PECARN

Pediatric Emergency Care Applied Research Network

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STELAR - Spearheading Pediatric Emergency Care Implementation Science Research

Authors: Eileen Klein and Bonnie Strelitz and reviewed by Casey Lion (STELAR)

As PECARN continues to accelerate the quality and quantity of pediatric emergency medicine evidence-based best practices, our network is faced with an issue common to clinical and social science researchers across the globe. Once we know which interventions and evidence-based practices benefit the health of our patients, how do we best disseminate that evidence and ensure that it is implemented into all practice settings providing emergency medical services to children? Implementation Science is a cross-disciplinary research field that seeks to close the gap between the evidence for best practices and the actual frontline health care provided to patients. Responding to this need, the STELAR node is leveraging Implementation Science methodologies to enhance dissemination of current research and to further the science of implementation in new projects and proposals. The STELAR node recently developed two Implementation Science concepts that have been approved to move to protocol development by the PECARN Steering Committee: IMPPACT and LEAPED. Implementation Mapping for Prehospital Pediatric Asthma ExaCerbation Treatment (IMPPACT), led by PI Jennifer Fishe, MD at the University of Florida College of Medicine - Jacksonville aims to apply implementation frameworks to the prehospital EMS environment in order to better understand how EMS clinicians can adopt best practices for treating pediatric asthma exacerbations. Currently most children with asthma treated by EMS do not receive systemic corticosteroids, and many do not receive first-line inhaled bronchodilators. For this project, Dr. Fishe and collaborators will operationalize the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) and the Consolidated Framework for Implementation Research (CFIR) frameworks for the unique EMS setting. In Aim 1, the team will apply those frameworks and combine qualitative and quantitative data from 8 EMS agencies using a mixed methods multiple case design to identify barriers and facilitators to EMS administration of evidence-based pediatric asthma treatments. In Aim 2, a user-centered design process will develop a suite of support tools (e.g., electronic medical record clinical decision support, educational toolkits, quality improvement processes) to increase EMS adherence to pediatric asthma Standard Operating Procedures. In Aim 3, Dr. Fishe and team will test the suite of tools in 4 EMS agencies. This project is currently in the protocol development phase and with the help of the University of Utah EDC will be presented at the February 2024 PECARN Steering Committee meeting for review and feedback as the protocol is further refined. Dr. Fishe aims to submit the protocol for funding in fall 2024. In Language Equity and Access in the Pediatric Emergency Department (LEAPED), PI Casey Lion, MD, MPH at Seattle Children's Hospital will lead a Type III hybrid implementation-effectiveness trial, using a factorial design to compare 3 strategies to support effective interpreting use for patients and their families in the pediatric emergency department (ED) setting. In Aim 1, the team will determine the effectiveness of each of 3 implementation strategies, alone and in combination, to increase uptake of professional in-

terpreting, improve parent comprehension, and decrease 72-hour returns for families speaking a language other than English in the pediatric ED. Study strategies—multimodal education, creation and review of an interpreting use dashboard, and increasing access to video interpreting devices--were selected with input from participating sites and informed by the Theoretical Domains Framework, to target Capability, Opportunity, and Motivation as necessary precursors to behavior change. In Aim 2, the team, will explore the relationship between strategy implementation and provider and organizational attributes, to understand when, how, and under which conditions strategies are most effective. In Aim 3, the team will determine the incremental cost-effectiveness of each implementation strategy from a healthcare organization perspective, to calculate what investment is needed in a pediatric ED to produce a 10% improvement in interpreting use rate with each strategy. This project is in protocol development and will be presented at the April 2024 PECARN Steering Committee meeting for review. Implementing best practices into common usage is an ongoing goal within PECARN, and within clinical research in general. Implementation Science is a methodology that can help with the dissemination and integration of best practices into clinical settings. STELAR node is proud to be at the forefront of the future of implementation research and dissemination of best practices.

