Winter 2018

PECARN In a nutshell

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Adaptive Designs and Bayesian Analyses

Submitted by
John VanBuren, PhD
Pediatric Biostatistician, DCC

Grant submissions become increasingly competitive with each passing year. Funding agencies are looking for more efficient studies to answer clinical questions without jeopardizing the study integrity. In some scenarios, adaptive designs and Bayesian analyses (described below) may be useful methods to provide this efficiency. A common misconception is that adaptive designs are always Bayesian. When in fact, they are not inclusive of each other as illustrated below.

Adaptive Designs

The FDA defines adaptive designs as: A study that includes a prospectively planned opportunity for modification of one or more specified aspects of the study design and hypotheses based on analysis of data (usually interim data) from subjects in the study.

To simplify, adaptive designs are pre-specified changes that may occur while a study is ongoing. These changes are planned for and implemented if the interim data present a certain way. For example, if we are studying two different drugs compared to a placebo, at an interim analysis, we may want to randomize more subjects to the drug currently showing a higher chance of efficacy and fewer subjects to the inferior drug (i.e., response adaptive randomization). A different adaptive design may allow for sample size re-estimation to achieve the desired statistical power. Adaptive designs can vary in nature, but they all incorporate some pre-specified change to the current study based on interim results.

So-called 'traditional designs' (non-adaptive) are well understood and have reliable statistical properties associated with power and Type I error rate ("false positive" trials). Preparing an adaptive design trial often requires more extensive work for the statistician and study PIs because power and Type I errors need to be determined through complex simulations. Multiple scenarios of potential effect sizes need to be assessed to obtain an overall understanding of how the adaptive design affects the trial.

Bayesian Analyses

Bayesian statistics is a method of statistical inference that allows the incorporation of prior information during study design and analyses. For example, the medication Enoxaparin has been thoroughly studied in adult literature for deep vein thrombosis prophylaxis; however, there is minimal literature on this drug in pediatrics. A Bayesian analysis would allow the incorporation of the adult findings (e.g., success rates for adults on Enoxaparin) in a pediatric study to maintain power while reducing the necessary sample size. Bayesian analyses also alleviate other problems such as the incorporation of subjects who have not yet completed follow-up in interim analyses. The Bayesian framework can be applied to both traditional trial designs as well as adaptive trial designs. However, similar to adaptive designs, Bayesian analyses require extensive work in the design of a study. In addition, individuals (both clinicians and statisticians) may be skeptical of the use of prior information.

TIC-TOC

The DCC, along with Drs. Nishijima and Kuppermann, with the assistance of Berry Consultants, are in the process of planning a Bayesian adaptive design for a Phase III trial studying Tranexamic acid (TXA) in children with torso and/or brain injuries. This study will assess three drug arms (placebo, lower dose TXA, higher dose TXA) in three different injury types (isolated torso injury, isolated head injury, combination of torso and head injury). This yields nine distinct study groups (e.g., lower dose TXA with an isolated torso injury). The Bayesian adaptive design clinical trial will allow for the borrowing of information across injury types within an intervention arm. For instance, if we observed a beneficial effect in the isolated torso group assigned to the lower dose TXA and a beneficial effect in the isolated head group assigned to the lower dose TXA, we would assume there would be a beneficial effect in the combined injury group assigned to the lower dose TXA. This design type allows for increased power to the study in all three injury types while only marginally inflating the Type I error in plausible scenarios. The design will also implement response-adaptive randomization and will allow distinct groups to be removed from enrollment at interim analyses.

Cont. on next page...

This project is supported in part by the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Emergency Medical Services for Children (EMSC) Network Development Demonstration Program under cooperative agreements U03MC00008, U03MC00003, U03MC22684, U03MC00007, U03MC00001, U03MC28845, U03MC00006, and H3MC26201. *This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.* MCHB/HRSA Contact: Diane Pilkey, RN MPH DPilkey@hrsa.gov.

(Continued from page 1)

Site Involvement

Bayesian analyses have no impact on site personnel; they only affect the statistical analyses. On the other hand, adaptive designs may or may not impact the site depending on the adaptation. For example, if the randomization frequency in the Phase III TIC-TOC study for the isolated head group is altered (e.g., 25% get randomized to low dose TXA, 30% get randomized to placebo, and 45% get randomized to high dose TXA instead of equal randomization of 33% each), then the sites will not be aware of the change since the drug is blinded. The process of randomization would not be affected and sites would enroll and administer drug in the usual fashion until the end of the study. Instead, if we remove an injury pattern (e.g., isolated torso injured patients) from the study, sites would be aware of this adaptation since they would not enroll these patients anymore.

