FALL 2020

PECARN's Playbook to Resiliance: Pandemic Recovery In Pediatric Research

by the PECARN Nodal Administrators

PECARN In a nutshell

PEDIATRIC EMERGENCY CARE APPLIED RESEARCH NETWORK

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PECARN'S PLAYBOOK TO RESILIANCE:

PANDEMIC RECOVERY IN PEDIATRIC RESEARCH

by Adrian Hamouda (CHAMP), Bonnie Strelitz (WPEMR), Erin Ryan (SPARC), Krista Wheeler & Sherry Goldfarb (GLEMSCRN), Maria Marois (PRIME), Tricia Cobb (HOMERUN), and Yakira Nolasco & Raquel Shrager (PEM-NEWS)

There is no doubt that the COVID-19 pandemic has placed a strain on sustaining clinical research throughout the country and the world. As we, and others, continue to unfold various plans to slowly reopen we are starting to shift our focus from the shor-term effects to the long-term impacts that we can expect in the months ahead.

CHAMP

The CHaMP node, the prehospital node for PECARN, has been effected by COVID across all sites in a number of ways:

Changes to enrollment - Prior to the COVID crisis we had one project that was prospectively collecting data. This pilot sudy weas enrolling EMS transported patients at 11 hosptial sites. Enrollment was halted as the local communities issued stay at home orders and academic insitutions put a hold on all prospective research that involved in-person interaction with study subjects in clinical areas. After careful consideration, the investigator decided to proceed with study closeout activities, and not reopen enrollment, since most of their samples had been collected by that point in the project. The other studies actively entrolling were retroscpective chart reviews and were able to continue with some creative alterations. Like many of us, the staff took on the challenge of navigating HIPAA compliant ways to access data from their homes in order to keep things running smoothly.

Travel restricitons - Collaboration, mentorship, and dissemination of findings are all important aspects of our day to day work. Travel restrictions and alterations to the structure of national meetings meant that our investigators did not have the opportunity to disseminate their findings to their peers and they were not able to benefit from feedback in the same way as before. We are continuing to be creative with alternatives to carry on with these meetings and collaborations in a virtual way. We have a number of pilot studies that are working on dissemination and new studies that are being developed within the CHAMP node. Although we prefer and enjoy the benefits of meeting in person to support each other in these activities, we have been able to hold virtual meetings to continue this work as well.

Timeline delays - We recognize that clinical care is the priority and institutional management of operations has required a lot of time and attention. All of our investigators have needed to concentrate much of their energy on their clinical and leadership responsibilities. This has impacted some timelines and created a few delays. However, overall work is continuing to move forward.

WPEMR

Though in person enrollments were stopped and a number of research projects were placed on hold due to COVID, **WPEMR sites** made efforts to continue some enrollment activities and used stay at home time to focus on preparation for PECARN projects such as EFIC activities for the PROMPT Bolus study. Impact on local enrollments differed by site:

CHLA research coordinators were required to work from home for approximately 3 months until July 2020. Upon return, research coordinators were able to recruit research participants from outside the room via videoconferences conducted using iPads supplied to families by clinicians entering patient rooms for clinical care.

UTSW research coordinators worked from home until mid-June. However, throughout the pandemic **UTSW** RCs have been able to continue recruitment from home by utilizing the EPIC messaging system to message ED attendings and fellows when an

eligible subject arrived to the ED. Since mid-June on-site research coordinators are able to approach patients not suspected of having COVID-19, while wearing appropriate PPE. If the patient is under investigation for potential COVID-19 infection, research coordinators partner with the fellow or attending to complete the enrollment.

SEAT research coordinators were designated essential personnel and were permitted to work on campus. IRB approval was awarded for some projects to waive documentation of consent allowing for verbal consent from outside of patient rooms via phone. The nursing staff entering the room would then collect study specimens including respiratory specimens where COVID testing was added to the protocol.

