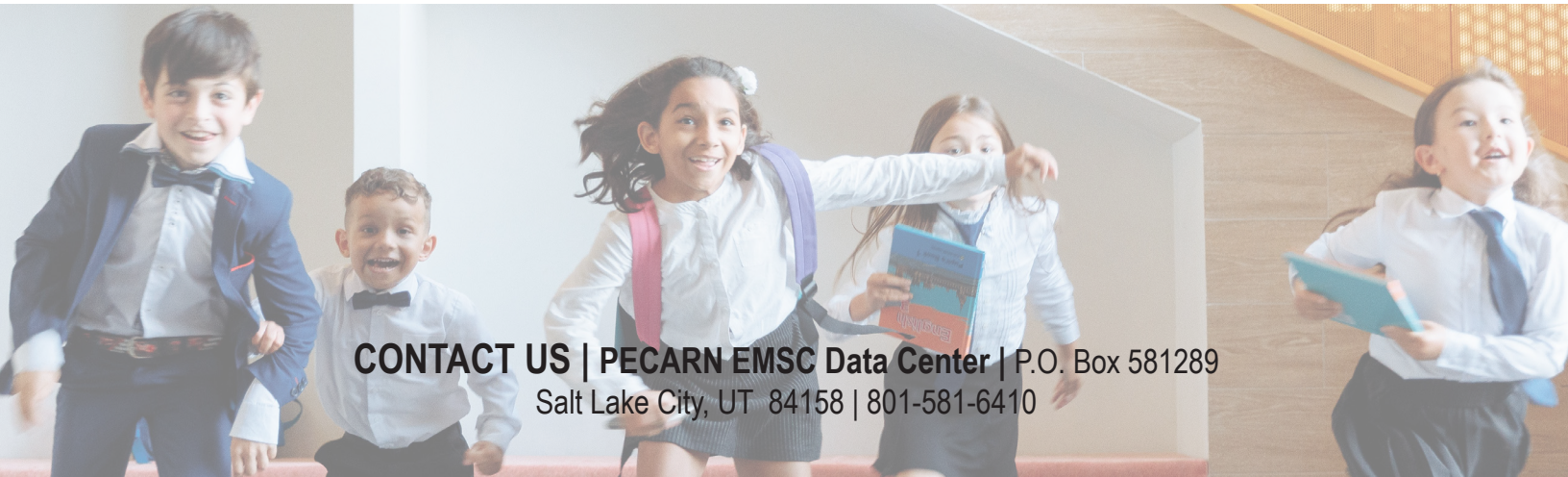
PECARN
Pediatric Emergency Care Applied Research Network

WINTER 2023



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All About SPARC

Author: Bridget Wynn

SPARC is one of the newest Nodes in PECARN, established during the current 2019-2023 funding period. It is the San Francisco-Oakland, Providence, Atlanta Research Collective and contributes to the geographic diversity of the United States specifically the far west and southeast, with University of California San Francisco Benioff Children's Hospital, the Alameda County EMS, Emory University/Children's Healthcare of Atlanta, and Brown University/ Hasbro Children's Hospital.

Our node works in underrepresented research areas, specifically mental and behavioral health, sickle cell disease vaso-occlusive pain, injury prevention, child abuse, and substance use disorder. Our EMSA has been highly productive, with on-going work on diversion of medically stable pediatric patients with a mental health crisis, EMS pre-hospital and HEDA data linkage activities, reviewing network pre-hospital projects, and starting up the Pedi-DOSE study within Alameda County EMS. One of SPARC's strongest PECARN contribution to date has been starting up the STArT Trial, Sickle cell disease Treatment with ARginine Therapy (NHLBI-funded UG3/UH3 HL148560, PI: Morris). The study is a ten-center randomized controlled trial of IV arginine for the treatment of acute pain associated with sickle disease. STArT has met or surpassed all of its proposed study milestones and is 50% ahead of projected study enrollment goals to date.

Brown University with the Hasbro Children's Hospital is the SPARC Research Node Center and HEDA site. Dr. Thomas Chun is the SPARC Nodal Co-PI and Dr. Mark Zonfrillo is the HEDA PI. Nicole Hinz is the HEDA Research Coordinator.

