Fall 2014

PECARN In a nutshell

What's Inside?

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Modern Site Monitoring: Has anyone seen my Pocket Calculator?

By: Sally Jo Zuspan RN, MSN, Program Director, DCC

Is on-site monitoring going the way of the typewriter, the VCR and the 8-track cassette? On-site monitoring has been a cornerstone of clinical trials for decades for purposes of assessing data quality, protocol adherence, and regulatory documentation. But recent regulatory changes could alter the way that clinical trials are monitored. This will affect all sites in PECARN.

Historically, most sponsors of industry trials conducted regular, comprehensive on-site monitoring with 100% checking of source data against database entries, known as source document verification (SDV). Sponsors and investigators typically spend extensive resources on monitoring activities, sometimes as much as 30-50% of the study budget. This practice continues in industry studies mostly due to a perception that 100% SDV is *required* by Federal and International regulations[1]. In reality, Federal regulations require sponsors of clinical investigations to ensure adequate protection of human subjects and quality of the clinical trial data, but they do not specify details[2]. Some Federal funding agencies provide general guidance on monitoring as well[3]. However, the regulations are not specific about *how* sponsors are to conduct such monitoring. The determination of how much monitoring is the 'right' amount is generally left up to investigators and sponsors; this makes for difficult decisions especially if funding for monitoring is limited.

In keeping with PECARN's goal of providing "high quality" research, investigators have worked with the DCC to develop sensible monitoring plans for PECARN studies. The Network's approach has been to integrate monitoring into almost every PECARN clinical trial, observational, and even retrospective studies. PECARN has always been creative about organizing monitoring based on the perceived needs of the study and available resources. On-site monitoring has been supplemented by remote monitoring (DCC review of uploaded source documents), nodal quality assurance plans, and central monitoring (the query system) all in an effort to assure high quality study practices. But the question remains: What is the right amount and type of monitoring for PECARN studies?

Fortunately, a new Federal Guidance called *Oversight of Clinical Investigations-A Risk-Based Approach to Monitoring* [4], published in 2013, opens the door to the idea of customizing monitoring approaches. This document outlines a more practical process for determining the monitoring necessary for a study. Risk-based monitoring encourages investigators to tailor monitoring plans to the needs of the trial, and to utilize centralized, remote or other approaches in place of extensive source verification and expensive on-site monitoring visits. Assessing risk involves reviewing aspects of the specific study, such as the complexity of the trial, study endpoints, the patient population and the amount and type of data captured. The monitoring plan is then developed to mitigate the identified risks through focused monitoring efforts. For example, a complex interventional trial might require review of 100% of outcome variables, in-depth regulatory reviews, and specific data reports; a simpler study with straightforward endpoints might have a targeted data review, central data monitoring and remote review of regulatory documents.

While the new guidance document still leaves the final decision about monitoring up to the investigator, the idea of customizing monitoring plans is appealing and can easily be applied to PECARN studies. The DCC has developed a new monitoring template to help guide investigators in matching monitoring methods to their specific trial. In addition new innovative monitoring methods have surfaced. Recently, sites have been working with the DCC to allow remote access to the Electronic Health Record (EHR). Several PECARN sites have successfully set up remote EHR access for the DCC Project Manager as an alternative to an in-person monitoring visit. This allows the Project Manager to verify clinical data in real time, with a significant reduction in cost. In addition, the Data Coordinating Center has begun to work on implementing centralized statistical monitoring, a statistical approach that identifies differences or outliers in data variables across sites to identify

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error. Centralized statistical review complements other monitoring efforts by detecting data error that might not otherwise be recognized by the query system or remote monitoring. Going forward, monitoring plans will likely use a combination of methods to assess data quality and subject safety. From a site standpoint, this may mean storing consent forms and other documents electronically so that they can be easily reviewed by electronic means or working with IT departments to allow remote access to the EHR. There are many details to work out, but the movement is on. So banish your shoebox-sized camcorder, those old floppy discs, and your rusty cassette deck; the future is here!
The following is a brief summary of just some types of activities that are a part of a customized monitoring plan, and activities that you may see utilized in upcoming PECARN studies.