GLEMSCRN

On March 14, 2020, **MICH** suspended all non-therapeutic human subject's research that required direct person-person contact. As the number of COVID-19 cases increased only essential personnel were allowed to enter the medical center. Research staff worked remotely when possible or used a special COVID leave bank. During this time, University research management and the IRB worked diligently to set-up procedures for remote enrollment and electronic consent. Remote enrollment was difficult and not very successful. On June 22nd, the University began a phased re-opening of human subject's research. Reengagement was done in phases based on the benefit level to the participant and COVID community transmission risk. On July 20th, our PECARN staff was allowed to resume in-person research activity. We are restricted to having only one staff member in the coordinator office at a time and research staff are not allowed in patient rooms that detail droplet and/or special precautions. In these instances, external room phones are used when allowed to obtain consent. All staff must complete a daily health screen, maintain social distance, wear PPE during face-to-face interactions and follow cleaning protocols. Contact tracing is recorded for all study interactions and kept for 2 weeks minimum.

NWCH's clinical research ramp-up plan was a phased approach as well, with changes over time as permitted by state, local and institutional policy. Phase I started June 1, 2020, and Phase II started on August 3, 2020. In Phase I, only research visits for ongoing studies that could be performed as part of clinically indicated visits were allowed to resume. In Phase II, new policy allowed for more than one research staff member to be present. Emergency medicine research coordinators returned on June 1, but without support from undergraduate students. During the prior work from home period, the team completed data quality checks on enrolling studies, complete additional clinical research training in areas such as GCP, REDCap, and data management.

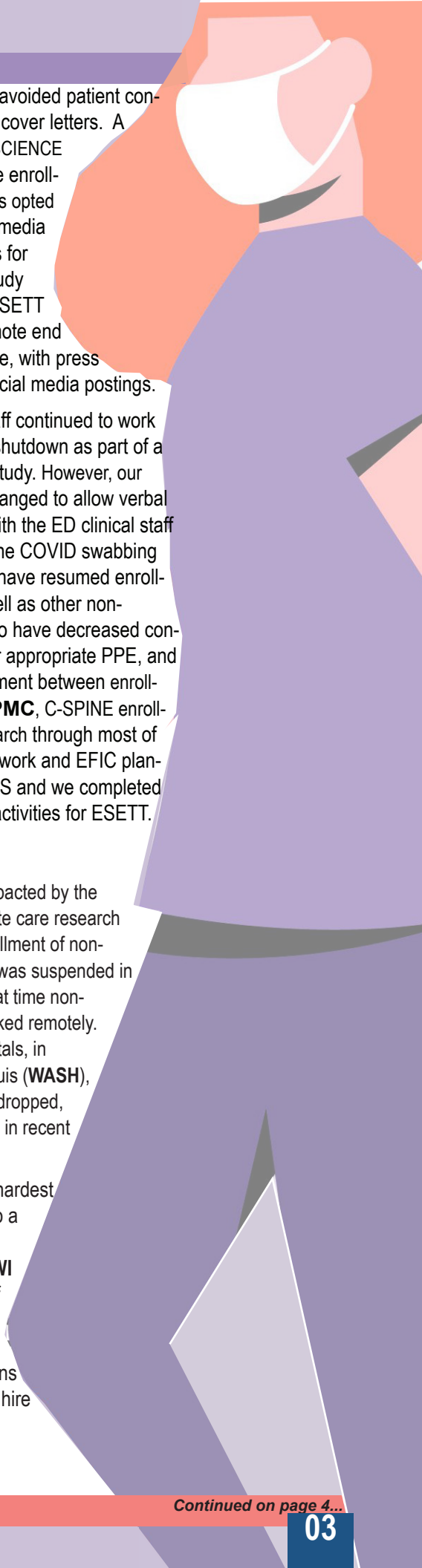
NWCH adapted enrollment protocols, specifically for the C-SPINE study, to adapted enrollment protocols to include single use coverings on all iPads during the EMS and ED provider surveys. The team also avoided patient contact by opting to mail all cover letters. A protocol change in the SCIENCE study allowed for remote enrollment options. **NWCH** has opted for greater use of social media and telecommunications for PRoMPT BOLUS pre-study public disclosure. The ESETT team completed the remote end of study public disclosure, with press releases, letters, and social media postings.

The **UPMC** research staff continued to work through the COVID-19 shutdown as part of a CDC viral surveillance study. However, our consent process was changed to allow verbal consents. We worked with the ED clinical staff and did the majority of the COVID swabbing for the department. We have resumed enrollment for C-SPINE as well as other non-PECARN work. We try to have decreased contact with enrollees, wear appropriate PPE, and wipe down IPads/equipment between enrollments. Specifically at **UPMC**, C-SPINE enrollment was closed from March through most of July. We continued IRB work and EFIC planning for PRoMPT BOLUS and we completed EFIC public disclosure activities for ESETT.