Children's Healthcare of Atlanta is home to the largest Pediatric Emergency Department in the Southeast, seeing more than 250,000 children annually across 3 state-of-the-art EDs in the Metro Atlanta area. Children's Healthcare of Atlanta-Egleston is the home of the only Pediatric Level-1 Trauma Center in the state of Georgia. Dr. Claudia Morris is the SPARC Nodal Co-PI, Dr. Mark Griffiths is the HEDA Co-PI, Hal Simon is a HEDA co-investigator and Laura Benedit is the HEDA Research Coordinator. Bridget Wynn is the Nodal Administrator and is based at Emory University.

University of California San Francisco and the UCSF Benioff Children's Hospital Oakland (BCHO) San Francisco (BCH-SF) is a leader in Emergency Medicine and the only Pediatric Level 1 Trauma Center in the Bay Area. Dr. Jacqueline Grupp-Phelan and Dr. Aaron Kornblith are the HEDA co-Is, Dr. Nicolaus Glomb and Dr. Karl Sporer are the EMSA co-I's. Lisa Lavrisha is the HEDA Research Coordinator.

SPARC investigators across the node are actively developing multi-site pediatric emergency care research studies. In addition to STArT, we are pursuing research in the areas of child abuse, injury surveillance, appendicitis, mental health and specifically, adolescent mental health.

Our EMSA at UCSF has been seamlessly integrated with the PECARN EMSA Consortium, contributing to all their meetings, developing new research, and participating in offered studies. The Alameda County EMS Agency is focused on completing their Health Data Exchange (HDE) with ESO and our local 14 hospitals. This system will link EMS records with ED records allowing our paramedics to get follow up data on their patients. This data includes outcomes, diagnosis, procedures, as well as emergency department notes. We believe that this system will allow for clinical feedback for our clinicians, for Quality Improvement, and for research. The HDE is currently functional for six

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of our receiving facilities and we expect most of our other hospitals to be functional in 2023.

In addition to serving as the co-chair of GAPS (Morris), SPARC PIs chair PECARN's Mental Health Interest Group (Grupp-Phelan), and founded and chair the network's newest Interest Groups, Injury Prevention (Zonfrillo, Fraser Doh), Child Abuse (Chun), and Sickle Cell Disease (Morris), areas which historically have all been under-investigated and are important gaps in PEM research.

SPARC is a leader in important publications. Recently we authored research on alcohol use screening in adolescents, substance abuse, gastroenteritis, sickle cell pain treatment, and pediatric firearm and motor vehicle collisions injuries.

Part of SPARCs mission is to mentor the next generation of PEM Investigators. We actively participate in PECARN's Future Investigator meeting, and provide mentoring in the areas of Adolescent Health, Mental Health, Trauma, Violence (UCSF HEDA PI Jacqueline Grupp-Phelan and Nodal PI Thomas Chun), Injury Prevention, Child Abuse, Trauma, QI (Hasbro HEDA PI Mark Zonfrillo, Emory Nodal Co-PI Claudia Morris, Emory HEDA Co-I Hal Simon), Adolescent sexual health (Emory Nodal Co-PI Claudia Morris, Emory HEDA PI Mark Griffiths, HEDA Co-I Hal Simon), and Ultrasound (Emory HEDA PI Claudia Morris). Mentors also serve as advisors in multicenter research (PIs Chun and Morris) and Time Management, Work/Life Balance and Mentor/Mentee Relationships (PI Grupp-Phelan).

To date, each HEDA is either actively participating, or has plans to participate in the following studies: Emory: C-Spine, HEADACHE, STArT, AZ SWED, Registry, PRoMPT Bolus, HIKO-STEC, PediDOSE, FAST; and if funded, PedCAPS, TIC TOC &, KESETT | Hasbro: PRoMPT Bolus, Headache, BEEPER; and if funded, TIC TOC, PedCAPS, & PEDs TREATOUD | UCSF: C-Spine, PRoMPT Bolus, Headache, STArT, PediDOSE; and if funded, TIC TOC.

All HEDAs have also been identified as sites for PECARN projects in the protocol & concept development phase. Nodal co-PI Thomas Chun served as a co-investigator for a SPARC co-sponsored Registry study investigating pediatric ED diagnosis of child abuse during the COVID-19 Pandemic, which currently has a manuscript submitted for review at JAMA Pediatrics.

SPARC
San Francisco-Oakland, Providence, Atlanta Research Collaborative

Study Updates

ED-STARS

The ED Screen for Teens at Risk for Suicide (ED-STARS) study is in the final manuscript writing phase with 1 manuscript under review, 8 manuscripts in progress and of those 3 have been approved by the PECARN GAPS Subcomittee.