In a different example, if there is one drug and we are considering three methods of administration (e.g., oral through liquid form, oral through capsule form, or intravenously), then

the sites would notice if the randomization frequency shifted. The site may start treating patients predominantly through one method (e.g., intravenously) over the other two methods and be aware of the adaptation. The ESETT trial uses response-adaptive-randomization to identify the most effective treatment arm. If there is a trial that incorporates an adaptive design that affects the site, the DCC and study PIs will train the sites on the adaptation.

Takeaway Message

Adaptive designs and/or Bayesian modeling are two potential approaches that may improve efficiencies and make a grant more competitive if the trial design would benefit from it. ■

PECARN

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

Upcoming Federal & PECARN Events

March 1, 2018: EMS Agenda 2050 project public meeting, Dallas, Texas. Link for additional information: http://emsagenda2050.org/whats-happening/

April 7-11, 2018: American Academy of Emergency Medicine Scientific Assembly, San Diego, CA. Link for registration: http://www.aaem.org/aaem18/register

April 20, 2018: PECARN Teleconference

May 5-8, 2018: Pediatric Academic Societies' Meeting, Toronto, Ontario. Link for registration: https://www.pas-meeting.org/attendees/

May 15-18, 2018: Society for Academic Emergency Medicine Annual Meeting, Indianapolis, Indiana. Link for registration: http://www.saem.org/annual-meeting/

May 21-24, 2018: NASEMSO Spring Meeting, Providence, Rhode Island.

July 11, 2018: PECARN Teleconference

August 22-24, 2018: Annual Scientific Grant Writing Work shop, Chicago, Illinois. Visit www.nedarc.org for online registration.

September 24-26, 2018: Fall 2018 In-Person PECARN Meeting

Good Clinical Practice Tip

???EDB-What???

Submitted by
Amy Watson
PECARN Project Manager, DCC

WHAT is it?
An "Essential Document Binder" or "EDB" is defined as documents, which collectively permit evaluation of the conduct of a trial, and the quality of the data produced.

WHEN do we do it?
An EDB is required for every trial and created prior to study start. This is a requirement at both the study site and DCC. Filing documents in a timely manner can greatly assist in the successful management of a trial. These documents are also those that usually audited or inspected by the regulatory authorities as part of the process to confirm the validity of the trial conduct and integrity of the data collected.

WHAT do we put in it?
To help identify what is required in the binder, the DCC will provide either physical binder tabs or an electronic organization structure for you. If you have a question regarding where to locate these items, contact your study specific project manager. ■

eBinder

Example of EDB Checklist:

Item	Preparation
Protocol	Set aside time to review all materials & correspondence before your visit. If you failed to submit an amendment (i.e. to add enrolling physicians) then submit it immediately so it is documented during the monitoring visit as submitted. Make sure all versions of the protocol are included in this section.
Initial protocol submitted to the IRB	
Protocol modifications	
Protocol amendments	
Current approved version	
Supplemental Protocol Instructions (ex. e-mails, additional documents, study updates, etc.)	Make sure you have a note referencing the location of the study updates.
Participant Log	Make sure you have all versions, most recent first.
Patient Files and Source Documents (note indicating location of completed patients study files)	Screening log and Site Sample Tracking/ Cold Chain Maintenance Logs should be filed or referenced here.
Regulatory Documents	
Investigator Commitment Form	
Federal Wide Assurance (FWA) Documentation	Check your IRB website for this document if you do not have it.
Current and previous years CV for PIs	Review CV version, add revised version if necessary.
Medical license for PI	Make sure these are current, and keep all old licenses even if expired.
Documentation of Human Subjects training (both PI and RC)	Provide documentation of human subjects training for the RC and PI as well as any additional RCs & physicians obtaining parental permission/enrolling. (Check with your IRB/institution to confirm the training required to obtain parental permission/ consent.)
Lab Certificates	If the site is using a laboratory, you need to provide certification and/or accreditation documentation for the lab such as CLIA or OSHA. Also, any laboratory personnel that are handling study samples must provide documentation that they have completed sample handling training. (IATA).