HOMERUN

HOMERUN has been impacted by the COVID pandemic as acute care research and all clinical study enrollment of non-COVID related research was suspended in early to mid-March. At that time non-essential employees worked remotely. Census at all three hospitals, in Cincinnati (**CINC**), St. Louis (**WASH**), and Milwaukee (**MCWI**), dropped, but has started to pick up in recent weeks.

Staffing was one of the hardest hit areas primarily due to a hiring freeze at all three institutions. At both **MCWI** and **WASH**, members of their research teams were furloughed early in the timeline. All institutions were unable to utilize or hire students for



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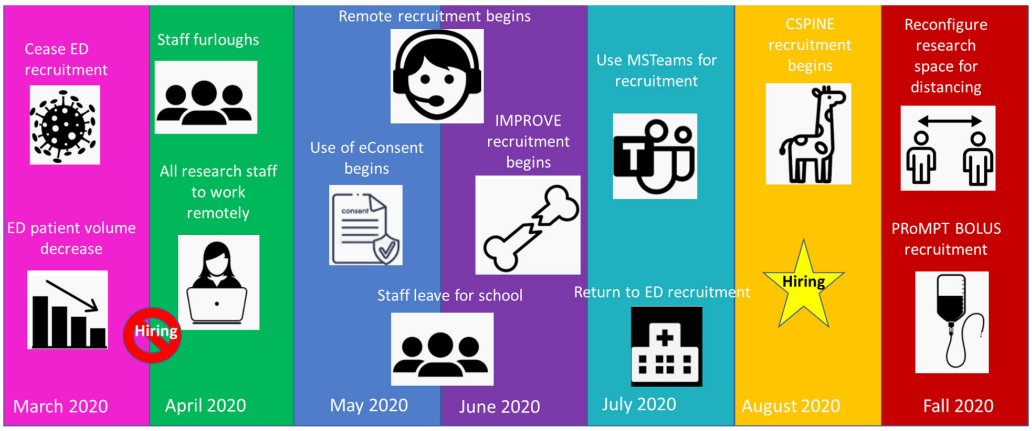
HOMERUN's timeline of research during COVID



recruitment. However, the hiring freeze was lifted by early August.Subsequently, leadership at WASH successfully petitionedthe medical school to allow hiring of two new research assistants and two student research assistants. **CINC** is now in the hiring process for two new RCs to assist with ED recruitment and **MCWI** was able to reinstate two of the three furloughed team members in August to staff the ED full-time.

All three institutions transitioned to remote recruitment in late May. **MCWI** and **CINC** are recruiting patients via telephone for various studies. **CINC** began using REDCap to obtain eConsent from research participants over the phone. **MCWI** was able to recruit their first remote patient for the IMPROVE study on July 13th. Upon return to the ED, all institutions had to rethink recruitment space and strategies. Staff at **MCWI** had to reconfigure their prior research space which was repurposed for COVID front-lines. **CINC** has consulted with Infectious Disease department to gain additional space for RCs to appropriately social distance while at work. Although challenging, the pandemic has forced **HOMERUN** to think creatively on research operations, technology, patient recruitment and enrollment. COVID may have stopped us from recruiting in the ED for a short time, but it has not stopped the node from continuing to advance our science forward.

SPARC

HASB paused all non-COVID-19 research in mid-March. Research staff transitioned to other roles in the hospital, like screening visitors at the door for COVID-19 symptoms, while others worked remotely. Since June 1st, RCs and RAs have resumed working in the office on a rotating schedule while frequently sanitizing and maintaining social distancing. Hasbro has since reopened all non-COVID research studies for enrollment, though research volunteer efforts remain on hold and site administration continutes to encourage employees to conduct remote work wherever possible. All study staff have been individually trained on donning an doffing procedures by hospital directors and have resumed consenting and enrolling procedures as were conducted pre-COVID. Before approaching a patient, staff discuss COVID-19 likelihood with the treating provider. Patients with moderate to high risk are not approached until their COVID test has resulted. Participants returning to the site for research visits are screened over the phone for COVID symptoms and in-person follow-ups are being conducted via telephone whenever possible.

