary purpose of this document is to identify the safety issues facing the industry and develop a strategy for a new culture of safety within EMS. Relevant to both clinical practice and EMS-related research, this unique resource speaks to the often untold risks in the field of EMS to providers, patients, and the community, and recommends strategies to reduce those risks. The report can be downloaded from the ACEP website at <http://www.emscultureofsafety.org/>.

EMSC Federal Program Staffing Updates

Theresa Morrison-Quinata Promoted to Program Director. The Emergency Medical Services for Children (EMSC) Program would like to congratulate Theresa Morrison-Quinata on her appointment as the new Health Resources and Services Administration (HRSA) EMSC program director. In this new position, Tee will be the lead on State Partnership and State Partnership Regionalization of Care grant portfolios and will collaborate with HRSA's Elizabeth Edgerton, MD, MPH, Branch Chief, EMSC and Injury and Violence Prevention, on the Targeted Issues and PECARN grants. Tee will also be active in HRSA's strategic partnerships and program management.

Tee was the EMSC state coordinator in Guam, then, in 2003 joined the EMSC National Resource Center. Later Tee joined HRSA's EMSC Program as a public health analyst.

Diane Pilkey joins HRSA EMSC Team. Diane Pilkey, RN, MPH, has joined the EMSC Program as a nursing consultant/epidemiologist. Diane will serve as the project officer for the Targeted Issues grants and the PECARN cooperative agreements. Beth Edgerton will remain as scientific advisor to PECARN.

EMSC Program Featured at NAEMSP Annual Meeting

In mid-January, Joseph Wright, MD, MPH, principal investigator and medical director for the EMSC National Resource Center, and Marianne Gausche-Hill, MD, director of Emergency Medical Services (EMS) and director of the EMS and Pediatric Emergency Medicine Fellowships for Harbor-UCLA Medical Center in Torrance, CA, presented on 30 years of progress in emergency medical services for children at the 2014 National Association of EMS Physicians (NAEMSP) Annual Meeting in Tucson, AZ. Beth Edgerton, MD, MPH, Branch Chief, EMSC and Injury and Violence Prevention had the distinct honor of introducing Patrick DeLeon, former chief of staff to EMSC Champion Senator Daniel K. Inouye as a keynote speaker.

Other NAEMSP Annual Meeting speakers from the EMSC grantee community included: Janice Brice, MD, MPH, University of North Carolina at Chapel Hill, who spoke on the first EMS subspecialty board exam; Phillip Engle, Oregon State Partnership manager, and Manish Shah, MD, Baylor College of Medicine, both of whom spoke on pediatric simulation in the urban and rural environments; and Paul Sirbaugh, DO, Texas Children's Hospital, who spoke on lessons learned from prehospital pediatric medical direction.

In addition, the agenda included a pediatric-related pre-conference session on pediatric simulation facilitated by former EMSC TI Grantee Mark Cicero, MD, Yale University, and a pediatric research session facilitated by Lenora Olson, PhD, MA, National EMSC Data Analysis Resource Center, Julie Leonard, MD, MPH, Washington University School of Medicine and Brooke Lerner, PhD, EMT-P, Medical College of Wisconsin.

Finally, the Evidence-Based Guidelines in EMS supplement to the January/ March 2014 issue of *Prehospital Emergency Care* was unveiled at the NAEMSP Annual Meeting. The supplement was funded jointly by NHTSA's Office of EMS and HRSA's EMSC Program, with several current and former EMSC grantees serving as co-authors of the articles.

Have you ever run a marathon?

By:

Marci Ejelstad MPH, MBA and Melissa Metheney BS, RN, Data Coordinating Center



As PECARN embarks on its next Randomized Controlled Trial (RCT), it is a good time to look back at what we have learned and how we can make improvements moving forward. One of the biggest and sometimes most stressful tasks with RCTs is study start-up. Once funded, implementing a multi-center trial takes months of planning and hard work from

many PECARN participants. For the Probiotics trial, we wanted to take all the lessons learned and best practices shared from previous RCTs and use them to help make this start-up process the best one yet.

The start-up of a new trial can be described as a marathon; with any great race, there is a start, a finish and a plan to get there. Getting the Notice of Award is like the pistol shot at the race. Ready! Set! Go! Structure and organization are the key to a successful implementation; knowing where to start, and how fast to go are essential items to get the trial up and running. There are several DCC **checklists** that have been developed to help DCC Project Managers keep on task with the activities that must happen prior to enrollment of that first subject. Multi-tasking is the name of the game, and it helps to plan and act as efficiently as possible. One activity that has become an integral part of start-up procedures is the RC Advisory Committee protocol review. RCs are able to identify potential study challenges early on, allowing for solutions to be developed minimizing delays down the road. For example, we learned from previous trials that electronic order sets may take a long time for sites to implement. Releasing these very early may minimize this delay. Additionally, sites can work with their Institutional Review Boards (IRB) to allow for training activities to occur *simultaneously* with the IRB application process instead of delaying training until after approval.