1. Internal Site Monitoring- Internal audits completed at the site typically by an internal compliance office or other regulatory body within the institution.
2. Nodal Review- periodic site reviews by Nodal Administrators
3. Query Manager- a central DCC system that identifies data discrepancies and sends notifications to the sites.
4. Study Performance Reports-centrally produced reports detailing enrollment, adherence to protocol, and other aspects of performance. (SharePoint)
5. Central Source Monitoring-a remote review of data sources uploaded to a secure location for review by the DCC.
6. Remote Access Monitoring via the site EHR- direct, remote access to the EHR and regulatory documents for monitoring purposes. This may be done via a secure VPN type connection, webinar, or through a secure shared folder at the host site. Remote access to the site's EHR allows access to source data, regulatory documents and other study items without the associated costs of travel.
7. Centralized Statistical Monitoring- a statistically-driven method using complex algorithms to detect variability among individual data elements.
8. In-person Site Monitoring- a monitor travels to the site and reviews study documents.

[1]Getz, Kenneth. Low Hanging Fruit in the Fight Against Inefficiency. Applied Clinical trials online. March 1, 2011 http://www.appliedclinicaltrialsonline.com/appliedclinicaltrials/Articles/Low-Hanging-Fruit-in-the-Fight-Against-Inefficienc/ArticleStandard/Article/detail/711311
[2] Food and Drug Adminiatration; 21 CFR part 312, subpart D (Responsibilities of Sponsors and Investigators) and 21 CFR part 812, subpart C generally (Responsibilities of Sponsors).
[3] The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Clinical Research Policy Guidance Document. Clinical Research Monitoring. September 8, 2007 Revised: October 3, 2008 v. 1.2, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (National Institutes of Health)
[4] http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm269919.pdf

WHAT DOES IT TAKE TO PUT TOGETHER A MINI-MOO?

By: Kim Pham
Clinical Research Coordinator, University of Michigan, GLEMSCRN

Let's begin with a quick clarification: a mini-MOO isn't a cutesy name a kid gives to a baby cow. It refers to a condensed version of the Manual of Operations (MOO), which is an all-inclusive, step-by-step guide instructing the research staff on how to perform study operations. MOOs can span hundreds of pages, which is immensely helpful for understanding all aspects of a study. In addition, we all understand that the MOO is required for regulatory reasons and we are not attempting to substitute that action. However, it can be difficult for members of a research team to be familiar with the entire MOO document. Thus, the mini-MOO was born.

A mini-MOO is nothing more than a shortened, structured outline of the MOO. The only difference between the two documents is that one is synthesized into succinct language and bullet points, while the other offers longer, detailed explanations. Whether research sites decide to construct a mini-MOO, will depend on site-specific workflow, staff needs, and personal preference. When creating a Mini-MOO, keep your target audience in mind: research coordinators (RCs), research assistants (RAs), and students/volunteers. Since MOOs detail intricate specifics of study design, you need to remember that your staff needs **a training tool that's efficient, easy-to-follow, and accessible as a quick reference** when questions or mistakes arise. Next, you'll need patience and time. When professors create outlines of lectures, they aren't likely written overnight; neither is this. You should create a mini-MOO with the mindset of your role as a teacher and the mini-MOO as a teaching guide for your students (the research staff). Consider key aspects of successful site operation: patient flow in the ED, clinical staff communication, and office/administrative workflow. See how this study will fit in that flow. Recognize areas where your RCs and RAs have encountered trouble previously and address them as appropriate.