FEDERAL CORNER

News from U.S. Health and Human Services (HHS)

HHS Launches New Medicaid/Children's Health Insurance Program (CHIP) Hub to Help Keep People Covered

As part of continuing efforts by the Biden-Harris Administration to help people access comprehensive, high-quality health coverage, HHS launched a new, user-friendly hub for partners to access critical Medicaid and CHIP renewal and transition resources. The outreach and engagement resource hub pulls together materials from across the federal government. It is a key part of the Administration's all-hands-on-deck effort to ensure people with Medicaid or CHIP coverage are aware of states' renewal process and can easily renew their coverage or get connected to other coverage through their job of the Affordable Care Act Marketplaces. HHS will continue to work with partners and stakeholders to maximize coverage for as many people as possible and will monitor states' renewal efforts to ensure their compliance with federal Medicaid renewal requirements. More information about Medicaid and CHIP renewals can be found here.

News From Health Resources and Services Administration (HRSA)

HRSA Joins White House Roundtable on Innovation in Maternal Health

HRSA Deputy Administrator Jordan Grossman and Maternal and Child Health Bureau (MCHB) Associate Administrator Dr. Michael Warren joined a White House roundtable led by Domestic Policy Council Director and Domestic Policy Advisor to the Vice President to discuss the Agency's efforts to improve maternal and infant health. In addition to announcing the release of a funding opportunity for the State Maternal Health Innovation program, which supports state maternal health task forces, HRSA highlighted several of its foundational maternal health programs. More HRSA news and information here.

Click here for more Federal Updates, Resources and Research Opportunities

Study Updates

IMPROVE

IMPROVE 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. 7,462 English and Spanish-speaking subjects were enrolled between July 2019 and our last enrollment date of August 31st, 2023. Linkage to the Registry is completed and manuscript writing and manuscript analyses are in progress.

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 2,200 patients. We continue to exceed our enrollment milestones with 227 enrolled participants! Remote monitoring for year 2 of the grant has concluded and will begin again in late summer 2024. In-person site visits are planned in 2024 for Texas, CHOP and Wash U. The STArT protocol manuscript was recently published in Trials. In August, STArT was recently highlighted during an invited talk at the NHLBI's annual sickle cell research symposium and at the December American Society of Hematology Meeting. Our project period runs through the end of August 2026 and our goal is to enroll 360 subjects.

T-RECS

The Treating Respiratory Emergencies in Children Study (T-RECS) study was funded in the summer of 2023. T-RECS is a pilot trial designed to evaluate the feasibility of implementing a prehospital treatment bundle for children with life-threatening asthma that includes ipratropium and dexamethasone. The overall goal is to reduce the hospitalization rate and improve participants' quality of life. The primary aim of the pilot study is to evaluate the feasibility of collecting the study outcomes. The three sites have either completed or are nearly finished with community consultation, and waiting for final IRB approval to start enrollment. We expect enrollment to start in early 2024.

PEACH

The PEACH study aims to determine the association between race/ethnicity, insurance type and rate of post emergency department follow-up for children with headache. In addition, this study aims to understand the lived experience of caregivers seeking follow-up for their children with headache as it relates to race/ethnicity and insurance type. PEACH is continuing participant enrollment, questionnaire distribution, and qualitative interviewing at 4 sites. As of January 10, 2024, 268 participants out of 360 have been enrolled. The study is set to conclude in June 2024.

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 complete for all centers and there are 3 manuscripts in progress.

PediPART

The Pediatric Prehospital Airway Resuscitation Trial or Pedi-PART will help determine the best strategy for prehospital airway management in critically ill children. The study was funded in September 2023 and many pre-enrollment activities are underway. Since this study will utilize an Exception for Informed Consent (EFIC), Community Consultation and Public Disclosure for the study is expected to begin for sites in January 2024. The first patient enrollment is expected in May 2024.

IMPACT-ED

Study enrollment is complete for this 3-arm pilot randomized trial of intravenous magnesium in children with severe acute asthma at three sites - Primary Children's Hospital, Nationwide Children's Hospital, and Children's Hospital of Philadelphia. The study team is working on analysis, publications (a main study manuscript and separate manuscripts on safety and pharmacology), and a grant application in 2024 to fund a conclusive trial at more sites.