FAST

In the evaluation of hemodynamically stable children who have experienced blunt torso trauma the benefits of using the Focused Assessment with Sonography in Trauma (FAST) examination is unclear and therefore is variably used. The PECARN FAST study is an RCT of the FAST examination in 6 PECARN centers to definitively determine its utility in hemodynamically stable pediatric trauma patients. Pre-enrollment work is ongoing, site training will occur at the February 2023 PECARN meeting, and enrollment will begin during the Spring of 2023.

SCIENCE II

The investigators on the SCIENCE trial have successfully enrolled 1,664 patients and moved 3 sites to study implementation, with one site transitioning towards study implementation. In August we had our second DSMB meeting and the central IRB approved the continuation of the study. We are excited to continue our work improving the emergency department pain treatment for children with sickle cell disease.

HIKO STEC

Hyperhydration to Improve Kidney Outcomes in Children with Shiga Toxin-Producing E. coli Infection (HIKO STEC): A Multinational Cluster Randomized Crossover Trial successfully launched in September 2022. HIKO STEC is a 26-site phase III, embedded, cluster-randomized, crossover trial comparing hyperhydration (e.g. early aggressive intravenous treatment) with conservative fluid management as treatment for STEC-infected children. This study aims to discover which treatment method most effectively mitigates the renal and extrarenal complications of hemolytic uremic syndrome (HUS) and improves health outcomes in STEC-infected children. To date, HIKO STEC has enrolled 32 participants with the ultimate goal of enrolling 1040 over 4 years.

DKA FLUID

The DKA FLUID study enrolled ~1,800 children with diabetes: ~1400 with DKA and 400 without DKA. The main analysis was published in the NEJM and demonstrated no significant differences between fast and slower fluid rates on neurological outcomes. This liberates clinicians to use their clinical judgment when hydrating children with DKA. Most recent publications include "Biochemical Correlations in DKA," "Cognitive Function Following Diabetic Ketoacidosis in Young Children with Type 1 Diabetes", "Degree of Dehydration in DKA" (only minor revisions needed). We are also preparing an NIHN grant submission exploring inflammation and perfusion in a new DKA cerebral injury discovery grant due February 2023.

PRoMPT BOLUS

PRoMPT BOLUS is a large pragmatic clinical trial comparing normal saline to balanced fluids for resuscitation in pediatric sepsis. The primary outcome is MAKE30: a composite outcome that includes persistent kidney injury, dialysis, and death. PRoMPT will be the largest pediatric acute care trial in history, and aims to enroll 8800 children at 46 sites across 3 international networks. This effort is led by PECARN and includes our sister networks PERC in Canada and PREDICT in Australia/ New Zealand. We have enrolled 2600 children so far at 39 sites around the world: 20 PECARN sites and 19 international sites, with 7 more sites expected to come on board soon.

IMPACT-ED

The IMPACTED Trial is a three sites began enrolling in September 2022 and has enrolled 22 children of a planned 90 total. IMPACT-ED randomizes children with severe asthma to IVMg 50 mg/kg, IVMg 75 mg/kg, or placebo, and collects information on drug safety, pharmacology, and timeliness of drug delivery. IMPACT-ED will inform the development of a larger trial to answer whether IVMg given early in the ED can prevent hospitalization. If found effective, increased use of IVMg could avoid 16,500 hospitalizations a year, reduce direct costs by $60 million yearly, and decrease indirect costs of missed school and work.

STArT

The STArT study investigates the benefits and safety of arginine for the treatment of patients with Sickle Cell Disease and pain. There are 10 sites enrolling and to date our sites have screened more than 1,300 patients. We have exceeded our November 2022 enrollment milestone with 123 enrolled participants to date! In-person monitoring visits have been completed for 2022 and will begin again in the spring of 2023. The American Journal of Hematology recently published the R34 manuscript "Adherence to NHLBI guidelines for the emergent management of vaso-occlusive episodes in children with sickle cell disease: A multicenter perspective".

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 captures 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 are automating the determination of organ dysfunction in children with sepsis directly from structured and narrative data in an expanded multicenter EHR patient registry. That data are being used to derive and validate prediction models of pediatric sepsis that predict 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 prediction models of risk of sepsis. Data transmissions are almost complete for all centers and there are 3 manuscripts in progress.