When you begin, have your notes and the MOO side-by-side. First, do a quick scan of the MOO and take note of bolded words or phrases, as well as helpful "MOO Clues". These signs indicate essential material that should be included in your mini-MOO. Do you also notice certain things being repeated over and over again? Flag those as well. Once you've finished your initial scan, go back and comb it for the details – this is where you'll find tips, tricks, and potential FAQs to anticipate while producing a site-specific workflow. Although this can be laborious, the more thorough you are, the smoother your research operations will be.

In general, **think of the mini-MOO as a companion to the MOO** – it should complement it, not replace it. Remember that site PIs and RCs are responsible for the contents of the mini-MOO and for making sure the shortened version is a current and accurate reflection of the most current DCC MOO. This is crucial! Be aware that a site monitor might check to see that both documents match; if there is a discrepancy, the site PI will be held responsible. In addition, **anyone using a mini-MOO must know how to access the full MOO** in case of questions.

Lastly, it is a good idea to **mirror the same numbering and headings as the original MOO** as well as the version numbers. This way the reader will easily be able to follow along between both documents and ensure that the mini-MOO always reflects the latest version of the original. There is also nothing wrong with the mini-MOO containing page numbers, section numbering, or headings referencing the MOO if it is already explained clearly. We're not trying to reinvent the wheel here - just trying to make it run a little faster.

Pediatric Disaster Checklist

In response to findings from the National Pediatric Readiness Project assessment, which noted that half of hospital emergency departments did not have pediatric-specific components in their disaster plan, a multi-disciplinary team is developing the *Checklist of Essential Pediatric Domains and Considerations for Every Hospital's Disaster Preparedness Policies*. This checklist is designed to assess the inclusion of children in existing disaster plans. We anticipate a roll out in October 2014. For further information, contact Diane Pilkey at dpilkey@hrsa.gov.

EMSC Reauthorization in Process

In July, the House Energy and Commerce Committee and the Senate Health, Education, Labor, and Pensions Committee approved their respective versions of legislation to reauthorize the EMSC Program. Both bills, numbered as H.R. 4290 in the House and S. 2154 in the Senate, would extend the EMSC Program's authorization, set to expire this fiscal year (FY), through FY 2019. Note, however, that the Senate version reduces the Program's authorized funding level from $30.4 million to $20.2 million per year from FY 2015 through FY 2019. This, however, is just a suggested funding level, intended to guide federal appropriators. As you will recall, all federal program funding is distributed through the annual appropriations process, not program authorization. Next, both the House and Senate will have to vote on their respective versions of the measure, and, if they differ, will have to come to an agreement on a final bill before it can be signed into law.

EMSC Program Featured Nationally

Beth Edgerton, MD, MPH, presented *EMSC: Thirty Years of Advocacy* at the Advanced Pediatric Emergency Medicine Assembly in New York. Several national stakeholders participated in the lecture, highlighting the program's impact over the last 30 years and its plans for the future. Additionally, at the American Academy of Pediatrics and the American College of Emergency Physicians joint dinner meeting and reception, Dr. Edgerton discussed the National Pediatric Readiness Project (NPRP), including the survey results, next steps, metrics, and how to enhance emergency department preparedness. During this meeting, a healthy dialogue about what the NPRP means for physicians and emergency departments was discussed.

NEW Continuing Education Training Opportunity

The online course, "*Pediatric Disaster Triage: Doing the Most Good for the Most Patients in the Least Time*," by former Targeted Issue Grantee Mark Cicero, MD, is now available with continuing education credits through the Indian Health Service. This online course is designed to increase the knowledge base of emergency providers in the unique considerations of pediatric disaster triage.

Dr. Cicero has authored numerous publications related to pediatrics and disasters. His most recent publication, "***Creation and Delphi-method refinement of pediatric disaster triage simulations***," was published in the April-June 2014 issue of *Prehospital Emergency Care.* For a complete list of TI project descriptions and products, access the Targeted Issues Database on the EMSC NRC website.