C-SPINE

Enrollment and data cleaning are complete for the prospective observational study the Development and Testing of a Pediatric CSI Risk Assessment Tool (C-Spine study). The derived and validated clinical decision rule for neck imaging after blunt trauma abstracts were presented at the annual meetings of the American Academy of Pediatrics and the Pediatric Trauma Society. Eighteen secondary analyses are currently in progress 8 of which have been presented as abstracts at National meetings. Next steps for the clinical decision rule will be validation using the observations from EMS providers. The second and third manuscripts utilizing the user-centered design interviews are in the works. There are 2 manuscripts and 2 abstracts in progress related to the Diversity Supplement work. The follow-up implementation work is being presented for vote at the February 2024 meeting (CASPIAN). If approved, the goal is to submit a grant in Summer 2024.

AZ-SWED

The Azithromycin Therapy in Preschoolers with a Severe Wheezing Episode Diagnosed at the Emergency Department (AZ-SWED) trial launched in September 2021 with the goal of testing the hypotheses that azithromycin, given for 5 days to preschool children with severe acute wheezing, will decrease the severity of the acute episode in those who do and/or do not harbor pathogenic bacteria in their nasopharynx. Expected enrollment is 1476; a sub-group (n=370) will be tested for the development of antibiotic resistance. As of 1/16/2024, we have randomized 509 participants. If successful, AZ-SWED could greatly impact preschoolers with acute wheezing illnesses by decreasing the severity of symptoms and reducing the length of hospital admissions.

SCREEN SMART

The scientific premise of the ScreenSmart study stems from the PECARN STI study foundational work. This study seeks to adapt our previous intervention for STI screening to broad-scale opt-out HIV screening, specifically addressing diagnosis and prevention goals from the national End the HIV Epidemic (EHE) including increasing HIV screening rates in pediatric EDs using computer-facilitated collection of patient-reported outcomes to confidentially and efficiently assess PrEP eligibility, and leveraging mHealth to improve linkage to care for HIV prevention and treatment. We received the NOA in April and are currently finalizing data elements.

BEEPER

BEdside Exclusion of Pulmonary Embolism in children without Radiation (BEEPER) continues to be ahead of our enrollment goals with 3,402 enrolled at the beginning of January. Based on the current projections, we anticipate completion of enrollment summer of 2024 and data lock in the Fall of 2024. The rate of venous thromboembolism in the study population continues to be on target at ~4.3%. We have set the titles, authorship order and basic analytic plan for approximately 13 manuscripts. Thank you to the study teams who worked so hard over the past 4 years to make this study a success!

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 EDC 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 three new sites. Data are also used for health services research, comparative effectiveness research, hypothesis generation and grant planning for the network and is utilized in many other funded PECARN grants. Please plan to join us for the bi-monthly PECARN Registry Study Development Working Group meetings. The next two meetings are scheduled for Monday March 11 and Monday, May 13. Please notify Cara Elsholz at the EDC if you'd like an invitation sent to you.

SCIENCE II

The investigators on the SCIENCE trial have successfully enrolled 3,693 patients and moved 6 sites to study implementation, with one site pre-transitioning towards study implementation. We continue to publish and present our research demonstrating poor guideline adherence, with high hospitalization and return visit rates. Our hybrid effectiveness-implementation trial aims to improve pain control and decrease hospitalizations for children with acute pain related to sickle cell disease.

PedCAPS

The Derivation and Validation of the Pediatric Community-Acquired Pneumonia Severity (PedCAPS) Score study was successfully launched in August 2023 and in October all 7 sites were actively enrolling. To date, we've enrolled 783/2000 children (200% ahead of enrollment goals) and collected 106 biospecimens. 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.

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 and 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 in September 2022 and are currently cleaning and analyzing data. Two manuscripts have been published and one has been accepted for publication: 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. The third has been accepted for publication in Pediatrics describes racial, ethnic and gender discordance between the EHR and self-identification. Several manuscripts are currently circulating for final revisions.

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. Over 1900 subjects have been enrolled across the 20 sites, and enrollment will continue through July 2026 for this Exception from Informed Consent (EFIC) study. If the intervention is 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.

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. This NICHD-funded RCT of the FAST examination in 6 PECARN centers aims to definitively determine its utility in hemodynamically stable pediatric trauma patients. The study aims to make sure injured children are given the right diagnosis and avoid unnecessary CT scans, which makes healthcare better and safer for them. Across all 6 PECARN sites, 650 patients have been enrolled to date.