Updates from the National Highway Traffic Safety Administration (NHTSA)

Field Triage Guidelines: NHTSA's Office of EMS is collaborating with the **American College of Surgeons** to develop a strategy for the revision of the Field Triage Guidelines that will result in a more evidence-based trauma triage decision-making process. In support of this strategy, two literature syntheses have been conducted by AHRQ's Evidence-based Practice Center Program with funding from NHTSA's Office of EMS. The first of these reviews, examining level of consciousness as a predictor of the need for tertiary trauma care has been completed and posted on the AHRQ website; the second review on respiratory and circulatory system predictors is nearly completed. In addition, NHTSA's Office of EMS has awarded a Task Order to procure and analyze linked State EMS-trauma databases to identify other predictors of severe injury in the absence of physiologic derangement; expected completion is September 2018.

EMS Compass: Following the completion of the EMS Compass project, NHTSA's office of EMS has awarded a follow-on Cooperative Agreement to the **American College of Emergency Physicians (ACEP) and the National EMS Quality Alliance** to assist in developing a sustainable mechanism for facilitating consensus on EMS quality performance measures and to provide tools to measure and improve trauma care.

Data Linkage: In response to a recommendation of the **NASEM Trauma Report**, NHTSA's Office of EMS has awarded a Cooperative Agreement to the American **College of Surgeons**, in partnership with **NASEMSO** to develop a joint policy statement on the bilateral exchange of EMS and trauma data. The policy will be developed with input from other key stakeholders such as hospitals and software vendors and will ultimately be posted on the websites of the ACS and NASEMSO.

National Pediatric Readiness Project (NPRP)

In 2017, a **white paper** (https://emscimprovement.center/about/nprp-white-paper/) describing the NPRP's history, progress, and trajectory was published. This document provides a quality improvement framework for evaluating care that children receive within and prior to arrival in emergency departments. Partners in this endeavour include the **American Academy of Pediatrics, the American College of Emergency Physicians, and the Emergency Nurses Association**. While paediatric readiness scores have increased since the last systemic review in 2003, this document outlines the need for substantial improvement.

Revised National EMS Scope of Practice Model

The National Association of State Emergency Medical Services Officials (NASEMSO) was soliciting feedback on revisions to the 2007 **National EMS Scope of Practice Model** ("Practice Model"), see https://www.ems.gov/education/EMSScope.pdf. The first portion entails using terminology to describe prehospital providers that has similar meaning across communities. The second step is to then assign skills and tasks that would be within the scope of practice of different prehospital providers. An important part of this process is to reach community consensus on these descriptions, and to that end, a survey was designed. Survey results are now pending.

National EMS Information System (NEMSIS)

The National EMS Information System (NEMSIS) is a national repository for collecting, storing, and sharing standardized EMS data for States nationwide. NEMSIS provides a mechanism for collecting and storing standard data elements from EMS agencies. In November of 2017, the **NEMSIS Technical Assistance Center (TAC)** announced release of the final specifications for the updated version of NEMSIS, version 3.5. This video https://youtu.be/0x79l12-Ox4 explains the rationale behind the new metrics.

EMS Agenda 2050

The **EMS Agenda 2050 revised Strawman** is available for review and feedback. Download the new version of the EMS Agenda 2050 Straw Man and provide feedback by going to http://emsagenda2050.org/ and clicking on ***Share Your Ideas.*** See upcoming events for next regional meeting.

HRSA/EMSC Critical Crossroads Project

The **Critical Crossroads** initiative, initiated by HRSA's EMSC Program, seeks to collaborate across federal agencies to improve the identification of and care coordination for children experiencing mental health crisis in rural emergency care settings. The project will identify resources and best practice tools that can be disseminated to states and rural communities. The **Critical Crossroads Federal Steering committee**, composed of members across 10 agencies, meets monthly. The goals of the project are to: improve the coordination of care of children in emergency mental health crisis and post-crisis in rural regions; and Provide training and policy resources to EMS and ED practitioners. Expected outcomes include: the creation and dissemination of a provider Toolkit composed of consolidated/streamlined resources and best practices for educational/training resources and policy/procedures to be utilized as reference for emergency care providers, increased stakeholder engagement in the need to improve emergency medical care for children and adolescents experiencing mental health crisis; and fostered Federal partnerships dedicated to the mission of improving emergency care for children in mental health crisis.