EMSC National Resource Center (NRC) Staffing Updates

Farewell to Joseph Wright, MD, MPH. In June 2014, Joseph Wright, MD, MPH, transitioned to a new leadership position as chairman of the Department of Pediatrics at the Howard University College of Medicine. The EMSC Program would like to thank Dr. Wright for his 10+ years of leadership and direction at the EMSC NRC and congratulate him on his future endeavors.

Kathleen Brown, MD Appointed as New EMSC NRC Medical Director. Kathleen Brown, MD, is the new medical director of the EMSC NRC. Dr. Brown has a long history with the EMSC Program and PECARN. She formerly served as the medical director for the District of Columbia State Partnership grant and continues to serve as the Hospital Emergency Department Affiliate (HEDA) principal investigator for the WBCARN node, Children's National Health System location. Dr. Brown is a senior faculty member in the Division of Emergency Medicine and a recognized expert in prehospital pediatrics.

Angela Mickalide, PhD, MCHES, Appointed as New EMSC NRC Principal Investigator. The EMSC Program would like to announce Angela Mickalide, PhD, MCHES, as the new EMSC NRC principal investigator. Angela will continue to serve as the Center's program director, leading its efforts to support the federal EMSC Program, as well as providing support to State Partnership, Targeted Issues, PECARN, and State Partnership Regionalization of Care grantees.

2014 EMSC Program Meeting: Then, Now Imagine: Honoring the Past, Experiencing the Present and Visualizing

The 2014 EMSC Program Meeting took place from July 29 to August 1, at the Renaissance Arlington Capital View Hotel in Arlington, VA. This year's program was centered on the celebration of EMSC Program's 30th anniversary and had more than 200 participants. Of note is the positive feedback received about the ability to meet and collaborate during the Targeted Issue and PECARN pre-conference meet-and-greet.

Federal Corner

EMSC Federal Program Staffing Updates

Elizabeth (Beth) Edgerton, MD, MPH Promoted to Division Director. Dr. Edgerton is now the Division Director of the Child, Adolescent and Family Healthy Division in the Health Resources and Services Administration, Maternal and Child Health Bureau. She has been serving as the Division's branch chief for Emergency Medical Services for Children (EMSC) and Injury and Violence Prevention since February of 2011. Dr. Edgerton will remain as the scientific project officer for the Pediatric Emergency Care Applied Research Network (PECARN) and an advocate for EMS for Children.

Diane Pilkey Announced as PECARN Project Officer. Diane Pilkey, RN, MPH, joined the federal EMSC Program as a nursing consultant in October 2013 and will now serve as the project officer for the PECARN cooperative agreements. Additionally, Diane will continue to oversee the Targeted Issues grant program. She has experience as a nurse in the emergency department and critical care settings, as well as experience in public health at the local, state, and federal levels, including 11 years as a Maternal and Child Health epidemiologist in the Washington State Department of Health.

EMSC Partners with ASPR's HPP

During the last year, the Office of the Assistant Secretary for Preparedness and Response (ASPR), Hospital Preparedness Program (HPP) and the EMSC Program collaborated on ways to improve pediatric emergency care in the United States. The cornerstone of the HPP initiative is its Healthcare Coalitions (HCC).

HCCs are formal organizations consisting of acute care hospitals, EMS agencies, specialty and primary care providers, long term care facilities, behavioral health experts, public agencies, and private organizations that come together to prepare for, respond to, and recover from disaster. The goal of HPP and the HCCs they support is to comprehensively care for all patients, including those affected by a disaster and those who were already part of the medical system.

The EMSC Program encourages a multifaceted approach to healthcare in project planning, development, and implementation that incorporates the full-spectrum, from injury prevention, intervention, and tertiary care to rehabilitation and return to the community. Connecting the expertise and networks of HPP and EMSC would strengthen everyday pediatric preparedness efforts across the nation.

Stay tuned for more information regarding the HPP-EMSC partnership or contact Theresa Morrison-Quinata at TMorrison-Quinata@hrsa.gov.

