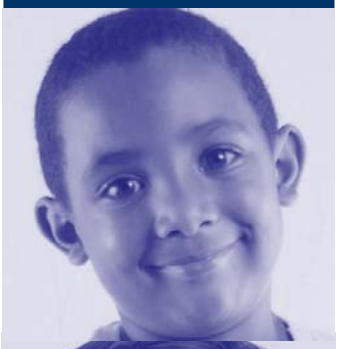
INSIDE



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PECARN In a nutshell

Innovative Systems at the DCC

Submitted by
Kammy Jacobsen & Melissa Metheney
PECARN Project Managers, DCC

Over the years, PECARN studies have increased in technical complexity. The DCC IT, DM and PM staff has responded by creating a number of technical 'behind the scenes' solutions to aid in collection, tracking, and cleaning of study data. This article summarizes some of the recent innovations to streamline and improve PECARN studies.

SharePoint- Not just for demographic reports
Sharepoint, the central location for PECARN study reports, https://sp.utahdcc.org/SitePages/Home.aspx, has recently been customized. This increased functionality allows investigators to identify and measure issues pertinent to primary outcomes, allowing for correction when possible. For example, the FLUID study's "Missed GCS measurements by patient" and "Fluid administration" reports allow sites to evaluate their protocol compliance for these primary outcome variables and compare their performance with other sites. Similarly, the "Probiotics Follow Up" report is used to compare follow-up compliance over time and between sites.

The PECARN Performance Metrics Reports are a new addition to SharePoint. These Summary Reports provide the same information from the demographic reports in individual studies; they also allow tracking of site performance measures *across* multiple studies. The PECARN Performance Metrics Reports still show the individual study reports for ASSESS, ED-STARS, FLUID, and Probiotics. However, if you select the "PECARN Enrollment Summary" you can view all studies by site at a glance. Race/Ethnicity reports, query aging reports, and study start metrics will also be available in summary form soon. The summary reports are a great tool for sites to assess their overall performance in the Network. You can sort by your site or your node and view all the studies you are part of in one screen as shown in Figure 1.

Query Manager-Measuring more than data discrepancies
Data cleaning for PECARN studies is accomplished through the data discrepancy 'query' system. This system also does 'double duty' by tracking IRB documents. The system provides automated alerts regarding study expiration dates and PI license renewals. In addition, the Probiotics study is using the query system to alert the central follow-up center when a follow-up visit/call is due and to send messages to sites if the data received during follow-up needs to be addressed. Query Manager can also be used to track study "to-do" items and may be implemented in the upcoming Biosignatures II study to alert sites, the DCC, and the study laboratory when batch shipping of study samples may be indicated. These innovations increase efficiency by automating actions to improve efficiency.

Automated Quality Review in PCDP
The PCDP Study team continues to streamline the data submission process. The DCC has created an automated email process that is sent at each step of the submission and quality review process. An automated message comes through that alerts each site to the status of their data: "data submitted and validated" and "Face Validity Reports available," etc. Face Validity (Quality) Reports are still available for viewing in SharePoint, but now sites can easily respond to error flags in the Data Submission Portal near where sites upload the original data file. When all error flags have been addressed, sites can easily indicate they are finished with their review process with the check of a box. The DCC is automatically alerted and can finalize the QA process with the main study PI. This automated system allows for easy communication and a smooth transitions.

Coming Soon
With the new Biosignatures study coming up, plans are in place to develop a sample management application that will streamline data collection and batch shipping preparation. The DCC continues to develop IT solutions and systems to simplify, verify, and track data entry and provide sites with up-to-date information for monitoring study progress. These ideas usually come from RCs and site staff. Keep them coming! ■

Figure 1: SharePoint - PECARN Enrollment Summary for One Site

Study	Screened	Eligible	Approached	Consented	Randomized	Randomized /Screened*
Fluid	72	72	59	41	41	57 %
ASSESS	626	466	427	322	NA	51 %
Probiotics	74	49	46	24	24	32 %
ED-Stars	461	336	260	142	133	29 %

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: Elizabeth Edgerton, MD eedgerton@hrsa.gov

Federal Corner

HRSA EMSC Funding Opportunities

The Health Resources and Services Administration (HRSA) has released an Emergency Medical Services for Children (EMSC) Funding Opportunity Announcement (FOA) for Targeted Issues grants.