Emory/CHOA has started resuming its research activities. With most staff working remotely 50% of the time, research study enrollments have continued. The research team has been tirelessly working on COVID-19 related studies throughout the pandemic. As the institution resumes its business as usual, **CHOA** is working on a phased reopening that allows employees to work as safely as possible and to conserve hospital supplies. Steps have been taken to ensure the safety of staff and research patients. Employees are screened upon entry and must answer a series of symptom-based questions. **CHOA** also requires that the symptom screener be completed prior to in-person contact with a research participant, and both the staff member and the patient must wear a face covering. Employees must also wear eye protection. If research staff anticipate that a group of subjects cannot wear protective face coverings, the **CHOA** IRB requires this to be included in the study protocol (or modify an existing protocol), and detail why. Researchers are encouraged to use remote technologies to conduct research whenever possible. For Emergency Department studies, research staff must refer to the patient's chart for COVID-19 symptom information, and record results in the research record.

Clinical research at **UCSF** paused in mid-March. By the end of March, clinical research activities had been broken into 3 categories; 1) COVID-19 research 2) research deemed essential to the health of the participant and 3) research deemed not essential to the health of the participant. All category 1 COVID-19 related research activities can enroll. All category 2 and 3 health research can also resume; however, there is a population census of CRCs allowed on campus, and no more than 12.5% of the pre-pandemic workforce should be on campus at any given time. In addition, 1) All clinical research protocols should accommodate telehealth whenever possible (remote consent, virtual visits, etc.). 2) All research in clinical areas can only resume after it is ensured that activities will not interfere with clinical care. 3) All staff must adhere to distancing and PPE guidelines. 4) All participants undergoing research-only visits must be screened for COVID-19 symptoms by phone/telehealth prior to and at the time of visit arrival. **UCSF** research staff are aligning workflows to adjust for screening, recruitment/enrollment and consent to comply with COVID policies, maximize enrollment capacity and minimize exposure risks. Specific strategies include reviewing consent over the phone when a parent is in the room, opt-out consent at follow-ups, and use of tablets for the consenting process.

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PRIME

PRIME sites, Philadelphia (**CHOP**), Salt Lake City (**PCMC**), and Davis **(UCDA**) have have experienced varying impacts from COVID on research. Sites stopped research mid-March and began the return to research early June. Currently, all sites have resumed research activities in the ED but face limitations on the number of staff present and continue to have staff working some of their hours remotely.

Some of the biggest challenges have been scheduling and workflows. Each site has approached scheduling and staffing differently since resuming ED enrollment, depending on needs. Through the summer, all sites have faced losses in staffing (those leaving for school or new jobs) and this placed a corresponding strain on remaining staff. Additionally, funding cuts and delays in hiring have lengthened the time to return to full staffing levels. Fewer staff are allowed onsite at one time, requiring flexibility and creative thinking in scheduling. At **PCMC**, in order in order to cover as many trauma hours as possible, coordinators rotated the weekend shifts with each person taking a shift every 6 weeks. At **UCDA**, coordinators monitor for overnight traumas and to catch overnights before the morning shift changes. **CHOP** initially had reduced ED coverage during the weekday with no weekend coverage but has been adding coverage as new RCs have been hired. **CHOP** anticipates having post-baccalaureate student volunteers to help with ED coverage beginning mid-September. At **PCMC,** Univerity of Utah students are back on campus in certain circumstances which has enabled ED coverage to return to more normal hours, but there remains uncertainty if this will continue. Student volunteers are currently not allowed in the ED with no anticipated return date at **UCDA**, and this presents challenges for reinstating late night and weekend coverage.

All sites have amended processes for enrollment and consent during this time and are utilizing technology to continue important research while maintaining safety for staff. This has included conducting enrollments over the telephone with verbal consent; electronic consent through REDCap; and emailing and texting copies of consent forms and letters of information. At **UCDA**, StudyPages has been in use for a couple of non-PECARN studies which allows a secure workspace for recruitment activities; keeps the team in sync with notes, status updates and screening logs; and allows connecting with participants via telephone or text messaging directly from the dashboard. Research in the era of COVID remains a fluid and ever-changing situation. **PRIME** recognizes that the current situation can quickly change, and one of our greatest lessons over these months is the need to adapt and remain flexible.