New Study Spotlight

Emergency Department Screen for Teens at Risk for Suicide (ED-STARS)

By: Jackie Grupp-Phelen, MD, MPH

Suicide is the second leading cause of death among youth ages 12 to 17 in the United States. However, most youth at high risk for suicide go unrecognized and untreated, and for half of adolescent suicides, the first suicide attempt is fatal.

The PECARN network is about to embark on a study to improve identification of youth at risk for suicide. The project, *Emergency Department Screen for Teens at Risk for Suicide (ED-STARS)* is led by Cheryl King, PhD, University of Michigan; Jacqueline Grupp-Phelan, MD, MPH, Cincinnati Children's Hospital; and David Brent, MD, University of Pittsburgh with support from the National Institute of Mental Health. The multi-site collaborative project will be conducted at 13 sites in the Pediatric Emergency Care Applied Research Network (PECARN) and the Whiteriver PHS Indian Hospital. These EDs serve geographically and socio-demographically diverse groups of youth. The goal of the study is to develop a suicide risk profile and computerized adaptive screening tool for predicting suicide attempts.

The optimal screen developed in this collaborative project will have the potential to be disseminated nationwide to enhance the capacity of emergency departments to identify and effectively triage youth at acute risk for suicide attempts. This project will develop and test a computerized adaptive screen (CAS), which results in individualized sequences of screening questions conditional on previous responses, and will test a wide range of acute suicide risk indicators for possible inclusion in the CAS. The CAS will be compared to a fixed suicide screen called the Ask Suicide Question Screen. It also will test the incremental value of the Implicit Association Test (IAT), a behavioral test of implicit suicidal cognitions, which is important as many at-risk youth may deny suicidal thoughts. This project will utilize PECARN's strong infrastructure and record of successful recruitment, and the investigative team's collective experience in multi-site studies, computerized adaptive testing, and youth suicide research in ED settings. Study training is set for February 2nd 2015 in Ann Arbor. More details to come.

TBI-KT

The study entitled "Implementation of the PECARN Traumatic Brain Injury Prediction Rules for Children Using Computerized Clinical Decision Support: An Interrupted Time Series Trial" was funded by the American Recovery and Reinvestment Act. The overall goal of the study was 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 prediction rules into clinical practice. We completed the clinical trial in June 2014, collecting data on more than 25,000 patients. Analysis is ongoing to determine the outcome of the trial, with multiple manuscripts being prepared for publication.

PECARN Registry

This project establishes 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 have been derived from the Registry and a clinician feedback intervention will be implemented to improve performance. Currently, data from 2012, 2013, and the first 6 months of 2014 have been transmitted to construct the Registry. There was an expert panel convened in February, 2014 to evaluate the performance measures populated from the Registry and determine ideal benchmarks for the quality measures. Ongoing transmission of data to populate the Registry is occurring. Performance measure report cards have been designed and will be generated and delivered to practitioners and sites this fall. 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.

TBI

We continue to analyze data and publish manuscripts from the TBI project. We have now published 16 manuscripts from this study, and currently have 4 manuscripts under review at journals (*TBIs associated with televisions; Sports-related TBIs; Epidemiology of TBIs; Clinical implications of isolated skull fractures).* All remaining 5 manuscripts have been through GAPS, and a few other manuscripts are being submitted for publication after analysis of the Public Use Data Set (PUDS). This will eventually bring the total productivity of manuscripts for this project to 25, plus a few others from the PUDS. Getting very close to closing the final chapter of this extremely productive 10-year project.

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 in PECARN. These data have been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2013.

PCDP Demographic Reports are available for the 2009-2013 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 2009-2013 data and can be accessed at https://www.utahdcc.org/reportportal. If you need help with access, please contact Melissa Metheney at the DCC. 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.