EMSC Targeted Issues Grants

This opportunity supports innovative, crosscutting projects focused on improving outcomes in pediatric emergency care across the continuum of care. Proposed projects must be of national significance, translatable into practice, meet a demonstrable need, and relate directly to improving the quality of care of pediatric emergency care services. Note that there are two categories of grant funding:

- Category I awardees will provide leadership for and implement a multi-site pediatric prehospital EMS Research Node Consortium.
- Category II awardees will include investigator-initiated projects that seek to improve the quality of pediatric emergency care in the prehospital and/or hospital emergency care settings through novel approaches.

Five awards totaling $1.5 million are available for this funding opportunity. This opportunity closes on February 29, 2016. Info is available at: www.grants.gov. Once there, search for "EMSC."

New MCHB and EMSC Performance Measures

The EMSC Program is proposing three new performance measures for the EMSC State Partnership program. The measures, which were developed by HRSA EMSC, NEDARC and subject matter experts, were released for public comment in November. The first public comment period ended January 5th. A second public comment period will begin February 1st. The new proposed performance measure are:

- NEMSIS V3 QI Data: The degree to which EMS agencies submit NEMSIS compliant version 3.x data to the State EMS Office for submission to NEMSIS Technical Assistance Center (TAC).
- EMS PECC: The percentage of EMS agencies in the state/ territory that have a designated individual who coordinates pediatric emergency care.
- EMS Skills Check: The percentage of EMS agencies in the state/territory that have a process that requires EMS providers to physically demonstrate the correct use of pediatric-specific equipment.

You can learn more about the performance measures via the recorded webinar at https://hrsa.connectsolutions.com/p87zh4g53z/. **A complete list of all of the proposed HRSA performance measures and more details on each of the EMSC performance measures is available at: http://mchb.hrsa.gov/dgis.pdf.**

EMSC Program Welcomes a New Pediatric Facility Recognition Program to Montana

Montana's pediatric facility recognition program recognizes hospitals at 2 levels: Pediatric Capable or Pediatric Prepared. After reviewing several standards and models, it became clear that facilities in Montana's rural environment were either Pediatric Capable (typically smaller communities that stabilize and transport severely sick or injured children to large facilities) or Pediatric Prepared (larger facilities with more resources that can treat children for most conditions). After implementing over a dozen facility visits since last spring, 4 Montana hospitals have been designated as "Pediatric Prepared" and 3 have been recognized as "Pediatric Capable." Other facilities are making dramatic improvements in their pediatric Readiness Scores as they prepare for recognition visits. For additional information about Montana's program, please contact Robin Suzor at rsuzor@mt.gov.

EMS Compass

EMS Compass initiative is a collaborative effort between the NHTSA Office of EMS and the National Association of State EMS Officials to develop EMS performance metrics to measure and improve the delivery of care in the prehospital setting. A call for recommendations for EMS performance measure in May, 2015 resulted in 416 submissions. The EMS Compass Steering Committee is currently considering performance measures related to stroke, STEMI, cardiac arrest, seizures, trauma, safety and public health. The first measures to be released for public comment are related to stroke and are currently under review. Some of the pediatric specific measures submitted include:

Domain: Patient Safety

- *Pediatric pain evaluation*: To measure the frequency of formal pain evaluation in pediatric patients with painful conditions
- *Accurate pediatric drug doses*: Percentage of drug doses delivered to children
- *Pain management for pediatric long bone fractures*: Percentage of pediatric patients with the impression listed as long bone fracture who receive narcotic pain medication
- *Pediatric patients with wheezing who received bronchodilators*: Percentage of beta 2 agonist administration by EMS personnel for pediatric patients younger than 14 years old with signs of symptoms of suspected bronchospasm.

Domain: Efficient Use of Healthcare Resources

- *Disaster Nurses Activation System for pediatric medical emergencies in the field*: The intent is to ensure a system is in place for immediate notification and activation of trained disaster nurses who are competent and capable of responding to pediatric medical emergencies in the field setting.
- *Improving quality and efficiency of Health Care for pediatric patients:*
  - α. Percentage of BLS/ALS agencies that have online/offline medical direction.
  - β. Provides pediatric equipment to EMS and emergency departments

To learn more about the EMS Compass project and sign up for updates, visit: http://www.emscompass.org/about-ems-compass/. See http://www.emscompass.org/important-dates/ for a list of dates and locations for upcoming EMS Compass events.

EMS COMPASS
Improving Systems of Care Through Meaningful Measures

SCIENTIFIC GRANT WRITING WORKSHOP

AUGUST 24-26, 2016

CHICAGO, IL

This is a valuable 2.5 day workshop for those who want to improve their skills, receive professional guidance on rigorous research-oriented grant writing, and to learn to:

- Write your specific aims
- Outline your significant, innovation, & the approach section
- Write your biographical sketch
- Plan your budget
- Put your NIH proposal together.