There are also several other tools developed for the sites to use during the start-up process. The **Task List** was developed after input from PECARN Research Coordinators and others. This list helps delineate what needs to get done before a site can enroll their first patient. It also groups the activities into 'bundles' by topic and timeframe. Grouping tasks together in bundles helps to make a list appear less daunting and more user-friendly. The **Site Specific Workflow** is another essential tool in the start-up process. It was developed to help sites document how

the study protocol and Manual of Operations (MOO) will be carried out at their specific institutions. The protocol and the MOO stipulate what needs to get done; the workflow details the: who, what, when, where, and how for each individual site. This document also helps the Data Coordinating Center (DCC) understand challenges and solutions that sites may have developed to carry out the study, ensuring that all things are completed uniformly. A template of both of these tools is shared from the DCC and can then be tailored to meet the site's needs.

At this point, the feeling of nausea may begin to set in as sites are overwhelmed by the flurry of tasks, lists, workflows, and checklists that are whirling about. This is normal...and the main reason for the next best practice: **Setting Timelines and Deadlines**. This is the roadmap to the race. With so much activity and so many details to accomplish, it is very easy to get sidetracked. Establishing deadlines helps ensure that DCC and site activities are being done simultaneously, avoiding unnecessary delays. It may be very easy to get pulled down a "side street" with all the demands during the study startup period. Setting a network-wide calendar of events, and establishing reasonable deadlines is a great way to stay on task.

The last and by far most important aspect to study start-up is **communication!** Maintaining good communication between the PIs, RCs and the DCC is the key component that can make or break the study start-up process. There are daily e-mails, creative questions, problem solving, and team work that all come together to complete the marathon. We have gone through rigorous training with our previous RCTs and are primed to win the race with Probiotics!

- **Have a plan:** use checklists and timelines to stay on track
- **Develop a Site Specific Work Flow early:** map your calendar with deadlines.
- **Get lots of input:** ED Nurses, IRB, RC advisory committee, Local Research Team, IT
- **Identify Barriers:** tackle items that take the longest first
- **Multi-task:** complete IRB application, staff training, and other startup activities simultaneously
- **Maintain communication:** frequent meetings with the research team and the DCC. Always ask questions!

Health Affairs Quick News

December Issue of *Health Affairs* Dedicated to the Future of Emergency Medicine

The December 2013 [issue](#) of *Health Affairs* is dedicated to the future of emergency medicine and its challenges and opportunities. This month's issue also features an article, "Emergency Care for Children in the United States," written by EMSC grantees Jim Chamberlain, MD, Steven Krug, MD, and Kathy Shaw, MD, MSCE. The article discusses the challenges faced by pediatric emergency care and the methods in place for overcoming the barriers to providing proper care.





TBI-KT

The study entitled “Implementation of the PECARN Traumatic Brain Injury Prediction Rules for Children Using Computerized Clinical Decision Support (CCDS): An Interrupted Time Series Trial” is funded by the American Recovery and Reinvestment Act—Office of the Secretary (ARRA OS): Grant #S02MC19289-01-00. The overall goal of the study is to promote the appropriate use of cranial CT for children with blunt head trauma by creating a generalizable model to translate the PECARN Traumatic Brain Injury (TBI) prediction rules into clinical practice.

We are currently in year four of the project and have continued data collection in the clinical trial using the electronic health record blunt head injury data collection tool. Enrollment has remained high with ongoing monitoring; we have collected data on over 25,000 patients in the time series trial. In October 2013, two sites successfully completed data collection. Analysis planning is ongoing as the trial nears completion. Since our last update, one research panel proposal was accepted for presentation at an informatics symposium; several manuscripts are in progress.

TBI

We continue to analyze data and publish manuscripts from the TBI project. We have now published 14 manuscripts from this study, and currently have two manuscripts under review at journals (*Practice Variation in CT Use; Isolated LOC and TBI*). Several others are about to be submitted. The final manuscripts are nearly complete. This will eventually bring the total productivity of manuscripts for this project to 25! The TBI Public Use Dataset has been released, and there are some projects being developed from that dataset as well.

Seizure

Nearly all sites have completed their public disclosure activities. Data analysis and manuscript development are ongoing.