IAI (Intra-Abdominal Injury)

We continue to analyze data and publish manuscripts from the IAI project. The IAI project enrolled 12,044 subjects with blunt torso trauma. Manuscripts accepted/published from this database include 1) Main decision rule paper, 2) Inter-rater reliability of variables for a decision rule, 3) Injuries in children with normal CT scans, 4) Pneumothoraces in children, 5) Abdominal ultrasound in injured children, 6) Importance of seatbelt sign, and 7) Pelvic fractures in children. Two additional manuscripts are currently under review. Finally, three manuscripts are being prepared for submission/resubmission.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials is in its 5th year of enrollment. Since the last update, we've brought on 6 new sites from the UK to help increase enrollment. From January 2014 to July 2014, THAPCA enrolled 28 IH subjects. To date, the IH trial has screened a total of 2370 subjects; 660 were eligible and 287 were enrolled. Cheers to all THAPCA sites for another 6 months of hard work and dedication.

MAGiC

The MAGiC Study completed patient follow-up in March 2014, with site and pharmacy monitoring concluding in May. Since then, we've been working rapidly to complete initial data cleaning and analyses. As a result, 3 abstracts were recently submitted for the 2014 ASH Annual Meeting with the first manuscript expected to be submitted to GAPS this Fall. Further analyses are planned in anticipation of PAS abstract submissions. There continues to be a small amount of work for the sites and we thank you for your continued efforts! We hope to see presentations and publications in the near future.

Public Use Data Sets

To enhance the public health benefit of completed PECARN studies, public use data sets are available to qualified researchers. PECARN public use data sets are generally made available after study completion in accordance with PECARN policy. Data set creation and distribution will be performed by the data coordinating center. There are currently 8 public use data sets available for request. Interested investigators can obtain more details at http://www.pecarn.org/studyDatasets/index.html

FLUID

The FLUID study is progressing well. This NICHD-funded study will enroll approximately 1,400 children with DKA and 400 non-DKA patients over five years at 13 PECARN centers. We recently crossed the 850 DKA patient enrollment mark! We have also enrolled over 140 non -DKA comparison patients – children with type 1 diabetes who have never had DKA. All sites are currently enrolling in one/ both arms of the study and doing a great job! The "Methods" manuscript was published in Pediatric Diabetes, and we are generating a list of papers of interest for when we complete enrollment. We have one ancillary study awaiting grant funding decision (biomarkers of brain injury in DKA). Two abstracts from the ancillary study were presented at the May 2014 PAS meeting in Vancouver.

PATIENT SAFETY

The Patient Safety group is currently working on writing, reviewing and submitting manuscripts from the Patient Safety study data. Manuscripts on radiology errors, laboratory errors, and near-miss/unsafe conditions have all been submitted to academic medical journals, awaiting word on publication. The main manuscript for the NYS Patient Safety project has been submitted to GAPS, as well as a manuscript on Process Variance errors. Monthly conference calls are ongoing, as we discuss the future of patient safety studies in PECARN.

BIOSIGNATURES STUDY

Biosignatures continues on behind-the-scenes. Final review of the remaining rate review cultures is in progress and microarray sample analyses continue to move forward. GAPS and ensuing journal submission for the second paper are anticipated to occur very soon with subsequent manuscript planning to follow. Lastly, the Study PIs have been further developing the Biosignatures II grant submission with plans to submit in October 2014.

PROBIOTICS

The Probiotics Study has opened enrollment at the lead site, Washington University, with 28 patients enrolled to date. Central pharmacy logistics are being finalized and enrollment is expected to begin in September or October at the remaining 8 sites. All sites have IRB approval and are finalizing site specific training. The goal is to enroll 80 patients (40 patients <1yr old) by fall 2014 and hold the first DSMB meeting in early 2015.