PedCAPS

The PECARN-endorsed R01 grant, Derivation and Validation of the Pediatric Community-Acquired Pneumonia Severity (PedCAPS) Score, was officially funded by NHLBI. This project will enroll 2000 children with pneumonia across 7 PECARN EDs to derive the PedCAPS score. An additional 2000 will be enrolled at 7 different PECARN EDs to externally validate it. In addition, we will be evaluating the role of biomarkers in risk stratification for these children and developing a biorepository of blood and nasopharyngeal specimens. The PedCAPS score will be the first widely developed and validated ED-based score in children with CAP. Once developed and validated, we can work to implement this score to avoid many unnecessary hospitalizations in children at low risk, while targeting more focused therapies towards the lower proportion of children at highest risk for severe disease.

C-SPINE

Enrollment and data cleaning are complete for the prospective observational study aimed at the Development and Testing of a Pediatric CSI Risk Assessment Tool (C-Spine study). Currently, 9 manuscripts are in development. Abstracts presenting the derived and validated clinical decision rule for neck imaging after blunt trauma has been accepted for oral presentations at the annual meetings of the American Academy of Pediatrics and the Pediatric Trauma Society. Next steps for the clinical decision rule will be validation using the observations from EMS providers. Additionally, we have begun coding the transcripts from the first 70 user-centered design interviews and are preparing manuscripts that will inform implementation of the clinical decision rule. The diversity supplement, which was awarded to support Dr. Jordee Wells, has been completed. Two manuscripts are now in development for this portion of the study as well. Dr. Leonard has been asked to submit a grant continuation for the implementation portion of the C-Spine study, the CASPIAN grant.

BEEPER

BEdside Exclusion of Pulmonary Embolism in children without Radiation (BEEPER) is a large multi-center, observational study. This project is prospectively testing if the Pulmonary Embolism Rule out Criteria (PERC-Peds), or PERC rule, can safely exclude PE in approximately 4,030 children ages 4 to 17 years old who raise a suspicion of PE in the emergency department setting. Since November 30, 2020, the 21 study sites have enrolled 2,398. Approximately 13 manuscripts have been identified and preliminary meetings began late last year to discuss analysis plans. The rate of venous thromboembolism in the study

PediDOSE

The Pediatric Dose Optimization for Seizures in Emergency Medical Services (PediDOSE) study aims to measure the effectiveness and safety of a standardized pediatric seizure protocol with age-based midazolam dosing. Approximately 400 subjects have been enrolled among the 20 sites, and national presentations are underway to present the community consultation findings for this Exception from Informed Consent (EFIC) study. If the intervention is safer and more effective than current practice (calculation-based dosing), the potential impact is a paradigm shift in EMS pediatric seizure treatment that can be implemented across the country.

PECARN Registry

The PECARN Registry is an emergency care visit registry with automated transmission from the electronic health record data for pediatric patients at participating sites. The Registry currently contains data from all ED visits from ten healthcare systems including seventeen EDs with data spanning calendar years 2012 through 2022. Each site transmits data to the DCC monthly. Comprehensive data quality assurance rules have been automated to assess data quality and validation of the transmitted data. The Registry has just upgraded its data collection system and is currently onboarding four new sites. The Registry has data on over 7.8 M visits. Data are also used for health services research, comparative effectiveness research, hypothesis generation and grant planning for the network. The Registry is utilized in many other funded PECARN grants.

STI

The STI study aims to determine the most clinically efficient and cost-effective ED STI screening method among adolescents who would otherwise not receive preventive healthcare. The study also has the potential to improve diagnosis of asymptom¬atic STIs and decrease the time interval to treatment, consequently decreasing reinfection rates as well as healthcare costs for children. The STI study team completed data collection for phase one (workflow analysis) and the pragmatic trial. All sites ended enrollment and data collection September 2022 and are currently cleaning data. Two manuscripts have been published: one, in JAMA Pediatrics, comparing the cost-effectiveness of these two screening strategies based on literature estimates, and a second manuscript describing the results of the workflow analysis. We also presented an abstract at PAS 2021 describing the impact of the COVID pandemic on ED-based STI testing and detection and have several more manuscripts currently circulating for final revisions.