PRIME's timeline of research during COVID

	CHOP	PCH	UCD
Research pause period	3/13 – 6/8	3/25 – 6/8	3/17 – 6/8
Have all studies resumed?	All but one	Yes	All but one flu study
What are the current hours of ED coverage?	M-F 10am-10pm, Sat. 2-10pm; mid-September return to full coverage	M-F 6am-midnight; Sat. & Sun. 12pm-8pm	M-F 5:30am-8:30pm, Sat. & Sun. 12-8:30pm
Able to have student volunteers in ED?	Yes, beginning mid-September	Yes, currently	No
What methods of consent currently using?	Electronic/Verbal	Verbal/Telephone	Verbal/Telephone
Were changes in workflow needed?	Yes	Yes	Yes
Are you enrolling with direct patient contact?	Yes, except not in rooms where aerosolized procedure is occurring	No	No
What staffing changes occurred?	2 RCs left, in process of hiring replacements	2 staff left, still working on hiring one position	1 RC left, in process of hiring replacement

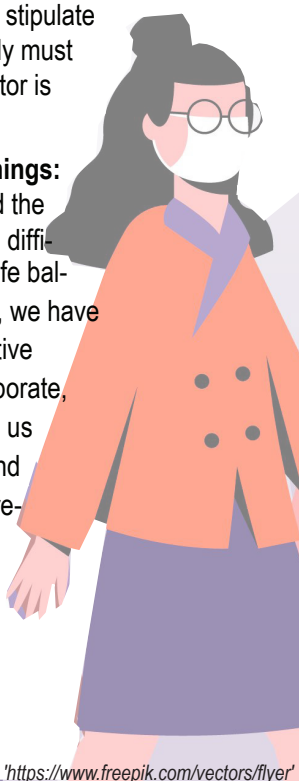
PEMNEWS

Research Pause: All three of our **PEM-NEWS** sites have been significantly impacted by the COVID-19 pandemic. Our sites are in three separate regions; as such, our timelines varied but with relatively similar experiences regarding the requirement to pause and its consequences.

At **CUMC**, the research pause occurred early, as New York City was one of the first to experience the onslaught of COVID positive patients. On March 7th, we were required to remove all "non-essential employees" from the ED, including our Research Coordinators. On March 13th, all studies with prospective enrollment were placed on pause and all staff were required to work from home. The investigators and research coordinators adapted by focusing on data management, analysis, manuscript preparation and grant-writing. The other two **PEM-NEWS** sites subsequently went through similar pauses. All three sites were able to conduct many research activities remotely, including working with our IRBs on EFIC activities.

Research Ramp-up: At **DECH**, prospective research partially resumed on June 1st and resumption of full-time staffing took place on August 1st. Currently, there are few restrictions in terms of enrollments, though patients with primary respiratory complaints and those under investigation for COVID-19 cannot be approached in person, per institutional regulations. The investigators at **CUMC** and **TCBC** only recently received approval to resume enrollment in the ED, with some restrictions. The restrictions stipulate that all activities that can be performed remotely must remain so and that only one research coordinator is allowed in the ED at a time.

Overall Impacts and perhaps a few silver linings: As expected, this crisis has significantly altered the way we do research and has introduced some difficult scenarios into work / life balance. On the positive side, we have found creative and innovative methods to connect, collaborate, and communicate, helping us to streamline processes and conduct some aspects of research more efficiently. ■



All vector images created by freepik - 'https://www.freepik.com/vectors/flyer'

Electronic Informed Consent

by Cara Elsholz, PECARN IT Project Manager, DCC

The research community is showing increasing interest in using electronic methods for seeking, confirming and documenting informed consent for participation in research.

Electronic Informed Consent (eIC) enables potential research participants to be provided with the information they need to make a decision via a tablet, smartphone or digital multimedia. It also enables their informed consent to be documented using electronic signatures. This approach can be used to supplement the traditional paper-based approach or, where appropriate, replace it. An eIC may be used to provide information usually contained within the written informed consent document, evaluate the subject's comprehension of the information presented, and document the consent of the subject or the subject's LAR.

If your site is using eIC processes, it it important to ensure you are still able to:

- Ensure protections of the rights, safety, and welfare of human subjects
- Facilitate the subject's comprehension of the information presented during the eIC process
- Ensure that appropriate documentation of consent is obtained when electronic systems and processes that may employe multiple electronic media are used to obtain informed consent
- Ensure the quality and integrity of eIC data included in FDA applications and made available to FDA during inspections

Here are some common Questions and Answers to help you ensure you are meeting current regulations and guidelines taken from the Use of Electronic Informed Consent Questions and Answers:

How should information in the eIC be presented to the subject?