HIKO STEC

Hyperhydration to Improve Kidney Outcomes in Children with Shiga Toxin-producing E. coli Infection (HIKO STEC): A Multinational Cluster Randomized Crossover Trial that is currently in its 2nd year of recruitment. 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 381 participants with the ultimate goal of enrolling a total of 1040 over 4 years. We anticipate that the study crossover will occur in fall 2024 once we have reached 50% enrollment.

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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 10,500 children and completed over 690 interrater assessments over the past 35 months. Emergent intracranial abnormalities have been identified in approximately 1% of children. Approximately 36% of children received ED neuroimaging, with over 60% of them undergoing CT scans.

BIOSIGNATURES I & II

The Biosignatures study is a prospective, multi-center, cross-sectional study of over 2,600 febrile infants ≤ 60 days of age. Bacterial infections in infants younger than two months with fevers may be difficult to diagnose. This often leads to unnecessary invasive tests, antibiotics, and hospital stays for these infants. The use of messenger RNA (mRNA) "Biosignatures" offers a novel method for diagnosing infections in these young febrile infants. We enrolled 2,612 infants, with 306 sequential samples. We have published more than a dozen manuscripts from the Biosigs I and II grants, have several manuscripts under review, and are working on others, including the main Biosignatures 1 and 2 transcriptomics manuscripts. We are planning to revise and resubmit a PECARN-endorsed grant to federal agencies (yet to be determined) regarding Implementation of the PECARN SBI 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.

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 are now enrolling at 43 sites around the world: 21 PECARN sites and 22 international sites, and have over 5100 enrollments! PROMPT also continues work on two NIH funded ancillary studies: one investigating blood biomarkers of endothelial dysfunction and the other studying long term kidney outcomes by linking with PEDS NET data at several sites. The DSMB met in July and determined that both arms are safe and that the study should continue without modification.

Good Clinical Practice Tip

Compiled and written by Ella Dixon (EDC)

ICH E6(R3) Draft: Updates Coming to Good Clinical Practice Guidelines

Over the years, the ICH E6 Guideline for Good Clinical Practice (GCP) has been modified and revised to align with the evolving landscape of clinical research. The International Council for Harmonization (ICH) developed and released the very first version of ICH E6 in 1996. The guideline has since been revised with an addendum and the current version, ICH E6(R2), which was adopted in 2016.

In May 2023, a new draft of the third and latest revision to ICH E6 was released and endorsed by ICH regulatory members. According to the ICH website, the E6(R3) Draft Guideline is currently on Step 3 out of 5 in the ICH process. The proposed ICH E6(R3) draft contains many significant changes and updates, but a key overarching theme that emerges is the modernization of clinical trial design and conduct for increased efficiency and flexibility.

"The intent of the revised guideline is to facilitate innovations in clinical trial design and conduct, while at the same time provide guidance to help ensure participant safety and that the clinical trial produces reliable results." - E6(R3) Step 2 Presentation. An overview of some of the key changes included in the proposed ICH E6(R3) Draft Guideline is provided below.

Reorganization of principles and changes to structure:

The layout of ICH E6(R3) has been changed. A total of 11 principles are featured instead of the existing 13 in E6(R2). None of the existing principles have been deleted, but some of them have been merged together and two new principles, Risk Proportionality and Roles and Responsibilities have been added. The Glossary has also been updated with modifications to existing definitions and includes new terms to familiarize yourself with such as assent, metadata, and data acquisition tool.

GCP Tip continued...

Increased focus on quality and risk-based approaches:

The concept of quality assurance has been expanded upon. This could mean transitioning to a more proactive process which prioritizes quality not only during the conduct and operation of a trial, but also in the design of a trial itself. There is additional emphasis on using a risk-based approach which may translate to using risk to guide more decisions including the extent and nature of monitoring. A new section on Site Monitoring allows for more flexibility and aims to reduce burden on the site with the inclusion of remote monitoring activities and remote access to source records.

Participant protection and the informed consent process:

Protection of participants remains a central theme in E6(R3). Additional details have been provided to improve the informed consent process. The informed consent process has been supplemented with guidance on assent, which is defined in E6(R3) as the "affirmative agreement of a minor to participate in clinical trial." Changes to the informed consent process also permit documentation of consent using an electronic signature and obtaining consent remotely where appropriate.