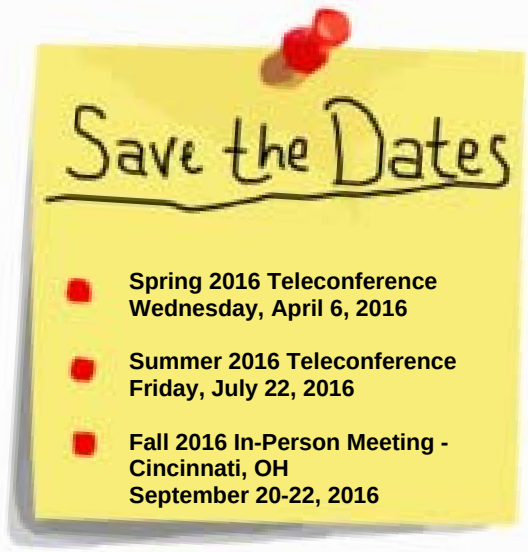
At this workshop, attendees will work on each section of their research grant proposal, receive continual feedback from experienced grant writers, and leave with a well-defined draft.

Visit **www.nedarc.org** for online registration.

Federal Corner cont. on page 3...

Translating PECARN Research for Families

The EMSC Program has released its third issue of EMSC Research Highlights. The purpose of this quarterly fact sheet is to increase awareness among families/caregivers about pediatric health care best practices utilizing results from PECARN studies. The current issue, which focuses on the use of computed tomography to identify traumatic brain injuries in children, can be downloaded at http://www.emscnrc.org/emsc-research/research-highlights.



NEMSAC

NEMSAC held its fall meeting on December 1-2, 2015 in Washington, DC. Sub-committees were established to address (1) EMS system funding and reimbursement; (2) roles, professionalism, and education with a special focus on mobile integrated health care and community paramedicine (MIH-CP; see http://www.naemt.org/MIH-CP.aspx); (3) data integration and technology; and (4) patient care, quality improvement, and general safety issues. The Recognition of EMS Personnel Licensure Interstate Compact (REPLICA) project is being led by NASEMSO to address the need to address barriers to EMS provider credentialing, information sharing and patient care across state borders. Detailed information on the project is available on the NASEMSO website at http://www.nasemso.org/Projects/InterstateCompacts/index.asp.

CDC Releases New CDC Injury Center Research Priorities

The Center for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control has released the new *CDC Injury Center Research Priorities*. For more than 20 years, CDC's Injury Center has studied injuries and violence and researched the best ways to prevent them. *Research Priorities* is a living document that will guide the Center in identifying solutions to emerging injury and violence issues, to encourage innovative research, and to focus CDS's public health expertise.

NASEMSO Releases National Model EMS Clinical Guidelines

The National Association of State EMS Officials (NASEMSO) released "National Model EMS Clinical Guidelines." These guidelines are intended to be a resource to prehospital clinical practice as well as maximize patient care, safety, and outcomes. The guidelines were also endorsed by the American Academy of Pediatrics in the December 2015 issue of *Pediatrics*.

National Pediatric Readiness Project Update

The National Pediatric Readiness Project (Peds Ready) assessment portal reopened on November 1st, providing hospitals an opportunity to reassess their readiness in caring for ill and injured children. The portal will remain open for 10 months, during which time a hospital can complete the reassessment one time. Upon completion of the assessment, respondents will receive an electronic gap analysis report containing their new Readiness Score, compared to their 2013-14 Readiness Score (if applicable), as well as a breakdown of the overall scoring.

Building upon current momentum of the Peds Ready project, the EMSC Program hosted three webinars, the first two targeted knowledge gaps identified during the national assessment and the third focused on the opportunity to utilize the portal reopening for rapid-cycle quality improvement initiatives. These webinars listed below are available at: http://www.emscnrc.org/Events/Webinars.aspx

- Next Steps in Quality Improvement: Measuring Your ED Readiness Improvement – Peds Ready Assessment Portal Now Open.
- National Pediatric Readiness Project: Preparing the Emergency Department to Provide Psychosocial Support to Children and Families in A Disaster.
- Is Your ED Ready for Children? Pediatric Emergency Care Coordinators Lead the Way to Readiness!

In other Peds Ready news, the EMSC Program has established a National Pediatric Readiness Project Steering Committee. This steering committee will be comprised of 12-15 representatives from national organizations and key Peds Ready stakeholders. The Peds Ready Steering Committee will have its first meeting on February 17th, in Washington, DC.