PECARN Registry

This project is to establish a data registry from electronic health records at four PECARN sites (Children’s Hospital Of Philadelphia, Cincinnati Children’s Hospital Medical Center, Children’s National Medical Center, Children’s Hospital Colorado) to collect and report quality measures of emergency care provided to children. Measurable benchmarks will be established and a clinician feedback intervention will be implemented to improve performance. The project will allow systematic and widespread collection and reporting of performance and outcomes and is critical to allow clinicians and emergency care stakeholders to improve care beyond the local level. Currently data from 2012 has been transmitted to construct the Registry. There was an expert panel convened on February 24, 2014 to determine ideal benchmarks for the quality measures. Ongoing transmission of data to populate the Registry is occurring. Performance measure report cards will be generated and delivered to practitioners and sites in mid-2014.

Quality of Care

The long term objective of the study is to create a generalizable instrument to measure quality of ED care that can be used to improve the quality of care provided to children in the ED. We will accomplish this by applying and further validating a previously developed implicit review instrument that measures quality of care delivered to children in EDs. Data collection at the performance sites is now completed. Physician reviewers completed all quality assessments and scoring. A Nurse Researcher completed the review process for the Gausche-Hill instrument for the purpose of validating the quality of care instrument. The study PIs are drafting the first manuscript from this study and working with the data center to finalize the analysis for assessing the reliability and validity of the implicit quality instrument.

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. This NICHD-funded study will enroll approximately 1,500 DKA patients and 400 non-DKA patients over five years at 13 PECARN centers. We just crossed the 700 patient enrollment threshold recently! All sites are currently enrolling and doing a great job! We have also enrolled more than 100 “non-DKA” comparison patients – children with type 1 diabetes who have never had DKA. Our “Methods” manuscript was recently published in *Pediatric Diabetes*, and we are generating a list of papers of interest for when we complete enrollment. We have two ancillary studies submitted as grant applications: one investigating cerebral hemodynamics in DKA and another investigating biomarkers of cerebral injury.

Patient Safety

Manuscript writing is ongoing in the Patient Safety and New York State (NYS) Patient Safety studies. Progress is being made on manuscripts involving diagnostic errors, falls, process variance errors, near-miss/unsafe conditions and the NYS Patient Safety data. A manuscript on radiology errors and laboratory errors has been reviewed and will soon be submitted to an academic journal. We are investigating the possibility of submitting a concept to the PECARN Steering Committee with the purpose of measuring the change in incident reporting rates over time and the change in reporting rates for unsafe conditions and near-miss events, as well as measuring the culture of safety and the changes in implementation of safety structures and processes at each site.



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



PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information on all ED visits from each participating hospital within PECARN. These data have been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2012.

The PCDP 2013 data submission is ongoing with a submission deadline of April 15, 2014. Review the PCDP MOO available in eRoom. XML format is the preferred submission format. However, CSV is accepted as well. Add your site's data dictionary to the Site Data Dictionaries folder in eRoom. This should be added at the same time as your data submission. Remember to submit through the PCDP data submission portal (<https://pcdp.utahdcc.org/pcdp/>). If you need a log-in ID for the portal, contact the project manager, Melissa Metheney. If you have questions or concerns on submitting data in XML format, please contact Jamie Bell (Jamie.bell@hsc.utah.edu) or Libby Alpern (EAlpern@luriechildrens.org)

PCDP Demographic Reports are available for the 2009-2012 data through SharePoint (<https://sp.utahdcc.org>). You may use your Active Directory account login and password to access SharePoint. There are 2 reports available: "PCDP Demographic Data - Site Totals" and "PCDP Demographic Data - Study Totals." PCDP cubes have also been updated with 2009-2012 data and can be accessed at <https://www.utahdcc.org/reportportal>. If you need help with access, please contact Melissa Metheney. Information on using the cubes is available in the eRoom. If you need a PCDP data analysis, please complete the PCDP Data Analysis Request Form, found in eRoom.

MAGiC

The MAGiC study enrolled its last (208th) patient on December 11, 2013! Congratulations to everyone on the project for a tremendously successful study! Your accomplishment is a testament to both your personal dedication and the cooperative efforts of PECARN. Next steps include completion

of final site and pharmacy monitoring visits and biomarker sample shipment. Data cleaning and biomarker analysis are underway and data lock is anticipated this summer. Thanks to all sites and the DCC for their strong work over these past 3 years!