The eIC must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25). The information must be in language understandable to the potential subject or the subject's LAR and conveyed in a manner that minimizes the possibility of coercion or undue influence regarding the subject's decision to participate in a study (45 CFR 46.116 and 21 CFR 50.20). Understandable means that the information presented to subjects is in a language and at a level the subject can comprehend, including an explanation of scientific and medical terms. Electronic informed consent may be used to either supplement or replace paper-based informed consent processes in order to best address the subject's needs throughout the course of the study.

What steps may be taken to facilitate the subject's understanding of the information being presented?

To assist the subject in understanding the material, the eIC may use interactive electronic-based technology, which may include diagrams, images, graphics, videos, and narration. The eIC may contain various methods to help an investigator assess the subject's understanding of the information being presented during the eIC process. For example, the eIC may include optional questions at any time during the eIC discussion that can be used to help educate the subject about the information presented, as well as assess the subject's understanding of the informed consent materials. Such optional questions and other methods may be used as tools to gauge subject comprehension of key study elements and highlight areas where the subject might need further explanation and discussion before signing the informed consent to enter the study.

What methods may be used to verify the identity of the subject who will be electronically signing an eIC for FDA-regulated clinical investigations?

Compliance with the requirements in Part 11 is meant in part to prevent fraudulent use. Therefore, the regulations found at 21 CFR part 11 require that an organization verify the identity of an individual before it establishes, assigns, certifies, or otherwise sanctions an individual's electronic signature or any element of such electronic signature (see 21 CFR 11.100(b)). Verifying someone's identity can be done by using information from some form of official identification, such as a birth certificate, government-issued passport, or a driver's license. In addition, use of security questions to confirm an individual's identity can also be considered.

What special considerations should be given to the use of eIC for pediatric studies?

The eIC process can be used to obtain assent from pediatric subjects (when required) and parental permission from their parent(s) or guardian. The general requirements for informed consent, found in 45 CFR 46.116 and 46.117 and 21 CFR 50.20, 50.25, and 50.27, apply to parental permission, in addition to the requirements for permission by parents or guardians and for assent by children found at 45 CFR 46.408 and 21 CFR 50.55.13 Therefore, parental permission may be obtained and documented using the same eIC procedures as would be used for informed consent. Absent a waiver of the assent requirement (see 45 CFR 46.408(a) and 21 CFR 50.55(d)), or a determination that assent is not necessary (see 45 CFR 46.408(a) and 21 CFR 50.55(c)), the IRB must determine that there are adequate provisions for solic-

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iting the assent of children when, in the IRB's judgment, the children are capable of providing assent (see 45 CFR 46.408(a) and 21 CFR 50.55(a)).

For FDA-Regulated Clinical Investigations:

Depending on the method of identity verification used to satisfy the regulations in 21 CFR part 11 for electronic signatures in FDA-regulated clinical investigations, a child may lack the documentation necessary to verify their identity for the purposes of preventing fraudulent use of electronic signatures (e.g., driver's license). If so, depending on the clinical investigation, it may be reasonable for the parent to initially document the child's assent, which can then be verified when the investigator first sees the child.

Should subjects receive a copy of their eIC and have easy access to the materials and information presented to them in their eIC?

Yes. HHS and FDA regulations require that the person signing the informed consent (i.e., the subject or the subject's LAR or the parents or guardians of subjects who are children) be given a copy of the written informed consent form (45 CFR 46.117(a) and 21 CFR 50.27(a)), unless the requirement for documentation of informed consent has been waived under 45 CFR 46.117(c) and 21 CFR 56.109(c)). Although FDA regulations do not require that the subject's copy include a signature, FDA recommends that a copy of the signed informed consent form that includes the date when the eIC was signed be provided to the subject. The copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email. If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion. Note that if the eIC uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in any printed paper copy, if one is provided.

Can HIPAA authorizations for research, which are frequently combined with informed consent documents, be obtained electronically?