Manuscripts related to the Peds Ready project continue to be published. The latest manuscripts are:

"Overall State of Pediatric Readiness in U.S. Improved Over the Past 10 Years, but Gaps Remain," authored by Deborah McBride, PhD, RN, was published in the Nov-Dec 2015 issue of *Journal of Pediatric Nursing*.

"Pediatric Readiness in Indian Health Service and Tribal Emergency Departments: Results from the National Pediatric Readiness Project," authored by Juliana Sadovich, PhD, RN; Terry Adirim, MD, MPH; Russell Telford, MAS; Lenora Olson, PhD, MA; Marianne Gausche-Hill, MD; and Elizabeth Edgerton, MD, MPH, was published in the October 2015 issue of *Journal of Emergency Nursing*.

"Pediatric Readiness and Facility Verification," authored by Katherine Remick, MD; Amy Kaji, MD, PhD; Lenora Olson, PhD, MA; Michael Ely, MHRM; Patricia Schmuhl, BA; Nancy McGrath, RN, MN; Elizabeth Edgerton, MD, MPH; and Marianne Gausche-Hill, MD, was published in the August 2015 issue of *Annals of Emergency Medicine*.

For more information about Peds Ready, visit http://www.PediatricReadiness.org.

PECARN Study Updates

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 goal of the study was to promote the appropriate use of cranial CT for children with blunt head trauma by implementing clinical decision support to translate the PECARN Traumatic Brain Injury prediction rules into practice. The clinical trial collected data on more than 25,000 patients. Four manuscripts have been published or accepted for publication, each describing important aspects of the development and implementation of the decision support.

ASSESS

To date, over 1,600 participants have completed their 12 month follow up (follow up rate=70.7%), and nearly 300 have completed the 24 month follow up survey (follow up rate=67%). The last 12 month ASSESS surveys went out this month. The 24 month follow-up is ongoing.

TBI (Traumatic Brain Injury)

All manuscripts are complete and have been through the PECARN process**.** 30 total manuscripts have been published from this study. *TBI Prediction Rule versus Clinician Suspicion* was accepted, and the three final manuscripts are all under journal review. In 2015, there will have been 9 manuscripts published from this study (either from main study or from the Public Use Dataset) . This extremely productive 10-year project is finally coming to a close and Dr. Kuppermann would like to thank everyone for their great collaboration. A major electronic heath record vendor is interested in incorporating the PECARN TBI prediction rule into the next version of its software. We now turn our attention to the interventional trial of tranexamic acid (TXA) for TBI.

Biosignatures Study

The main manuscript of RNA biosignatures to identify infants with bacterial infections is currently under review at a major, high-circulation journal. We are currently responding to reviewers comments. The revised manuscript was estimated to be submitted by mid January 2016. Expression and clinical data is still being analyzed in preparation of various abstracts and manuscripts. Manuscripts are being prepared for submission over the next few months including epidemiology of bacteremia in febrile infants, practice pattern variation in the evaluation of febrile infants, the SBI prediction rule, and the accuracy of the Yale Observation Scale and clinician suspicion. An abstract, *The Risk of SBI in Febrile Infants with Viral Infections* has also been submitted for the 2016 SAEM meeting.

Biosignatures II

The protocol has been completed and the team is getting all of the participating sites ready for a formal biosignatures II training session during the PECARN meeting in February 2016. The Manual of Operations is currently being edited and will be available to sites by late February.

IAI (Intra-Abdominal Injury)

All manuscripts are complete and have been published. The IAI project enrolled 12,044 subjects with blunt torso trauma. Twelve manuscripts were published from this study, including 4 in 2015 (one in *Academic Emergency Medicine* entitled "*Relationship of Physician-Identified Patient Race and Ethnicity to Use of Computed Tomography in Pediatric Blunt Torso Trauma*.") This study group would like to thank everybody for their great collaboration on this project. This groups attention is now going to be directed to the interventional trial of tranexamic acid (TXA) for blunt torso trauma.

Patient Safety

Writing and publishing of manuscripts is ongoing. Manuscripts on process variance errors, near-misses/unsafe conditions, laboratory errors, radiology errors, and medication errors have all been published. Manuscripts on the methodology of the Patient Safety study and ED characteristics/climate of safety in PECARN EDs have also been published. The New York state medication error paper is currently being revised and will be re-submitted to Pediatric Emergency Care.

Arginine

The Arginine Feasibility study is currently completing chart abstraction and volume data entry. 16 out of 18 sites have received IRB approval and are either beginning the chart review process or will be soon. The database is finalized and accepting data entry by all sites that are ready. Training on the study was completed in November 2015 and data entry should be completed by April 2016. Thank you to all sites who are participating!