For additional information and to view the full E6(R3) Draft Guideline along with the E6(R3) Step 2 Presentation, visit www.ich.org and navigate to the Efficacy Guidelines page.

NODAL NEWS & NEW FACES

CHaMP

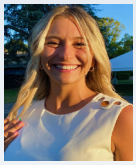
CHaMP mourns the loss of Dr. Brooke Lerner, our friend, colleague, and nodal PI. Dr. Manish Shah now serves as the nodal PI, and Dr. Brian Clemency leads Buffalo's emerging EMS affiliate. CHaMP congratulates Dr. Jon Studnek for his new role as EMS Director for Wake County EMS. We welcome Dr. Kathryn Kothari as the site PI for Houston.





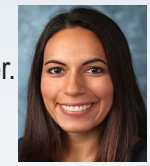
SPARC

Claudia R. Morris successfully renewed her NCCIH K24 grant entitled "Patient-Oriented Research for Arginine Deficiency Syndromes" for another 5 years.



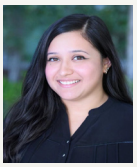
SPARC welcomes 3 new resesarch coordinators at UCSF and CHOA, Elizabeth Ziola, Ryman Crone and Natoli Bora (pictured left to right)

Jennifer Hoffmann, Lurie Children's Hospital of Chicago has joined the SPARC Node as an affiliate member. She is also serving as Co-Chair of the Mental Health Workgroup along with Jackie Grupp-Phelan.



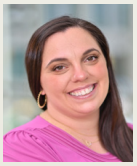
STELAR

STELAR is excited to introduce two new Research coordinators, Monet Tosch-Berneburg (left) of Seattle Children's and Gabriela Sant'Ana Sapio (right) of Children's Hospital of Los Angeles.

PRIME

Congratulations to Tiffani Johnson, MD, MSc, PRIME's Health Equity Expert at UC Davis, who received an Equity, Diversity and Inclusion Excellence Award in November from the American Academy of Pediatrics for her work on the AAP Board of Directors. She was recognized for exemplary achievements impacting the care of children. Congratulations to Angela Ellison, MD, MSc, HEDA PI at CHOP and BEEPER Co-PI was elected to the AAP Board of Directors and assumed office on January 1st! PRIME also welcomes Jessica Albert, MEd as the HEDA RC at CHOP. Jessica has more than 10 years' experience in clinical research studying child and maternal health. She holds a Master of Education in Counseling Psychology and a BA in Political Science, both from Temple University. Jessica's passions include mental health and well-being, improving access to mental health care, eliminating the stigma behind seeking treatment, and providing trauma informed care. She has worked on both investigator initiated and industry sponsored trials in a range of roles. Jessica lives in Lafayette Hill with her husband and son. She spends much of her free time cheering (and booing) Philly sports teams and chasing after her 5-year-old son.



PRIME welcomes new research coordinators, Olivia Fedio, Emem Kierian, Kristen Lau, Steven Rich and Patricia Villaneuva



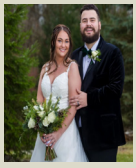


GLACiER

GLACiER would like to congratulate our own Dr. Sylvia Owusu-Ansah for the release of her new movie "In Good Hands"! In Good Hands is based off Dr. Owusu-Ansah's memoir. The film follows an emergency medicine physician's encounter with two patients: "a white boy who has never seen a Black female doctor and an African American teenager arrested by an unsympathetic officer and facing possibly dire medical issues." For more information please visit "In Good Hands" Screening & Panel | Center for Creativity | University of Pittsburgh and please join us in congratulating Dr. Owusu-Ansah!!

HOMERUN

HOMERUN welcomes new research coordinates; Kavya John of Washington University, St. Louis, Erika Kreuser of Medical College of Wisconsin, Kyle Farris of Medical College of Wisconsin, Hayder Jaafar of Medical College of Wisconsin and Norah O'Toole of Cinicinnati Children's Hospital.



Congratulations to Jordan Baker on her recent wedding to Jack Groene and Nicole Gamel on the birth of her son, Samson.

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