QUALITY OF CARE

The PECARN Quality of Care study is progressing well. This AHRQ-funded R01 is evaluating an implicit review quality of care instrument and evaluating the association between a variety of care factors and quality of care. The study is evaluating the care delivered in twelve PECARN EDs. We have completed the 620 chart reviews done by 8 reviewers as well as 271 chart reviews done by a nurse applying four instruments for patients with asthma, febrile seizure, gastroenteritis, and head trauma. The first manuscript is in final stages of preparation (evaluating the consistency, reliability and validity of the implicit review instrument). Subsequent analyses will focus on hospital, ED, physician, patient and presentation level factors and their association with quality of care.

SEIZURE

The primary manuscript was published in JAMA in April 2014, and 4 manuscripts are under development or have been submitted for publication. All sites have completed their public disclosure/ community consultation activities. The initial final Case Study Report (CSR) has been submitted to the FDA for review.

ASSESS

As of August 2nd, 3522 participants have completed baseline activities in the ASSESS study. Enrollment is ahead of schedule and all sites are doing a great job! Hasbro Children's Hospital completed its enrollment in July and several more sites are expected to finish enrollment in the coming months. Hasbro Children's Hospital completed the 1 week follow up assessments in July 2014 with a 71% follow up rate. The one year follow up assessments began in May 2014. Hasbro Children's Hospital has completed 37 of the one year follow up assessments to date.

Site Enrollment Complete

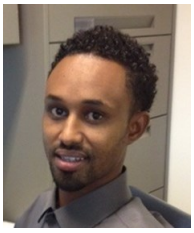
The Hasbro ASSESS team celebrated the end of their site enrollment with a beach party!

PECARN New Faces

PEM-NEWS Node

Brooke Peery, MPH is the new CHONY PECARN Research Coordinator. Brooke's public health background includes 2 years as a Peace Corps volunteer in West Africa, 4 years as an EMT/Critical Care Tech in the Emergency Department, and medical mission work to Haiti, Peru, and Rwanda. She is a recent graduate of Emory University where she received her MPH from The Rollins School of Public Health. In her free time, she enjoys exploring French bakeries in NYC, bike riding, and hiking.

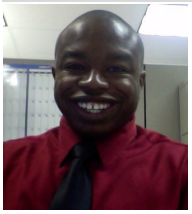
Leah Clemente is a new research assistant at Children's Hospital Colorado. Leah graduated from Cornell College with a B.A. in Sociology and Women's Studies. After working for the University of Iowa's Department of Epidemiology for two years, Leah moved to Colorado to pursue her Master's degree in Epidemiology. When not in class, Leah enjoys spending time with her friends and family, reading, cooking and relaxing by the pool.



Muse Jama is a new Research Assistant at Children's Hospital Colorado. He lived in Denver for 8 years, and is originally from Somalia. He graduated from Metropolitan State University of Denver with a BS in Biology in 2014. He would like to earn a doctorate degree in public health in the near future so he can fulfill his passion of helping people. He has a wife (Safiyo) and two little children with whom he spends most of his spare time.

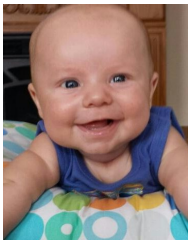
PEM-NEWS is excited to announce that Anita Patel has taken the position of Nodal Administrator as of April 2014. Anita has worked with PECARN in many different capacities, first as the federal liaison at the EMSC NRC, then as a Research Coordinator at CHONY. She is looking forward to continuing her work with PECARN and can be reached at ap3133@cumc.columbia.edu.

HOMERUN Node



St. Louis-
Nnaemeka Ejiaga graduated from California Baptist University with a B.S. in Biology. He is currently in the Washington University (in St. Louis) College Post Baccalaureate program. Nnaemeka was originally hired as a work-study student and is now a full-full-time RC. He enjoys working out and exploring the city.