EMSC Performance Measure Data Collection: Updates from the National EMSC Data Analysis Resource Center (NEDARC)

NEDARC staff are busy surveying for the **EMSC State Partnership** program performance measures. These measures (http://www.nedarc.org/performanceMeasures/) are standards to benchmark progress in pediatric emergency care at the state and national levels. There are nine measures, for both prehospital and hospital settings. They include: skill checking in use of pediatric equipment, recognition of centers for pediatric traumatic and medical emergencies, prioritization of children (as evidenced by inclusion of stakeholders on national committees, presence of pediatric emergency care coordinators, and integration of EMSC priorities into statutes), NEMSIS data collection, and interfacility transport. NEDARC will wrap up EMS agency surveys gathering baseline data for performance measures 02 and 03 on skill checking and pediatric care coordination. Currently, 72% of the nearly 11,000 agencies surveyed have responded, and more are coming in! In May – Aug of 2018, as requested by HRSA, NEDARC staff will survey hospital emergency departments for performance measure 06 and 07, regarding the presence of interfacility transfer agreements and guidelines. NEDARC staff will work with EMSC program managers in each state beginning early 2018 to verify hospital information, prepare for the survey, and to encourage high participation from hospitals. NEDARC staff will clean and analyze in August, and then send final results to both HRSA and individual state EMSC programs.

Funding Opportunities

Several organizations have annual or semi-annual calls for proposals on topics relevant to pediatric emergency medicine and prehospital care. While the deadline for some of these may have passed, there are potential funding sources for future years:

American College of Emergency Physicians: https://www.acep.org/Content.aspx?id=31962#sm.000002xoe3mxdf3fq7c1i38hahx28

Patient-Centered Outcomes Research Institute (PCORI): https://www.pcori.org/funding-opportunities?qt-funding_opportunities=1#qt-funding_opportunities

Society for Academic Emergency Medicine: http://www.saem.org/saem-foundation/grants/funding-opportunities/what-we-fund

Thrasher Research Fund: https://www.thrasherresearch.org/default.aspx ■

Interview Questions and Strategies for Hiring Outstanding Research Coordinators

Submitted by
Kristin Beiswenger, MS
PEM-NEWS Node

Hiring a Research Coordinator (RC) is something that every site faces at some point. Often the process can be easy, like when you have identified a remarkable Research Assistant already working in your emergency department. However, sometimes you will need to formally post the job and complete a full interview and selection process.

What characteristics should you look for in an RC? We polled many current RCs and found that organization, planning, communication, team work, and stress management skills, along with having a passion for research and being self-motivated, were the qualities most often found in successful RCs.

While a degree in a science or health-related field, research experience, and attention to detail can be determined from a candidate's resume and cover letter, the in-person interview is really where you can figure out if the person possesses the critical qualities listed above or at least has a high potential to quickly develop them.

During the in-person interview, after describing the priorities, challenges, and expectations of the RC position, the typical work day, and your management style, some good questions to ask the candidate are:

"How do you stay organized?"
Encouraging answers include list making and using calendar-based task managers. Remembering everything in their head is risky and increases the odds of dropping the ball or missing a deadline.

"Give an example of how you managed a stressful time when you had a heavy workload and competing priorities. Have you ever missed a deadline?"
These questions probe at the candidate's ability to be proactive, plan ahead, and complete tasks ahead of schedule when possible. Decreasing unnecessary stress reduces the risk of becoming overwhelmed when last minute tasks arise (and they always do!). The ability to effectively manage stress is key to maintaining good judgment in high-pressure situations.

"Do you believe you are an effective communicator? Can you give an example of a time when your communication in a professional situation made a difference?"
Superior communication skills are crucial to ensuring that daily, monthly, and yearly research operations run smoothly. This includes timely and clear email responses, frequent and consistently scheduled meetings, and voicing important action items to all parties involved. The importance of solid, professional communication skills cannot be overstated.

"Have you ever worked with someone you didn't like? If so, how did you handle it? How do you deal with conflict? Can you give an example of when you worked as part of team?"
These are additional questions that dig at the potential candidate's communication style as it relates to their interpersonal skills and ability to establish productive relationships across all levels of the research and clinical teams. If the prospective RC will be working together with other RCs across several studies, the interviewer should also try to recognize how this candidate could contribute to the building of a team that performs better together than just the sum of the individuals. Several investigators mentioned that some of their best RCs were student athletes.