PROBIOTICS

Probiotics is a randomized controlled trial (RCT) of LGG vs. placebo in 900 children, aged 3 – 48 months with Acute Gastroenteritis (AGE). We have 10 sites participating and just started year 3/4 of enrollment with a total of 391 patients to date. The second DSMB meeting was held in November 2015 where recommended continuation of the study without changes was received. Overall the follow-up rate is 91% across all time points and remote access monitoring is in progress. Additionally, Manuscript Analysis Plans (MAPs) continue to be developed from the 15 Manuscript Analysis Request Forms (MARFs) submitted by the study team.

Quality of Care

The PECARN Quality of Care study has submitted its first manuscript which is now under review at a peer-reviewed journal. This first manuscript describes and discusses this instrument as a valid way to measure quality of care delivered to children in the ED. A second manuscript, examining patient level factors associated with quality, is being written for a peer review journal. A third manuscript, which will examine physician and hospital level factors associated with quality of care, is in the data analysis phase.

THAPCA

The In-Hospital Trial was closed to further enrollment in February 2015 due to slow recruitment. We continue to wrap up the final 12-month follow-up exams for the remaining patients. Final data analysis for this trial will begin in Spring 2016. We anticipate publication of the In-Hospital Trial results in the summer 2016.

PECARN Study Updates cont. on page 5...

PECARN Registry

The PECARN Registry project has developed an emergency care visit registry from electronic health record data for pediatric patients at participating sites. The use of this registry will be to collect emergency care performance measures for important pediatric conditions and for deriving achievable benchmarks for each of the performance measures. It will also provide reports to providers and sites and will test the hypothesis that providing performance measure feedback will improve performance and decrease variation among clinicians and sites.

The electronic health record (EHR) registry has been established and currently contains data from all emergency department visits from the sites for calendar years 2012 through November 2015. Each site transmits data to the DCC 4 weeks after completion of the calendar month to allow for maturation of the data. Comprehensive data quality assurance rules have been automated to assess data quality and validation of the transmitted data. Monthly data quality reports are constructed for each site by month and entire year data breakdown to facilitate effective and efficient data quality review. The registry is currently being used to directly populate stake-holder endorsed pediatric emergency medicine quality of care performance measures and has derived achievable benchmarks for each of the measures using both 2013 and 2014 data. Some of the performance measures use text parsing and natural language processes in their derivation. Ongoing data validation with chart review containing spot and systematic checks are being done at each site for every performance measure. The site and individual-level quality performance measures are constructed directly from the data in the registry. The DCC produces site and individual provider report cards. Distribution of report cards to providers at each site have also been automated. 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.

SEIZURE

The group is actively working on the final manuscript for the Seizure study. They are also working with the Food and Drug Administration for approval for the use of Lorazepam for the treatment of status epileptics.

ESETT

There are 17 sites enrolling for the ESETT study. The PECARN sites enrolling are Children's National D.C., Primary Children's Hospital, University of Michigan, Cincinnati Children's Hospital, Nationwide Children's Hospital, Children's Medical Center (UTSW) and UC Davis Children's Hospital. As of January 25th, the total enrolled is 22; 6 of those are from PECARN sites. Please continue to diligently identify patients.

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 2002-2014.

The 2015 data submission deadline is April 15, 2016 - TAX DAY! The portal to receive data will officially open for submission on February 1, 2016. Please plan to include both ICD9 and ICD10 diagnosis codes and procedure codes this year as we anticipate all sites will have moved to ICD10 reporting. Data specifications for submission can be found on the publically available wiki (https://wiki.utahdcc.org/confluence/display/PCDP/PECARN+Core+Data+Project).

XML is the preferred format for submission. The Data Coordinating Center staff continues to offer ***One-on-One Training*** webinars to any site interested. This opportunity is meant to allow site IT staff or anyone else to directly ask questions about data submission instructions. To set up a webinar or if you have any questions, please contact Melissa Metheney (Melissa.Metheney@hsc.utah.edu) or Libby Alpern (ealpern@luriechildrens.org).

ED-STARS

With all 14 sites enrolling, including Whiteriver PHS Indian Hospital, the ED-STARS study continues full steam ahead with over 3,000 youth enrolled in the first of two sequential studies. In addition, 3 and 6 -month follow-up interviews are currently underway by the University of MI Survey Research Center and discussions regarding manuscript topics and collaborative opportunities move forward. During this busy time, we had the exciting opportunity to apply for an administrative supplement that could result in some enhancements to Study 2. We will keep research teams informed of any new updates. Kudos to everyone for their collaboration in moving this study forward!