ASSESS

As of February 8, 2014, we had enrolled 1,640 patients for the ASSESS study. Our target enrollment goal is 5,000. Based on suggestions from participating sites, we recently began an optional accelerated enrollment (protocol amendment v1.02) plan. Sites now have the option of enrolling 2 patients per enrollment block and utilizing their back up shifts for regular enrollment. One week follow-up is currently ongoing, while the one year follow-up will begin this spring. Our current one week follow-up rate completion is at 74%. A big thank you to all sites enrolling participants and the team at Hasbro Children's Hospital who are conducting the follow-up!

Probiotics

The PECARN Probiotic Study is a randomized controlled trial of LGG (a probiotic) vs. placebo in patients 3-48 months of age presenting to the ED with acute gastroenteritis. The study is funded by the NICHD (Drs. Schandower and Freedman co-PIs). We plan to enroll 900 patients in 9 PECARN sites over the next 4 years. The study is currently undergoing IRB approval at sites. Training is set for March 31st-April 1st (no jokes allowed) in St. Louis. We plan to start enrolling patients mid-April. Marci Fjelstad (DCC) and Melissa Metheney (DCC) are the Project Managers and Viani Dickey (Washington University) is the Study Coordinator.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continues to recruit In-Hospital subjects. For the year of 2013, THAPCA enrolled 70 IH subjects. To date, the IH trial has screened a total of 2100 subjects; 604 were eligible and 259 were enrolled. Thanks to all THAPCA sites for their hard work and dedication.

Intra Abdominal Injury (IAI)

We continue to prepare and publish manuscripts from the IAI project. Four manuscripts are accepted/published from this study, and currently three manuscripts are under review at various journals (FAST use, seatbelt sign, and Reliability of the abdominal examination). Several other manuscripts are in the final stages of preparation. Additional manuscripts will be done from the public use dataset.

Biosignatures Study

Since the end of enrollment in May 2013, the Biosignatures study has been busy with a number of post enrollment activities. Site monitoring close-out visits are in the process of being finalized, data review and data cleaning processes have been occurring behind the scenes, and manuscript planning with Study and Site PIs has been moving forward. The 'Methods' paper was accepted by Pediatric Emergency Care, a second paper is near submission, and subsequent manuscript planning is underway!

C-Spine Pilot

In September, NICHD funded a HOMERUN pilot aimed at prospectively refining, validating and implementing a Pediatric C-Spine Injury Risk Assessment Tool in the prehospital and ED settings. Wash U is the lead site and Cincinnati and Milwaukee are participating sites. A planning meeting was held in December to review and discuss IRB submissions, project details and study worksheets. Wash U has received IRB approval. Cincinnati and Milwaukee are under IRB review for the study. We anticipate enrollment to begin March 1st.



HOMERUN

St. Louis

Michelle Jorke– Just joined the Pediatric Emergency Medicine Department. She graduated from the University of Missouri-St. Louis with a B.A. in Psychology. She has 8 years of experience running inpatient generic bioavailability/bioequivalence medication studies and outpatient clinical trials. She's excited to gain more knowledge of research from the hospital side! She also loves being outside, exploring anything new, and road trips!

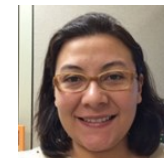


Milwaukee

Maura Coffey & Ellen Edwards were promoted from Clinical Research Assistant 2 to CRA 3, in recognition of their great performances. Nichole Graves is a 2013 graduate of the University of Wisconsin Milwaukee with a major in psychology and has also joined our team. Mark Nimmer is graduating with his Associates degree in IT Programming/Analysis. He has been supporting our section in database needs.

WASHU

Viani Dickey recently joined the PECARN team as a Clinical Research Coordinator working with the Probiotics study. She previously worked as a Research Assistant in the OBGYN Research Department at Washington University in St. Louis. Viani enjoys spending her free time with her kids and traveling to Mexico.



GLEMSCRN



Amy Nowakowski, B.S, CCRC is the new Clinical Research Coordinator Team Lead in Emergency Medicine at Nationwide Children's Hospital. Amy studied Pharmaceutical Science and Mathematics at The Ohio State University. Amy has spent the last five years living in Fort Myers, Florida working in clinical research. In her free time, Amy enjoys spending time with family, reading, shopping, and working out.

Ezra Brooks is an RA at Children's Hospital of Michigan and Wayne State University. Before coming to CHOM he worked as a programmer and system administrator. He is a graduate of Brandeis University and is working on an MA in Urban Ecology. Most recently he has put his computer skills to work on the PECARN Core Data Project (PCDP), and will be working on the upcoming Probiotics study, as well. In his spare time he can be found cooking, playing guitar and reading about ecology.