"Describe your previous research experience."
You know from their resume that they were involved in research, but you want to see that they can explain a project to you in a clear and simple manner since they will be doing this when enrolling patients. A great candidate should also sound enthusiastic about their research and/or research in general.

"Have you ever made a suggestion that was implemented and considered successful?"
This question explores the candidate's tenacity, level of initiative, and self-motivation to go above and beyond to contribute not only to just their work but to the overall mission.

"What motivates you about working in a pediatric emergency room setting?"
Some people might share a personal story, but this isn't necessary. Any reason they have to be motivated to do their best on the job will be valuable information.

"What are your career goals? What are you looking for in your next job and why do you want this position?"
Being an RC can be rewarding, but it can also be challenging, especially in the beginning. If the position fits into their career trajectory and allows them to develop skills they need for their next step, then this is another good sign that they will be motivated and committed to doing great work.

While it may seem like the candidate is the only one under pressure, the interviewer also has a critical responsibility to follow best interview practices, which include having an awareness of personal preferences and implicit biases and taking deliberate steps to minimize their effect. Although we typically believe we are completely fair and objective, that is not how our minds work – everyone is susceptible to cognitive biases that affect their judgment and ability to choose the best applicant.

The most relevant bias in interviewing is the affinity bias, which is the natural tendency to be warm toward and prefer a person like yourself. To reduce this bias, current recommendations suggest that an interviewer use a structured interview to ask the same questions to each candidate and immediately rate their answer to each question during the interview (https://hbr.org/2016/04/how-to-take-the-bias-out-of-interviews).

As we all know, one of the greatest strengths of PECARN is the excellent core of RCs. As the foundation of our clinical research enterprise, all of our success as a network starts with them, so it is our responsibility to continue to successfully interview and hire outstanding RCs.

Thank you to the all of the RCs, NAs, and PIs who contributed their ideas with special thanks to Kyle Pimenta and Julie Ochs. ■

PECARN Study Updates

PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basicepidemiological information on all ED visits from each participating hospital in PECARN. This data has been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2016. The Public Use Data Set request form can be found on http://www.pecarn.org.

Currently, each site in PECARN has been asked to hold off on preparing the PCDP data for submission until after our Steering Committee meeting. There have been ongoing discussions about the costs and resources needed to maintain the PCDP moving forward. On the Feb 5th Nodal PI call there was discussion around insuring that sites have good data on patient characteristics in preparation for new studies, the use of the Registry, and wanting to be careful of directing resources to where they will be most impactful. All sites will be updated as soon as a decision has been made.

Arginine

Two abstracts ("Pediatric Emergency Department Use of Intranasal Fentanyl to Treat Pain in Children with Sickle Cell Disease and Its Impact on Discharge Rates: A Multicenter Perspective" and "Pediatric ED Adherence to the 2014 NHLBI Guidelines Targeting Analgesic Therapy in the Management of Vaso-Occlusive Pain Episodes in Children with Sickle Cell Disease: A Multicenter Perspective") were presented at the 45th National Sickle Cell Disease Association of America (SCDAA) in October 2017, with great hematology clinician enthusiasm. Three manuscripts are in development, including a manuscript on the ED use of IV fluids in this patient population. Grant writing for the phase III clinical trial begins later this year.

TIC-TOC

We anticipate enrollment for the Traumatic Inury Clinical Trial Evaluation Tranexamic Acid (TXA) in Children (TIC-TOC) trial to start in February 2018. This is a pilot and feasibility trial of TXA for Severely injured children that will be conducted at four PECARN sites. We have finalized the study protocol, finalized consensus on neurosurgical and transfusion recommendations, completed drug compounding, received IND approval from the FDA and Central IRB at University of Utah. We are drafting a methods manuscript and a manuscript about the transfusion consensus process and results. Training visits to sites are ongoing—very exciting!

ED-STARS

Study 2 launched July 24, 2017 and all 14 PECARN sites are enrolling. We anticipate the Whiteriver PHS Indian Hospital will begin enrollment soon. We are close to being ½ the way through recruitment, with 6,213 subjects screened and 1,931 enrolled as of February 19, 2018. In addition, 3-month follow-up interviews are underway by the University of Michigan Survey Research Center. The 6-month interviews started at the end of January. The 24-Hour Warning Signs study was funded and approved by the University of Michigan's IRB in December 2017. The new study began enrolling on February 9 and there are 13 enrollments as of February 19th. Several manuscripts are currently being developed using the data gathered in Study 1. Kudos to all of the sites who are participating!