FLUID

The FLUID study is entering its last year of patient enrollment. More than 1,210 of the anticipated 1,400 children with DKA, have been enrolled and more than 310 of the 400 children with Type 1 diabetes with no history of DKA have been enrolled at 13 PECARN centers. Our "Methods" manuscript was published in *Pediatric Diabetes* and an ancillary manuscript entitled "*Circulating Matrix Metalloproteinases in Children with Diabetic Ketoacidosis*" was accepted for publication. An additional list of papers of interest have been circulated among investigators, and we are actively working through the associated analysis plans.

NEW STUDY DATASETS

Public Use Data Sets

To enhance the public health benefit of completed PECARN studies, public use data sets are available to researchers. Public use data sets are generally made available after study completion in accordance with PECARN policy. A recent change makes the data sets even more accessible. We have waived the requirement for IRB review. In addition, data sets will soon be downloadable directly from the PECARN website. Find more details at http://www.pecarn.org/studyDatasets/.

Good Clinical Practice Tip

Updates to the Common Rule

Submitted by
Melissa Metheney
PECARN Project Manager, DCC

From www.HHS.gov News Release Sept 2, 2015, Sept 8, 2015 and Nov 25, 2015

"The current regulations that protect individuals who participate in research, which have been in place since 1991, are followed by 18 federal agencies and are often referred to as the Common Rule. They were developed at a time when research was predominantly conducted at universities, colleges and medical institutions, and each study generally took place at a single site. The expansion of research into new scientific disciplines, such as genomics, along with an increase in multisite studies and significant advances in technology, has highlighted the need to update the regulatory framework. Notably, a more participatory model of research has also emerged, with individuals looking for more active engagement with the research enterprise.

Changes proposed in the Notice of Proposed Rule Making (NPRM) issued September 2, 2015 include:

- Strengthened informed consent provisions to ensure that individuals have a clearer understanding of the study's scope, including its risks and benefits, as well as alternatives to participating in the study.
- Requirements for administrative or IRB review that would align better with the risks of the proposed research, thus increasing efficiency.
- New data security and information protection standards that would reduce the potential for violations of privacy and confidentiality.
- Requirements for written consent for use of an individual's biological samples, for example, blood or urine, for research with the option to consent to their future use for unspecified studies.
- Requirement, in most cases, to use a single institutional review board for multi-site research studies.
- The proposed rule would apply to all clinical trials, regardless of funding source, if they are conducted in a U.S. institution that receives funding for research involving human participants from a Common Rule agency.

"Proposed changes enhance protections for individuals involved in research, while modernizing rules and improving efficiency."

The NPRM can be accessed at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf. To be assured consideration, comments must be received no later than 5 p.m. on December 7, 2015 [Deadline extended to January 6, 2015]. For additional information about the NPRM, including a brief summary of the proposed changes, how to submit comments or browse posted comments, visit http://www.hhs.gov/ohrp/humansubjects/regulations/nprmhome.html." ■

PECARN New Faces & Nodal News

PRIME Node

Reena Karki is a new Regulatory Coordinator at the University of Utah. She received her graduate degree in public health from Brigham Young University. She is originally from Nepal and has an undergraduate degree in nursing from India. Reena loves travelling, reading, and spending time with her newborn, **Reevan Adhikari**, who was born on 11/12/15; he weighed 5 lbs. 12 oz. and was 18 in. long.

Prime Node Update:
The PRIME Node has little to report from its other members at this time, they are hunkered down to work on new and developing proposals.

WBCARN Node

Dr. Esteban Garcia is the newest addition to Children's National Medical Center Research team. He is the RC for DKA, non-DKA and Probiotics studies. Since graduating from medical school in Ciudad Juarez, Mexico, his research experience includes organizations such as Mexico's Ministry of Health and MedStar Washington Hospital Center. His ultimate goal is to become a burn surgery fellow and work in advancing burn victim treatments. He also enjoys cooking and is constantly on the lookout for that perfect hole-in-the-wall restaurant.

Sean M. Gillen is excited to be working as a new RA at Children's National Medical Center. He graduated from St. Francis College in Brooklyn with a B.S. in Chemistry in May, 2015. He plans on attending medical school and is interested in emergency medicine. He enjoys playing piano, composing songs, and listening to new music.

PECARN New Faces & Nodal News cont. on page 7...

PEM-NEWS Node

PEM-NEWS is excited to introduce it's newest member, **Cameron Bruce Mistry**, born on December 3, 2015 at 2:24pm. Cameron came screaming into this world at 6 lbs 12.5 oz and 20.25 inches, and thankfully looks more like mom than dad ;). Although he's only partially Indian, he is planning to graduate from medical school in 2038 and hopes to head multiple PECARN studies. **Sarah, Rakesh** and **Cameron** are all doing well and thank everyone for their well wishes.