Cincinnati-
Jenna Gilb is a Clinical Research Coordinator from Cincinnati Children's and will be joining PECARN as a lead coordinator for the Probiotics Study. Previously, Jenna was also a lead on the Progesterone Pilot Study and has enrolled for various other PECARN studies. Jenna graduated from the University of Kentucky in 2010 with a Bachelor of Science in biology and has been working as a CRC since then. Outside of work, Jenna has spent much of the past year planning for her New Year's Eve wedding and hanging out with her English Bulldog Mugsy.



Milwaukee-
Mark Nimmer is a daddy! A healthy 7 pound baby boy, Nathaniel David Nimmer was born 8/2/14. Mark also recently accepted a new position at the Medical College of Wisconsin in the role of a Data Analyst.
In more Milwaukee baby news, Ellen Edwards, CRA III gave birth to a healthy son named Calvin on 05/06! Both are doing well.

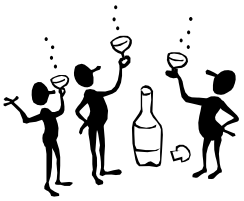
PECARN New Faces

GLEMSCRN Node

Morgan Butcher, research assistant, Nationwide Children's Hospital, is a recent graduate of The Ohio State University with a bachelor's degree in Health Sciences. Her ultimate goal is to go to medical school but she is very excited about the opportunity to be a part of the research team to help improve the standard of care at Nationwide Children's Hospital.

Kelsey Buhler, clinical research associate at the University of Michigan. Kelsey graduated from Madonna University in May 2014 with a bachelor's degree in Biology. She is very excited to be a part of the clinical research world and is also interested in marine biology. Photography, reading, and listening to music are her favorite things to do in her free time.

Cindy Lin, research assistant, Nationwide Children's Hospital. Cindy is a recent graduate of The Ohio State University with a B.S. in Biochemistry. She previously volunteered at Children's during undergrad and is excited to have the opportunity to join the ED research team. In the future she hopes to apply to medical school. Cindy is looking forward to working with everyone and joining the Nationwide Children's family!



Congratulations to Jennifer Kline, MPH, Clinical Research Coordinator at Nationwide Children's Hospital, on earning a Master of Public Health from The Ohio State University.

Congratulations to Clare Levijoki who has just received her Certified Clinical Research Professionals (CCRP) certification from the Society of Clinical Research Associates (SOCRA).

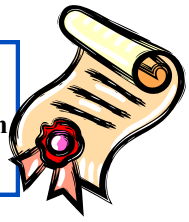
PRIME Node

Mira Henien just moved from Boston Children's Hospital, where she was a clinical research coordinator working on the FLUID study. She's applying to medical school this year for the class of 2019. She's the lead coordinator on the FLUID study at Children's Hospital of Philadelphia (CHOP). Outside of PECARN she enjoys running, Bikram yoga, dance, and the Philadelphia Eagles.

Hilary Spencer has recently joined the Division of Pediatric Emergency Medicine as a research assistant for Primary Children's Hospital. Hilary is a student at the University of Utah majoring in Health Promotion with an emphasis in Consumer Health and a Minor in Pediatric Clinical Research. When she is not in the Emergency Department, she enjoys volunteering at the University of Utah's Neurosurgery Department, baking, going on adventures with her husband, and teaching ballet to toddlers. Hilary will be working on the FLUID and THAPCA studies.

We would like to announce ACEP's rollout of a very large campaign and tool kit about the PECARN head trauma decision aid.

We'd also like to congratulate Kyle Pimenta (CRC- UCD) on his receipt of the UCD CRC Recognition Award in April.



WBCARN Node

Catherine Gordon is a new Research Coordinator at Boston Children's Hospital. She is originally from Vermont and graduated from Middlebury College with a BA in Environmental Studies and Global Health in 2013. Catherine is hoping to pursue a career in medicine in the future and is excited to learn more about clinical research with PECARN. In her free time, she enjoys skiing, hiking, biking, and spending time with friends and family.

Joanna Westerfield (Children's National Health System) was promoted to Clinical Research Coordinator-I Congratulations, Joanna!!