BIOSIGNATURES I & II

The Biosignature I/II studies evaluated the ability of the "RNA Biosignature" to distinguish febrile infants ≤ 60 days-old with viral versus serious bacterial infections (UTIs, bacterial meningitis and bacteremia). This technology has the potential for rapid and accurate diagnosis of febrile infants. Biosignatures II is assessing the stability of the RNA biosignature via sequential sampling. We enrolled 2,612 infants, with 306 sequential samples. We have published a dozen manuscripts on Biosigs I and II, one more recently published in Pediatrics including a video abstract (Urinalyses and Meningitis). Upcoming manuscripts included Pneumonia in Febrile Infants, Racial and Ethnic Disparities in Care of Febrile Infants, SBI Prediction Rules Using Machine Learning, and the final Biosignatures 1 and 2 transcriptomics manuscripts. We are also revising a PECARN-endorsed grant to PCORI regarding implementation of the PECARN febrile infant prediction rule which will involve computerized decision support and shared decision-making. All these studies will help facilitate a more expeditious, accurate and safer evaluation of the febrile infant.

AZ-SWED

The AZithromycin Therapy in Preschoolers with a Severe Wheezing Episode Diagnosed at the Emergency Department (AZ-SWED) Trial is testing two primary hypotheses: Azithromycin given for 5 days to preschool children with severe acute wheezing who are harboring pathogenic bacteria in their nasopharynx will decrease the severity of the acute episode; and Azithromycin given on an identical schedule and dose will decrease the severity of wheezing episodes in children who are not harboring pathogenic bacteria in their nasopharynx. Total expected enrollment is 1476; a sub-group of 370 will be tested for antibiotic resistance. Study Enrollment: First participant randomized on 9/22/2021. As of 1/10/2023, 258 randomized participants (36% female, 50% Black/ African American, 18% Hispanic/Latino).

IMPROVE

The IMPROVE study is a multi-center, longitudinal comparative effectiveness study combining Registry data with prospective outcomes data collected via text messages. IMPROVE aims to provide evidence to inform optimal pain treatment for children discharged home with a long bone fracture. Enrollment of English and Spanish speaking participants is ongoing at 7 sites and over 6063 subjects have been enrolled as of January 1, 2023. We are evaluating ways to continue enrollments across all sites beyond the planned 4-year enrollment period to make up for COVID down-time and a supplement was submitted to analyze COVID impacts on opioid use. Manuscript analyses and writing are in progress.

HEADACHE

The Headache Assessment in Children for Emergent Intracranial Abnormalities (HEADACHE) study aims to create the first decision-making algorithm that will allow physicians to determine the precise risk of emergent intracranial abnormalities in children with headaches, and accurately identify those who require emergent neuroimaging and those who do not. We have enrolled over 6700 children and completed over 440 interrater assessments over the past 22 months. Emergent intracranial abnormalities have been identified in approximately 1% of children. Approximately 33% of children received ED neuroimaging, with over 60% of them undergoing CT scans.

FEDERAL CORNER

EMSC Emergency Medical Services for Children

Congress Unveils FY2023 Omnibus Spending Bill

In May 2022, the National Academies of Sciences, Engineering, and Medicine recommended that the National Institutes of Health (NIH) create an Office of Autoimmune Diseases as part of a study addressing research on these lifelong chronic illnesses. See the study, "Enhancing NIH Research on Autoimmune Disease," here. In December, Congress allocated the funds necessary for this office in its 2023 omnibus spending package.

2022 National Healthcare Quality and Disparities Report

The Agency for Healthcare Research and Quality released its 2022 National Healthcare Quality and Disparities Report. The report provides a comprehensive overview of the quality of health care received by the general U.S. population, and disparities in care experienced by different racial and socioeconomic groups. Quality is described in terms of six priorities: patient safety, person-centered care, care coordination, effective treatment, healthy living, and care affordability. The report is based on more than 250 measures of quality and disparities covering a broad array of healthcare services and settings. 2022 National Healthcare Quality and Disparities Report | Agency for Healthcare Research and Quality (ahrq.gov)

National Institutes of Health (NIH) Request for Information

NIH has issued a request for information (RFI) seeking feedback on revising and simplifying the peer review framework for research project grant applications. They are proposing a Simplified Framework for NIH Peer Review Criteria that aims to focus review on the merits of the science proposed in each individual grant application.
Deadline for comments: March 10, 2023.

U.S. Department of Health and Human Services (HHS): Renewal of Determination that a Public Health Emergency Exists

HHS Renews Public Health Emergency for Another 90 Days. On January 11, HHS extended the current Public Health Emergency (PHE) declaration for another 90 days. The emergency was first declared in January 2020, when the coronavirus pandemic began, and has been renewed each quarter since then. The extension of the PHE means the continuation of flexibilities for health care providers and allows millions of Americans to continue receiving free tests, vaccines, and treatments.