PECARN PED SCREEN

PED SCREEN addresses the critical need to improve pediatric sepsis outcomes by developing methods to accurately identify at-risk children presenting for emergency care. The project will capture electronic health record (EHR) data to create a multi-center registry with the ultimate goal of improving the detection and treatment of pediatric sepsis in the emergency department (ED) setting. To accomplish this, we will automate the determination of organ dysfunction in children with sepsis directly from structured and narrative data in an expanded multicenter EHR patient registry. That data will be used to derive and validate a prediction model of pediatric sepsis that predicts subsequent organ dysfunction within 48 hours using ED EHR data from the first 4 hours of care. Innovative deliverables from this project include the existence of a broad and rich EHR registry, an automated process of outcome determination, and a predication model of risk of sepsis.

THAPCA

This past year, most of the sites sent a "layman's term" study results letters to the families whose children were enrolled into the In-Hospital THAPCA Trial. Most of the sites have now closed their IRBs and the DCC is assisting sites in closing down. The DCC statistical team continues to work with authors on secondary manuscripts related to the THAPCA Trials. To find any papers related to THAPCA, please go to the medical publications section of the THAPCA website:http://thapca.org/publications.html

Biosignatures I & II

This NICHD-funded study endeavors to assess the stability of the "RNA Biosignature" to distinguish viral and bacterial infections through obtaining sequential samples on febrile infants ≤60 days old. Enrollment in the Biosignature II study is progressing well with an overall enrollment total of 1,484. A recent analytic comparison of missed eligible and enrolled patients noted there was no significant difference between the two groups, confirming enrollment of an unbiased sample. We have also begun the process for manuscript analysis requests, which will allow a more rapid turn-around at the end of the project.

Finally, we have seen several Biosignature I manuscripts come to publication the past few months, in addition to the original *JAMA* publication. Biosignature I manuscripts have been accepted for publication in Pediatrics, *JAMA Pediatrics* and *Annual of Emergency Medicine*.

Probiotics

With enrollment complete for the Probiotics study, follow-up continues. The 12 month follow-up period with conclude at the end of June 2018. Rates remain high with a 91.8% follow-up rate across all time points. The main manuscript is complete and has been submitted to the NEJM for peer review. The investigators are thrilled to be at this stage and so thankful for all the hard work put into this study! MAPs are complete for the 15 remaining MARFs submitted by the study team. We will begin working on these manuscripts next.

ASSESS

Project ASSESS activated its last 3 year follow up participants this month! Of the 1520 who agreed to three year follow up, 1388 (91%) have completed the 3 year follow up to date. The follow up window will end March 1, 2018. Two ASSESS publications (Methodology and Primary Aim) have been published to date; two publications are under review (Risky Adolescent Behavior to Western Journal of Emergency Medicine and NIAAA and Other Drug Use to Pediatric Emergency Care); one publication (Mental Health Symptoms to Academic Pediatrics) is being revised based on reviewer feedback and two manuscripts (Newton screen & Risky behaviors in Latino youth) will be resubmitted. The NIAAA predictive validity manuscript is being reviewed by GAPS and several other manuscripts are in the pipeline for 2018.

PECARN Study Updates cont. on page 6...

(Continued from page 5)

PECARN REDUCE

The PECARN REDUCE (Racial and Ethnic Disparities among Underserved Children in the Emergency Department) working group is striving to develop interventions to achieve health equity for all children cared for in the emergency department (ED). The first phase of this study received NIH funding to identify racial/ethnic disparities in the management of pain for children presenting with long bone fractures or appendicitis using the Registry. This will lead to the development of interventions to reduce inequities in the provision of care for children presenting to the ED.

APPEND-X

Appendicitis in Pediatrics: the Non-operative Debate (APPEND-X) has been funded by the NIDDK for one year with a U34 planning grant. The goal of this non-blinded intention-to-treat trial is to compare the safety of non-operative management of uncomplicated appendicitis in children aged 5-18 years compared to urgent appendectomy. Subjects will be randomized to treatment with IV and oral antibiotics or urgent appendectomy. We are currently finalizing the U01 grant application for submission.

