Many people perceive a statistician’s role in a 3-5 year study as being primarily at study end for final analyses. But given the complexity and scope of research projects in PECARN, comprehensive statistical support is needed from the early design stage to manuscript publication. So what is the role of a DCC statistician throughout the various stages of a study?

**Protocol/grant development.** The statistician consults with the lead investigator in optimizing the study design and analysis plan to address the research objectives and hypotheses. While a sample size or power calculation is key here, this consultation involves a lot more than just crunching numbers! A formal Statistical Analysis Plan (SAP) is also written to provide additional details on study design and endpoints, planned analyses, and technical issues that may be encountered.

**Database/form design.** Once a study has a final protocol, the DCC team works to build the database. Here the statistician provides critical input on the data elements and organization of forms to ensure clear capture of data for analysis and optimize the efficiency of data collection. The statistician also reviews queries to ensure that these are in place for key variables.

**Analysis datasets.** Based on the SAP and ongoing consultation with the study team, the statistician writes the analysis dataset specifications to explain how each analysis dataset and variable will be created from the “raw” data collected by the site. This task is ongoing throughout study enrollment, and is perhaps, together with programming the corresponding analysis datasets, the greatest behind-the-scenes effort by the statistician. The MAGiC study, for example, has over 75 raw datasets that are the starting point for the statistician’s programming: the number of final analysis datasets will likely be less than 20. Each variable in the analysis datasets is carefully defined according to the analysis plan. For example, the primary endpoint for the FLUID trial is a confirmed drop in GCS in the 24 hours following randomization. Creation of this one variable involves evaluating more than 15 data elements in at least 5 different datasets. Also key for the analysis datasets and later analyses is that a second statistician provides quality assurance of the statistical coding and results. This may be a one-time occurrence near study end for descriptive or hypothesis-generating studies. For active interventional studies or those with a high potential impact on clinical understanding, it is ongoing throughout the study support and requires independent dual programming of the datasets and analyses.

**Analyses, reports, and manuscript writing.** Analyses include anything from basic data requests and report creation to comprehensive Data and Safety Monitoring Board reports and final hypothesis testing. Many of these tasks (or related preparation) are ongoing during study enrollment and may take a substantial time investment depending on the study needs. The final analyses and study publications are where the statistician gets to see the hard work in study development and creation of analysis datasets pay off.

The goal of the DCC statistical team is to provide quality statistical support throughout a study. Each statistician on a project strives to have a thorough understanding of the study design, objectives, and analyses in order to provide the highest level of technical support needed and make your study the best it can be!
The Use of Operational Databases in PECARN HEDAs

Duke Wagner, DC., CCRC and Melanie Hounchell, BA, CCRC (HOMERUN Node)

Everyone in PECARN is aware of the complexities of running research studies in busy pediatric emergency departments. It is a balance of the right staff, the right patients, and the right funding all at the right time. We don’t have the luxury of working in a controlled environment that allows us to proactively seek patients and schedule them for clinic visits. We work on demand, which for many of us has meant creating a flexible yet systematic operational infrastructure that includes a team based approach. That is, doing without the traditional model of one research coordinator (RC) assigned to a study and moving towards multiple RCs with responsibilities on multiple studies. This allows for increased efficiency and effectiveness within extended ED coverage hours. However, it also creates complexities related to operational tracking of enrollment and personnel effort. With multiple people working on multiple studies, how do you keep close track of who has been approached, refused, and enrolled? If a coordinator is responsible for multiple projects while in the ED, how do you know how to properly allocate effort towards a grant and track individual performance to adjust training needs? Additionally, how can this tracking complement, in an efficient manner, the documentation and reporting necessities to our IRBs, PECARN and, theoretically, federal compliance authorities. It is a challenge that two of the HOMERUN HEDAs, Milwaukee and Cincinnati, have specifically attempted to overcome with electronic resources. Milwaukee’s efforts started with the realization that all enrolled patients have to be tracked in enrollment logs to report to the IRB at continuing review as well as, when applicable, to outside sponsors like PECARN or industry.