Chris Allen, BS, is a new research assistant at Nationwide Children's Hospital in Columbus, OH. Chris graduated from The Ohio State University in December 2013 with a Bachelor's degree in Aerospace Engineering and a minor in Chemistry. He is fluent in Greek. In addition to his beloved Buckeyes, Chris is a fan of the Carolina Panthers and Indiana Pacers.

Good Clinical Practice Tip

Why are Essential Document Binders (EDB) so important?

EDBs provide a framework of organization for a Clinical Research Study. They function as the official documentation of what happened as the research study was conducted. They are used for monitoring and to validate the quality of the trial and the integrity of the data collected. The exact study activities performed should be able to be recreated from the information documented in the EDB. It is often stated, if it wasn't documented, it wasn't done!

A few key points to remember when creating/maintaining your EDB:

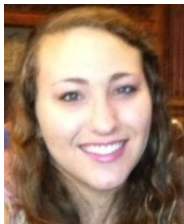
- Keep the Roles and Responsibilities/Delegation of Authority log up-to-date.
- Store items in reverse chronological order, with the most recent items at the front.
- Electronic documents should be limited to documents that are easily accessible by site staff
- General documentation guidelines:
 - * Use a ball point pen, preferably black
 - * Ensure handwriting is legible
 - * Don't use post-it notes or write notes in the margins. Create a note to file or other formal clarification.
 - * For errors: single line through, initials and date
 - * Never erase entries or use white-out



Submitted by: Melissa Metheney

For more information check out the DCC GCP Training Moodle coming soon!

PEM-NEWS



Allison Hyland joined the Columbia University / CHONY team in November 2013 after graduating from Harvard University with a neurobiology degree in May 2012. She is assisting the PECARN team on the ASSESS study and working with local PEM investigators on pain / sedation and adolescent medicine research. In her free time, Allison enjoys traveling, running, sleeping, and learning as much as she can about Spanish culture (of which she is an aficionado!). Allison is busy planning her wedding at the Alhambra, and plans to attend medical school

PRIDENET



Christine Briley

The PRIDENET Node would like to introduce its newest members: Christine is joining us as the PECARN RC at A.I. DuPont Hospital for Children. Christine joined the PECARN team in July 2013 as an RA but assumed her current RC position in November. She is a Delaware native and graduated with a BA in Biology from the University of Delaware. Christine is studying for the MCAT and hopes to pursue a career in medicine. In her spare time, she enjoys spending time with friends and family, working out, and cheering on the Philadelphia Eagles! Courtney has been working as an RA at Hasbro Children's Hospital since September. She has a BA in biology from Providence College, where she graduated in May 2013. Prior to this, she coached gymnastics and volunteered at Hasbro. She likes to travel and was able to study abroad in Copenhagen for 4 months. Courtney loves her dog Oscar and hanging out with friends and family! The rest of the PRIDENET node is well and enjoying life and spending time with family and friends!



Courtney Miller

PRIME

The PRIME node would like to introduce two new research coordinators at UC Davis. A dynamic husband-wife team, Shon and Ravneel "Neel" Singh are high school sweethearts who graduated from UC Davis recently with a BS (or two) in Biological Sciences. Shon worked with the PECARN team at UC Davis as an undergraduate student assistant for two years and was eventually hired as staff. Neel was hired as staff six months later. They share a common ambition of pursuing a career in medicine. Shon and Neel also enjoy playing tennis, dancing, and hiking together. By those who work with Shon and Neel, they are affectionately called "Shoneel."



WBCARN



Caroline Gordon is a new Research Coordinator at Boston Children's Hospital. She is originally from Rhode Island and graduated from Davidson College in North Carolina with a BS in Biology in 2013. She has been living in NYC the past 6 months and is now happy to be residing in Boston! Caroline hopes to attend medical school in the future. In her free time Caroline enjoys being outside, traveling, reading and spending time with friends and family.



Somaiah Ahmed joined the staff of Children's National Medical Center as a Clinical Research Coordinator for the DKA Fluid Study. She graduated with a BS in Biology from the University of Charleston in 2008 and is gaining her MPH from the George Washington University with a focus in Epidemiology. She hopes to combine her passion for medicine with her desire to travel by participating in the Peace Corps or Doctors Without Borders. Somaiah looks forward to applying her skills in clinical and public health research and is excited to be a part of the PECARN team.

Data Coordinating Center



Melissa Metheney, BS, RN, CCRC is a new project manager at the DCC. She comes to Utah from Columbus Ohio where she worked as an ED nurse and the Lead RC for Nationwide Children's Emergency Medicine Research Team. As an existing member of PECARN for the past 4 years, Melissa is very excited to explore this new side of PECARN and all the challenges it will bring.



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