Yes. HIPAA authorizations may be obtained electronically, provided that the signature of the subject (or the subject's personal representative) is a valid electronic signature under applicable laws and regulations. The Electronic Signatures in Global and National Commerce Act (ESign Act) (Public Law 106-229) addresses what constitutes a valid electronic signature and provides that a signature may not be denied legal effect because it is in electronic form. The HIPAA Privacy Rule requires that when a covered entity seeks an authorization from a subject (or a subject's personal representative), the covered entity must provide the individual with a copy of the signed authorization; this requirement also applies where a HIPAA authorization is obtained electronically.

https://www.fda.gov/media/116850/download

This guidance provides recommendations on the use of electronic systems and processes that may employ multiple electronic media to obtain informed consent for both HHS-regulated human subject research and FDA-regulated clinical investigations of medical products, including human drug and biological products, medical devices, and combinations thereof. FDA's requirements for electronic records/electronic signatures, informed consent, and IRBs are set forth in 21 CFR parts 11, 50, and 56, respectively. HHS requirements regarding the protection of human subjects are set forth in 45 CFR part 46. The information presented to the subject, processes used for obtaining informed consent, and documentation of the electronic informed consent (eIC) must meet the requirements of these and other applicable regulations. If the study is conducted or supported by HHS and involves an FDA-regulated product, the study is subject to both 45 CFR part 46 and 21 CFR parts 50 and 56, meaning that both sets of regulations must be followed. Where the regulations differ, the regulations that offer the greater protection to human subjects should be followed. ■

Federal Corner

Updates from the National Highway Traffic Safety Administration, Office of EMS

Information on NHTSA updates available at https://www.ems.gov

NHTSA

EMS Education Standards Revison Project – The project re-launched with a stakeholder call on August 11 after a brief hiatus due to the pandemic. The stakeholders agreed with the proposed format which combines the Education Standards and instructional Guidelines into one document and adds a resources section (appendices) to help guide EMS publishers and educators. The period of performance for this contract was extended to March 2021. More information can be found on www.EMS.blgov under the Current Projects tab.

Prehostpital Pain Management EBG – The National Association of State EMS Officials (NASEMSO) has recrutied a 15 Member Technical Expert Panel that met for the first time in August. Details can be found on the project website: https://nasemsco.org/projects/prehospital-pain-management-ebg/

Prehospital Airway Management Systematic Review – The Evidence Based Practice Center at Oregon Health Science University (OHSU) is working to finalize the first draft report on this systematic review for peer review. The review evaluated over 240 different study publications, a subset of which were included in a meta-analysis, to help address the four key questions. Peer review of the report, public comment and NHTSA review is planned before finalization of the systematic review report. The protocol has been posted at: https://effectivehealthcare.ahrq.gov/products/prehospital-airway-management/protocol

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Revision of the Field Trauma Triage Guidelines – The American College of Surgeons (ACS) has assembled a Technical Expert Panel who will utilize a supplemental literature review completed by the Pacific Northwest Evidence-based Practice Center at the Oregon Health Science University. ACS is working on a draft Stakeholder Feedback Tool to collect perspectives of EMS agencies on this revision.

grants/guide/notice-files/NOT-MH-20-073.html

Updates from the National Institutes of Health

Update from the US Department of Health and Human Services (HHS) Assistant Secretary for Preparedness and Response – The National Advisory Committee on Children and Disasters (NACCD) has been reauthorized. This Committee provides expert advice and consultation to the HHS on medical and public health needs of children in disasters. The MCHB Associate Administrator Dr. Michael Warren will be the HRSA representative. More information is available at: https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/default.aspx

National Institutes of Mental Health (NIMH): Fostering Innovative Research to Improve Mental Health Outcomes Among Minority and Health Disparities Populations (NOT-MH-20-073) – NIMH seeks time-sensitive input on the most innovative research and research priorities to improve mental health outcomes among racial/ethnic minority and health disparities populations. Of interest are ideas about novel engagement strategies, culturally and linguistically appropriate service delivery approaches, services research methods, and multilevel/multidimensional strategies to accelerate progress toward findings that have both scientific and public health impact in these populations. The due date is Friday, October 30, 2020. You can provide comments at: https://grants.nih.gov/

Goodbye and Welcome

I have been incredibly blessed to be the PECARN Federal Project Officer for the past 6+ years. This job has required navigating mostly smooth but occasionally choppy waters. It's a good thing I am a strong swimmer. I have learned so much from all of you! Your dedication to science and passion for children has been frankly uplifting. I will miss the close relationships I have developed, especially with the most recent PECARN Chairs Rich, Jim, and Brooke as well as Sally Jo and Melissa. I will miss all of you so much. However, I am not going completely away.