Rather than continue to have multiple enrollment logs, why not build a centralized database which could be the official record of all enrolled ED patients? In the creation of this tool, other needs were realized and incorporated into the design, such as:
- Realtime surveillance of enrollment
- Tracking of RC activities to assess training needs and performance. This includes time analysis & effort reporting
- Reporting of protocol violations
- Tracking of follow-up calls
- A centralized “key” for connecting study PHI with a unique identifier
- A secure audit trail which authenticates the database as a legal record

These data have broad reporting possibilities enabling staff to generate diverse reports according to the immediate need.

This Access database is moving toward effort reporting in its development. Work has been toward a “Time Study Pilot” which is a feasibility study of effort documentation. To accomplish this, RC’s maintain work journals with information in “units of task”. These units were identified as the common activities during patient enrollment (e.g. screening, enrollment, chart abstraction, data entry). These units can be translated into time or effort, by category for a given study. Focus has been given to the Biosignatures study for this pilot, and we will be reporting initial results at the March subcommittee meetings.

Cincinnati has created what is referred to as the “MasterLog”. It is an Access database that tracks participant enrollment and RC effort. In the participant enrollment component the RCs enter detailed information for every potentially eligible participant. These details include variables such as age, sex, complaint, the provider, the CRC, whether they were eligible, approached or screened and if not, why.

The database automatically records the date and time this information was entered. If a participant enrolls, the patient’s name, MRN, and an informed consent progress note is recorded. Real time reports can be run from the database to determine enrollment numbers, reasons for refusal, ineligibility etc. Reports can be run based on a single study or for all studies, including looking at such things as enrollment by individual RC or by the days of a week. It has value from a single study perspective, to real time management of team resources, and can facilitate future study planning.

The second component of the MasterLog is for tracking RC effort on projects and charging grant accounts accordingly. The RCs record the amount and type of daily effort on research projects. Each study or other activity is tied to its grant account. Every two weeks automatic reports are sent to the division’s payroll administrator who then enters each individual’s percent effort on the projects. Additionally, the database is set up so reports can be generated to provide detail on a per study or RC basis. This allows for resource planning and is particularly helpful when projecting time needed for future studies.

For both sites, the development and use of these electronic resources match efforts throughout business and healthcare itself, to move toward better electronic communications. Requirements for documentation and reporting to relevant agencies are only increasing, while the budgets supporting the staff necessary to comply with these tasks are getting smaller. Electronic records for research can help fill the gap and improve any site’s ability to accomplish study protocols accurately, comply with regulatory requirements and conduct their business efficiently. Both sites welcome questions regarding these tools for research.
EMSC Program Launches “PEDPrepared,” A Pediatric Disaster Clearinghouse

In its 2010 Report to the President and Congress, the National Commission on Children and Disasters drew attention to the limited availability and inaccessibility of resources for pediatric disaster preparedness. To help address this shortfall, the EMSC Program developed “PEDPrepared,” an informational network of resources targeting healthcare providers, emergency and community planners, and families. Its primary purpose is to help communities achieve an optimal level of emergency readiness for children who are involved in an environmental, health, or man-made disaster. This comprehensive clearinghouse compiles more than 450 resources from a variety of federal, state, and local government informational sources, including national health- and disaster-related organizations.

National Pediatric Readiness Project Begins

The EMSC Program is partnering with the American Academy of Pediatrics, the American College of Emergency Physicians, and the Emergency Nurses Association to conduct a reassessment on the pediatric readiness of the nation’s emergency departments. This initiative follows two separate national surveys, conducted in 2002 and 2003, which revealed a less than optimal degree of readiness of emergency departments to meet the needs of children. The survey was released in California in January 2012 and is anticipated to be released nationally through staggered rollout in mid- to late-2012.

Development of THAPCA Resource Materials

The EMSC National Resource Center (NRC) has partnered with the THAPCA resource team at the University of Utah and the National Heart, Lung, and Blood Institute (NHLBI) to produce a series of resources for the Therapeutic Hypothermia after Pediatric Cardiac Arrest (THAPCA) trials. The materials include posters, a brochure, a fact sheet, and a clinician education module, all intended to raise awareness among providers and families about the THAPCA trials. All of these resources will be posted in a new research section of the NRC website in early 2012 and are also available by contacting: Roshni Devchand, Program Coordinator rbhimani@childrensnational.org.

Dr. Michael Lu Appointed New MCHB Director

HRSA announced last November that they selected Dr. Michael Lu as the new Associate Administrator for Maternal and Child Health (MCHB Director). Dr. Lu joined HRSA from the University of California, Los Angeles Schools of Medicine and Public Health, where he was associate professor of obstetrics, gynecology, and public health.