SW-Node

Scott Oglesbee, BA, CCEMT-P, is a clinical research manager at the Department of Emergency Medicine, Division of Pediatric Emergency Medicine, at the University of New Mexico. He is a paramedic at Medicine Bow, a division of the Center for Disaster Medicine, and has been involved with EMS since 2001. He is currently a PhD/MPH student at University of New Mexico.

Susanne Olkkola, MEd, MPA, had worked in clinical research for approximately 20 years when she was hired as the Arizona Program Director of the Women's Health Initiative. This study tracked close to 5,000 elderly women for 12+ years. This was her first introduction to complex clinical research and the NIH. She continued working at the University of Arizona in clinical research and grant writing until 2008 when she was hired by the Office of the Director at NIH. She loved living in Bethesda and seeing the much larger research enterprise that is the NIH and other HHS partners.

Before research, she worked in the field of prevention of child abuse and neglect. That remains an area of passion and advocacy for her. She's lived in many places such as Chicago, New Hampshire, NY, Montana, India, Arizona, DC, Maryland and she jokingly blames this on her short attention span. Her new 7 month old puppy Charlie, a chocolate brown standard poodle, is keeping her very busy with his rascally behavior and bouncy energy.

Robyn Berent is the new RC for the Children's Hospital at OU Medical Center. Originally from Reno, Nevada, Robyn worked in both hospital and research institutions for many yrs. before moving to Oklahoma. Robyn has 2 Master's degrees in Biomedical Sciences and Cellular & Molecular Biology, and has co-authored several papers on epigenetics in gastrointestinal smooth muscle disorders. Robyn has taken up mixed martial arts and enjoys spending time with her siblings and nephew.

Jovanka Hall is the regulatory specialist and HEDA Coordinator for the Arizona Emergency Medicine Research Center. Jovanka worked for many years as Siemens Dental sales agent for the territory of former Yugoslavia. 17 years ago she moved to the United States. Jovanka has a Masters degree in Public Health and found her passion in research. She enjoys cooking, reading, making herbal remedies and traveling.

Ginny Stasinski is the new Senior Research Coordinator at the University of Arizona. She has worked in research for 15 years. Outside of research, she teaches indoor cycling classes and has two Lhasa Apsos named Boomer and Buffy.

GLEMSCRN Node

Jessica Saunders is the new Associate Nodal Administrator with GLEMSCRN. She started her position in October and had been at Nationwide Children's Hospital in Columbus for the past year. She was born in Ohio but grew up in Pittsburgh and Charlotte, NC. After completing her BA at the University of North Carolina Wilmington she decided to move closer to family in Columbus, OH. She is now completing a Masters of Applied Clinical and Preclinical Research with a focus in Research Management at Ohio State University.