PECARN Registry

PECARN Registry has developed an emergency care visit registry from electronic health record data for pediatric patients at participating sites. The Registry currently contains data from all ED visits from the sites for calendar years 2012 through mid-2017. Each site transmits data to the DCC 4 weeks after completion of the calendar month. Comprehensive data quality assurance rules have been automated to assess data quality and validation of the transmitted data.

The Registry is currently being used to directly populate stakeholder endorsed pediatric emergency medicine quality of care performance measures and has derived achievable benchmarks for each of the measures. Ongoing data validation with chart review containing spot and systematic checks are being done at each site for every performance measure. Each month we successfully distribute over 475 provider-level and site-level report cards. Data are currently being analyzed to determine the effect of the report cards on variation of care. The Registry Expansion project is also onboarding 3 new sites with projected production starting in early 2017.

FLUID

The FLUID study successfully enrolled approximately 1,400 children with DKA and 400 non-DKA patients over five+ years at 13 PECARN centers. This NICHD-funded study is now deep into analysis and manuscript writing. The main manuscript is under review at a prominent journal. Additional supplemental data collection is complete and incorporation into other manuscripts is underway. The DKA versus non-DKA manuscript is likely the next big manuscript from this project to be submitted. The manuscript analysis plans have been helpful to continue moving forward with each manuscript as the previous is completed.

ESETT

ESETT continues to enroll children. There are 163 children enrolled and our next interim anlaysis will be at 250. ESETT is also collecting blood specimens to determine the pharmacokinetics and pharmacodynamics of the 3 medications.

Public Use Datasets

Study data sets can be downloaded directly from the PECARN website at http://www.pecarn.org/studyDatasets/. ■

PECARN New Faces & Nodal News

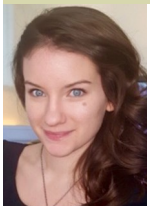
HOMERUN Node

Stacey Liddy-Hicks is the new HOMERUN Nodal Admin. She is a clinical research manager at Cincinnati Children's Hospital. She began her career in 2002 and is responsible for overseeing research operations in Emergency Medicine. Her education includes a BS and a BA in Biology and Psychology from Miami University of Ohio and a Master's Degree in 2001 from the University of Cincinnati.

Darius Johnson, RC at Cincinnati Children's Hospital, graduated with a BS from University of Cincinnati in Health Education & Promotion with a focus in Public Health. Darius' career began in 2015 as a CRA where his primary responsibility was monitoring FDA regulated drug trials. He transitioned to CCHMC in 2017 and is now responsible for recruiting patients and coordinating a R01 funded study and will be helping the HEDA RC at CCHMC.

Mhadhumithaa Naresh is a new HEDA RC at Cincinnati Children's Hospital. She graduated in 2013 from the University of Cincinnati with a Bachelor's in Biology. Mhadhu's research experience started as a Lab Assistant in Developmental Biology. She transitioned into clinical research in 2015 with primary responsibilities of study participant recruitment and study lead coordination, currently for ESETT and Probiotics.

PEM-News Node



PEM-NEWS is delighted to welcome their new NA, **Kristin Beiswenger**. Kristin graduated from Juniata College with a BS in Chemistry and a minor in Spanish. She then got her MS in Chemistry at Penn State University. Kristin is currently working toward an MHA at Columbia University.

PRIME Node

New PRIME Manager **Cindy Valencia, M.P.H.**, joined us in January from the California Central Valley. Valencia is a mother of four, including two year old twins. She has always had an interest in improving lives, and brings ten years of public health experience managing state, federal and foundation grants.

DCC

Emily Startup is the newest member of the DCC statistical team. She recently graduated from BYU with her undergraduate degree in Statistics. She grew up in Southern California. She played water polo on the BYU club team. She also enjoys rock climbing, snowboarding and volleyball.

GLEMSCRN Node

Nodal Admin, **Jessica Saunders,** along with **nodal representation of CRCs**, **Sally Jo Zuspan**, and **Dr. Rachel Stanley,** published the results of a nodal project regarding enablers and barriers in onboarding programs for clinical research coordinators in the Clinical Researcher journal.

RC, **Erin Fisher Kenny**, received the award for Best Poster "Improving Interdisciplinary Education and Communication through High-Fidelity Simulations" at the 2017 Ohio State University Fall Celebration Scholarship Conference. The poster discusses research the team has been compiling around the simulations Nationwide uses to train their staff for ESETT enrollments. ■