FICEMS Releases 2011 National EMS Assessment

The Federal Interagency Committee for Emergency Medical Services (FICEMS) has released the 2011 National EMS Assessment. This report provides the first-ever comprehensive description of emergency medical services, EMS emergency preparedness, and 911 systems at state and national levels using existing data sources. These data will allow the officials responsible for improving EMS systems to benchmark current and future performance and identify areas of strength and weakness.
Study Updates

TBI

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 TBI prediction rules into clinical practice. The study is progressing well. In December 2011, we initiated the clinical trial and data collection using the EHR blunt head injury data collection tool. We have developed a process for data reporting that allows electronic upload into the central database. After completion of the present phase in which we assess baseline rates of CT use, we will implement the computerized clinical decision support to then assess whether there is a change in the use of CT for children with minor blunt head injury.

TBI-KT

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in 2006. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Enrollment began in May 2007 and ended in January 2010. We enrolled 12,044 patients with a capture rate of 80.9%, including 762 patients with an IAI. Thanks to everyone for all their hard work! Data cleaning is complete and the decision rule has been generated. Analysis and paper writing is ongoing. Initial results were presented in May and June 2011 at the PAS and SAEM meetings, additional results were presented at the February 2012 PAS and SAEM meetings.

EMS

An abstract for this project was published in Prehospital Emergency Care and it was presented at the National Association of EMS Physicians' annual meeting in Tucson, Arizona. Data were reported for 521,239 runs from 14 partner EMS agencies covering the years 2004 to 2006. The manuscript is in preparation.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continues to enroll really well! To date, the study has screened a total of 2,729 subjects, 587 were eligible and 327 have been randomized. The participating sites have shown true commitment to the study and we thank everyone for their hard work on the project!

IAF-Appendix

The IAF-Appendix study aims to examine the role of intra-abdominal fat in CT imaging with IV contrast in visualizing the appendix and to determine if it is possible to predict which patients will have adequate intra-abdominal fat, and thus forgo oral contrast. Currently, the manuscript analyses are being prepared.

MAGiC

The MAGiC trial continues as over 367 patients have been screened and 51 enrolled to date. An interim data analysis is anticipated this summer. The initial four sites continue to enroll, and we have expanded to eight sites. New site training is nearly complete and study leaders are communicating regularly. Thanks to everyone for their hard work on the project!

PECARN REGISTRY

This grant was recently awarded RO1 funding from AHRQ. This project will establish a data registry from electronic health records at four PECARN sites 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.
PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information about all ED patient visits from each participating hospitals within PECARN. The PCDP has data from 2002-2008 and has been instrumental in hypothesis generation and grant acquisition for PECARN. All locked PCDP Data for 2002 – 2008 are now available in the cubes. For preliminary analysis of PCDP data, PECARN can use the cubes or complete a data request form (found in the PCDP eRoom). The cubes can be accessed at https://www.utahdece.org/reportportal.

To obtain or reset cube logins and passwords contact Greg Chandler at greg.chandler@hsc.utah.edu. An updated version of the IRB protocol for the PCDP has been submitted at all sites. An updated MOO has been presented via webinar and is available on the eRoom at https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_6a00.

April 13, 2012 is the deadline for data submission from all sites for the newly updated (Version 7) variables for the PCDP from 2009-2011. For any questions, please contact Libby Alpern at alpern@email.chop.edu.

Biosignatures Study

In its fifth year of enrollment, the Biosignatures study has now collected approximately 3,000 Biosignature samples (.5-1mL), with 1,012 of those collected in 2011 alone; we are close to reaching our total enrollment goal of 4,000 samples! In addition, over 600 PCT samples have been collected. Microarray analysis is moving forward and has been completed on the Year 2 and 3 samples. Other significant events include abstract acceptance by PAS and SAEM with plans to present at the meeting in April and May. Manuscript writing is subsequently underway.