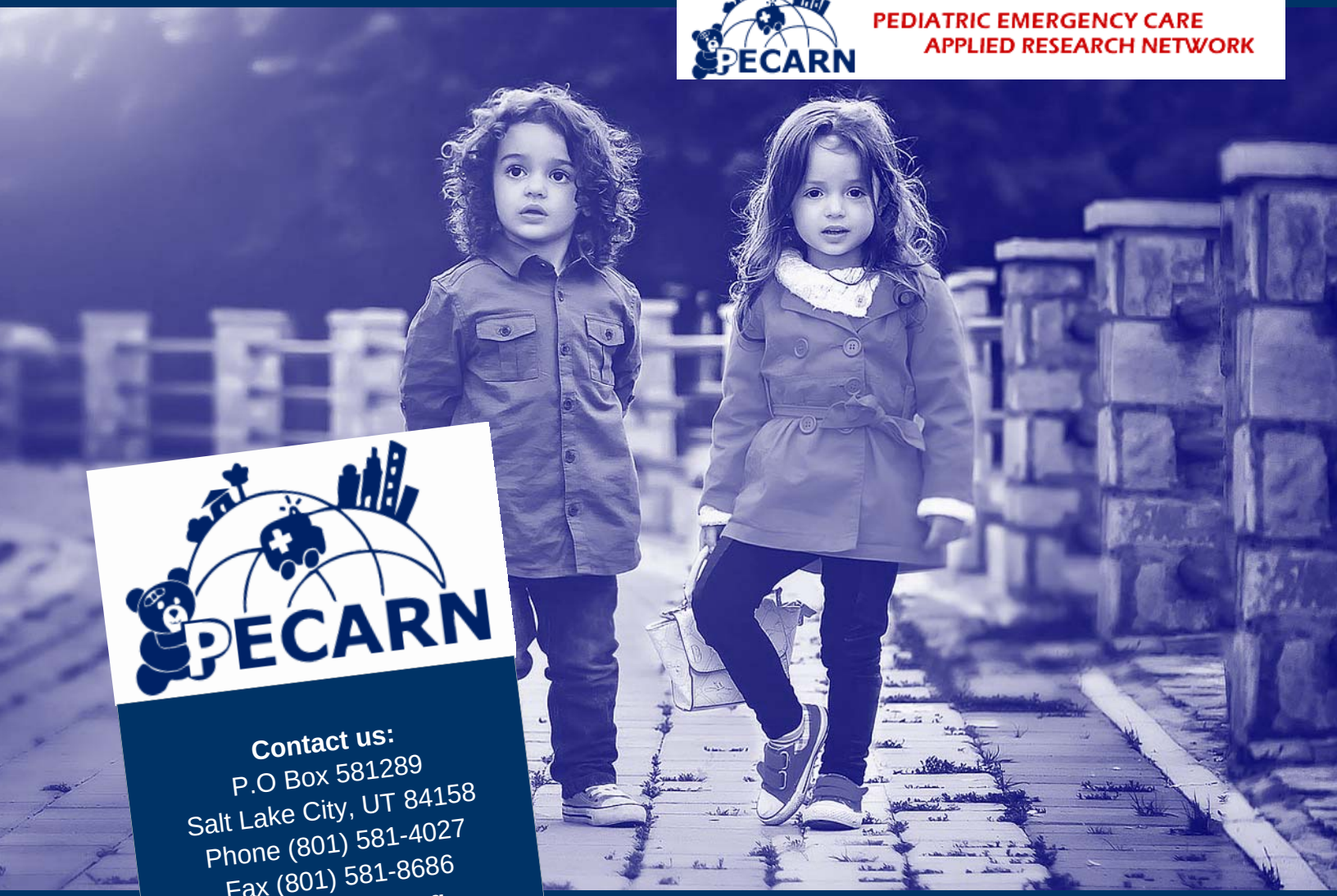
DCC

Andrew Joseph Wojdula (Joe) is the DCC's new IT Project Manager. He will be responsible for the overall planning, management and completion of DCC projects requiring IT/IS solutions such as the PECARN Registry as well as future PECARN projects requiring IT solutions. Joe has 10 yrs. of experience implementing and managing corporate IT solutions for a holding company in New York City. He holds a B.S. in Molecular Biology and J.D. from the University of Wisconsin-Madison.

Holdunn Rutkoski is the newest member of the Clinical Data Management team at the Data Coordinating Center. He obtained a Master's degree in public health (MPH) from Westminster College in Salt Lake City, Utah. He has experience in data management, research, SAS programming/ statistical analysis, collegiate education, and HTML coding/web development. He will be a strong addition to the DCC and PECARN team.

Russell Banks recently joined the DCC statistical team after completing his Master's degree in statistics at Utah State University. He will be providing statistical support for both the CPCCRN and PECARN networks. He enjoys reading novels, playing basketball, and snuggling his three daughters.

PEDIATRIC EMERGENCY CARE
APPLIED RESEARCH NETWORK



PECARN

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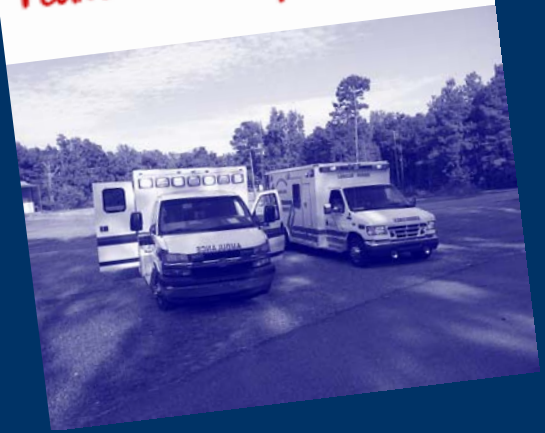
Conducting High Priority, High-Quality Research in Pediatric Emergency Care



What is PECARN?

PECARN, a project of the Health Resources and Services Administration/Maternal and Child Health Bureau's (HRSA/MCHB) Emergency Medical Services for Children (EMSC) Program, is the Pediatric Emergency Care Applied Research Network, the first federally-funded multi-institutional network for research in pediatric emergency medicine in the United States.

What is PECARN's goal?

The goal of this network is to conduct high priority, multi-institutional research into the prevention and management of acute illnesses and injuries in children and youth of all ages.