National Survey of Children's Health (NSCH): Compare NSCH Data Across States

For researchers, planners, and policy makers, the combined 2020-2021 National Survey of Children's Health (NSCH) Child and Family Health Data Findings are now available. These estimates are available through the interactive data query on the Data Resource Center for Child & Adolescent Health website. The combined 2020-2021 NSCH is the fifth multi-year dataset since the redesign of the NSCH in 2016 and includes data from 93,669 children ages 0-17 years.

HHS's Substance Abuse and Mental Health Services Administration (SAMHSA) Announced the results of the Annual National Survey on Drug Use and Health (NSDUH)

Detailing Mental Illness and Substance Use Levels in 2021
SAMHSA released the results of its annual NSDUH, which shows how people living in America reported their experience with mental health conditions, substance use, and pursuit of treatment in 2021. The 2021 NSDUH national report includes selected estimates by race, ethnicity, and age group. This report is the most comprehensive report on substance use and mental health indicators released to date.

National Academies Health and Medicine Division

Of the many supply chains whose fragility was exposed by the COVID-19 pandemic, none are more vital to public health and safety than those for medical products. A recent National Academies Health and Medicine Division report outlined recommendations to improve supply chain resilience in the face of trigger events, like the surge in demand for N95 masks that occurred early in the pandemic. Check out the report's full interactive page here.

HRSA: Maternal and Child Health Funding:

National Center for a System of Services for Children and Youth with Special Health Care Needs
-Apply by January 26
MCH Nutrition Training Program - apply by February 2
Maternal and Child Health Field-Initiated Innovative Research Studies (MCH FIRST)
-apply by February 7
Maternal and Child Health Secondary Data Analysis Research (MCH SDAR)
- apply by February 13
Autism Secondary Data Analysis Research (Autism SDAR) - apply by February 13

NODAL NEWS & NEW FACES

EDC




The EDC welcomes one new Director Shelly Roalstad, Associate Professors, Ron Reeder and Huong Meeks and Project Manager, Brittany Brown. We also want to wish Melissa Metheney (Laws) a big congratulations on getting married in October of 2022.

GLACiER

Nationwide Children's new staff:
Emily Stanciu – Research Intern, Dec 2022
Mohisha Sinh – Research Intern, Dec 2022
Keegan Rengal – RA, Jan. 2023
Grace Poncsak – RA, Jan. 2023

WPEMR

West/SW Pediatric Emergency Medicine Research (WPEMR) has changed its name to STELAR – Seattle, Texas (Dallas), Los Angeles Research. Same great people, easier to pronounce name!!

SPARC



Caroline Wuertz, BSN, RN
CHOA, Oct 2022.

Emory University and Children's Healthcare of Atlanta Nodal staff recently held a team building retreat, showing off our artistic side with a group painting class. The node also participated in the Prompt Bolus Gift Exchange.

PEM-NEWS

Joandalys Tejada, MPH - RC, 06/2021
Lisa-Pierre Tchoungui, MD - RC,12/2022
Eva Gomez-Huggard, MPH - RC, 12/2022
Lindsay Marin, MS - RC, 09/2022

HOMERUN

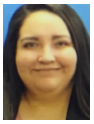
HOMERUN would like to welcome David Schnadower MD MPH as the Cincinnati Children's HEDA PI. David became one of Peter Dayan's professional children after spending many years working for doctors without borders and the international committee of the red cross across Southeast Asia, Latin America, and Africa. He has led two PECARN studies with his PERC partner in crime, Stephen Freedman (Probiotics and HIKO-STEC). He was the chair of the PEMCRC for 6 years and is now chair elect of the section on emergency medicine of the AAP. David is the academic director for emergency medicine at CCHMC, he is also a very average but passionate cello player and the father of two crzy teenagers.

HOMERUN also welcomes Michael Armanious BS MHA as the Medical College of Wisconsin's HEDA RC. Michael was born and raised in Milwaukee Wisconsin. This means Packers, Bucks, and Brewers for life. Research has been a beacon for him and has given him purpose. He is super excited for this new role and to represent our site in PECARN. He mentions that he has big shoes to follow from Duke but Duke has prepared him well!

PRIME

PRIME welcomes a new member to the PECARN family with the birth of Oliver Austin Lemon (proud mom Lexi Lemon-PCH RC)! Oliver was born on Sep 23rd, 2022, 7 lbs., 8 oz., 21". New Staff: Pradhita Kolluru – RC, CHOP, Oct 2022. Veronica Villalobos – RC, PCH, Dec 2022. (pictured left to right)



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