Quality of Care

The long-term objective of our study is to create a generalizable quality of care instrument that can be used to improve the quality of care provided to children in the ED. We will accomplish this by validating and applying a previously developed implicit review instrument that measures the quality of care delivered to children in EDs. We are near completing our pilot work for the third batch of patients (patients seen in May/June, 2011) and abstracting/entering data. Physician reviewers are conducting quality assessments and assigning scores. We plan to hire a Nurse Researcher by April, 2012 who will review records by applying the Gausche-Hill instrument for the purpose of validating the quality of care instrument.

Progesterone

In preparation for a future clinical trial, the Progesterone study has initiated a prospective yield study to pilot the inclusion/exclusion criteria, as well as test accrual feasibility. Sites have been enrolling patients as of July 2011, and study completion is expected by the end of March 2012, with all sites completing their 6 months enrollment period. To date, sites have enrolled 270 subjects.

Patient Safety and New York State Patient Safety

Since July 2007, PECARN sites have been transmitting incident reports to the Data Coordinating Center, resulting in over 24,000 reports received. Ongoing analysis of the incident reporting data is underway. Various manuscripts are currently being written regarding the different types of errors found in the incident reports. In addition, a grant was submitted to AHRQ last fall and is currently under review.

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. Additionally, the study will compare neurocognitive function in children with diabetes who have experienced DKA to that of children with diabetes who have not experienced DKA. The NICHD-funded study will enroll 1,510 patients over five years at 10 PECARN centers (soon to be 13 centers). Drs. Nathan Kuppermann and Nicole Glaser, Study Principal Investigators, are excited to have 190 patients enrolled so far. The "non-DKA" comparison group enrollment is getting started now. We are holding regular webinars for RCs and PIs, and the study leadership is communicating on a weekly basis. We will be starting monthly calls with all site PIs and site RCs in February. The whole team is great, and we are making steady progress!

Seizure

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) is winding down with only 4 patients left to enroll. With a total of 306 patients enrolled, we have now met approximately 99% of our projected enrollment numbers. With the successful initiation of our 2 Canadian sites (Alberta Children's Hospital (Calgary) and Children's Hospital of Eastern Ontario (Ottawa)), 11 sites are now actively enrolling patients.
Study Updates

C-Spine Injury (CSI) in Children

Case-control analysis: We published the results of our primary analysis in Annals of Emergency Medicine this August. The manuscript for the utility of plain films in the diagnosis of CSI in children was accepted for publication in Pediatric Emergency Care. We have working drafts on three additional manuscripts addressing method of spinal immobilization in children less than 2 years old at risk for CSI, outcomes of children with CSI stabilized at outlying hospitals and SCIWORA. Six other manuscripts are in development: age stratification analysis, description of CSI patterns in children, inter-observer agreement, AARS, sports-related cervical spine injury and epidemiology of CSI in children.

EMS Focus Group: This aspect of the study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed to limit immobilization to children who are at non-negligible risk for C-spine injury. Focus groups and focused interviews with all echelons of EMS leadership were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, DC and Baltimore. All transcripts were reviewed and comments were categorized into topics such as qualities, beliefs, barriers, motivators and suggestions. Manuscript was expedited for publication in the February 2012 issue of Academic Emergency Medicine.

Future Directions: Study investigators with assistance of nodal leadership are reconsidering opportunities for collaboration to continue work aimed at refining, validating and implementing a Pediatric C-Spine Injury Risk Assessment Tool and to identify best imaging practices.

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**PRIDENET**

PRIDENET is a brand new PECARN node with several bright new faces. Everyone has had the opportunity to become acquainted the Dr. Bob Hickey, PRIDENET’s Nodal PI, Dr. Thomas Chun, site PI for Hasbro Children’s Hospital in Rhode Island, and Dr. Jonathan Bennett, site PI for A.I. DuPont Hospital for Children in Delaware. Other new team members include Rosalie Berrios-Candelaria, MA, Hasbro RC, Tara Ketterer BS, BA, DuPont RC, Allison Barton RN, BSN, BA, Children’s of Pittsburgh RC, and Karli Carpenter RN, BSN PRIDENET NA. Rosalie joined PRIDENET in October. Prior to PECARN, she was a bilingual (English/Spanish) therapist working with autistic children. As a hobby, Rosalie enjoys heated yoga and salsa dancing! Tara possesses a B.S. in Business Administration and a B.A. in Industrial Psychology. After graduating from Alfred University, she did performance management consulting before realizing her passion for research. In her free time, Tara likes to read, dance, and eat great food! Allison graduated from Smith College with a Bachelor of Arts in Biology and the University of Pittsburgh with a Bachelor of Science in Nursing. She worked as an EMT in college, then as a staff nurse in the Cardiac Intensive Care Unit at Children’s of Pittsburgh, before deciding to enter the world of research. In addition, she has a little boy named Alex keeping her on her feet at all hours of each and every day. Finally, Karli graduated with a Bachelor of Science of Nursing from Wheeling Jesuit University. She is a few months shy of completing her MSN and MBA at Waynesburg University. Karli worked as a nurse in the ED at Children’s of Pittsburgh before becoming a part of PECARN. In her currently limited free time she teaches horse-back riding lessons and is working towards obtaining her pilot’s license.

**PEM-NEWS**

PEM-NEWS is happy to announce that Grant Jones, MSc has assumed the PEM-NEWS nodal administrator position. Grant studied zoology and pre-medical studies as an undergraduate and received his Masters of Science degree from the College of Physicians and Surgeons. Grant has proven himself in PEM-NEWS as a tireless worker and champion of research, particularly through organizing and administrating PECARN's traumatic brain injury knowledge translation study.

**Data Coordinating Center**

Angie Webster, MStat has recently taken on the position of supervisor and manager of the DCC statistical core. Angie started at the DCC in January of 2008 as a Master’s level statistician and has provided statistical support on many PECARN projects. Her previous experience was in the pharmaceutical industry. For fun, she enjoys playing tennis, hiking and spending time with family and friends.

**Scientific Grant Writing Workshop**

**August 22-24, 2012**

**Chicago, IL**

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

- Write the specific aims
- Outline the significance, innovation, and the approach section
- Write your biographical sketch
- Plan your budget
- Put your NIH proposal together. At this workshop, attendees will work on each section of their research grant proposal, receive continual feedback from experienced grant writers, and leave with a well-defined draft.

Visit [www.nedarc.org](http://www.nedarc.org) for online registration.
**New Faces to PECARN**

**WBCARN**

**Tara Shenoy, BA**, is the new Research Associate for the Biosignatures, MAGiC, and FLUID studies at Children’s Memorial Hospital in Chicago. She recently completed her undergraduate degree in Psychology at Northwestern University. She’s considering medical school and is taking the MCAT this spring. She’s excited to undertake clinical research in a hospital setting. In the future, she hopes to combine her love of travel with her passion for medicine by participating in the Peace Corps or Doctors Without Borders.

**Jill Winnett, BS**, is graduating this year in Health Psychology at Mass College of Pharmacy and Health Sciences. She currently volunteers for an adolescent substance abuse program at Children’s Hospital of Boston and enjoys waitressing at her local restaurant. She loves spending time with her close friends, and really hopes to pursue her interest in photography soon! In Boston, she will be recruiting for the PECARN DKA, Biosignatures and TBI- progesterone study.

**PRIME**

PRIME node would like to welcome **Amy Watson**, RC at PCMC in Utah. She has worked in PECARN for two years, but recently moved into a full time position, primarily supporting the Biosignatures and Quality of Care studies. Amy is an integral member of the Utah team. She keeps us all organized and on task- this owing to her experience as mother to 8 children! Amy enjoys the outdoors and traveling- especially to warm places. Previously an elementary school teacher, she left the profession to pursue a career in medicine.

**GLEMSCRN**

**Clare Levijoki** is the new Research Coordinator at the University of Michigan Hospital. She graduated from the U of M in 2011 with a B.S. in Neuroscience. Before joining PECARN, she assisted with biomedical bench research and sociological survey interviews. She is torn between future careers in medicine and research, and is thrilled to have this opportunity to learn more about each. Clare is delighted to be with PECARN!

**HOMERUN**

In October, **Venita Robinson** joined the team at Cincinnati Children’s Hospital. She recently completed an MSHA from Xavier University. Venita enjoys traveling, taking different classes like: dance, marksmanship and cooking, and catching up with family and friends.

**Valerie Andrew** joined the team at St. Louis Children’s Hospital in October, 2011. She has a BS and MS in Crop Physiology and recently completed an MSW specializing in health care. For fun, Valerie enjoys swimming teaching lessons at the YMCA and spending time with her 2 dogs, 2 cats and 18 nieces and nephews.