I have moved into a new position as Senior Nurse Consultant across our Division of Child Adolescent and Family Health so I can continue to explore my passions for injury prevention and child and adolescent health. I will also continue to support the EMSC program and be involved in many of the EMSC national partnerships and initiatives. And yes I will continue to be involved in PECARN, just in the background.

I am happy to say I am leaving PECARN in very good hands. Which leads me to the Welcome part.

Please Welcome Patty Fanflik, Health Scientist, as the new HRSA PECARN Federal Project Officer. She will also be the HRSA Project Officer for the EMSC Data Center and the Targeted Issues grant program. Patty is well suited to this position. She brings more than 20 years of research and evaluation experience to DCAFH.

Dr. Fanflik, PhD, MFT, MS, joined MCHB in 2017 as a Public Health Analyst in the Division of State and Community Health. She supported the Title V Maternal and Child Health Block Grant program as the Project Officer for states in Regions IV. More recently, she supported the State Systems Development Initiative Grant Program, which aims to develop, enhance, and expand state and jurisdictional Title V MCH data capacity for its needs assessment and performance measure reporting.

Prior to coming to MCHB, Dr. Fanflik served as Deputy Director of Evaluation for Maryland's Department of Juvenile Services managing large-scale studies focused on youth, trauma, and juvenile justice. In addition, Dr. Fanflik has served as the Deputy Director of Research and Evaluation for the National District Attorneys Association.

Dr. Fanflik earned a Master of Science degree in Human Development and Family Services from Kansas State University, where she trained as a marriage and family therapist; a Master of Arts degree in Sociology from Southern Illinois University; and a Doctor of Philosophy degree in Family Science from the University of Maryland, School of Public Health, where she holds an adjunct professor appointment. Patty enjoys spending time with her family, including her rescued fuzzy family members, Teddy, Biscy, and Yoshi.

My Best Wishes to you All!

-Diane Pilkey

" CONDUCTING HIGH PRIORITY, HIGH-QUALITY RESEARCH IN PEDIATRIC EMERGENCY CARE "

PECARN Study Updates

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 nine sites spanning calendar years 2012 through 2020. 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 is about to undergo an upgrade to the data collection system as well as onboard 3 new sites later this year.

The Registry is currently being used to directly populate pediatric emergency medicine quality-of-care performance measure report cards and has derived benchmarks for each of the measures. The Registry has data on over 4.4 M visits and 1.7 M unique patients. Data is also used for health services research, comparative effectiveness research, hypothesis generation and grant planning for the network. The Registry is utilized in four other funded PECARN grants.

Disparities

Racial and ethnic disparities in health care provision have received considerable attention in recent years. In 2002, the Institute of Medicine released a report assessing the extent of variability and disparities in the types and quality of health services provided in the United States. Given this role in our healthcare delivery system, there is a unique opportunity to understand whether care is being delivered equitably, independent of other access issues. For this study, PECARN Registry data have been used to explore racial/ethnic disparities in the emergency care of children with long bone fractures and appendicitis. We recently published a paper in Pediatrics describing disparities in the pain management of children with long bone fractures. An additional manuscript is currently under review and two additional manuscripts are in preparation.

ED-SAMS

ED-SAMS enrolled their first subject September 9, 2019. We have completed recruitment of subjects 6-12 years old who present to the ED with an acute asthma attack over a 90 day recruitment period and followed for 120 days. The study randomized 9 subjects and recruitment ended the first week of March with subjects being followed through the end of the school year. We are currently writing the primary outcome manuscript.

FLUID

The FLUID study enrolled ~1,800 children with diabetes: ~1400 with DKA and 400 without DKA. The main analysis was published in the NEJM in 2018 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. There are several secondary analyses ongoing and manuscripts being written. Our paper regarding hemodynamics in pediatric DKA was recently published in Journal of Pediatrics. An important secondary manuscript regarding neurocognitive comparisons of DKA patients and non-DKA controls was just accepted to the highest impact diabetes journal Diabetes Care. Our manuscript regarding frequency and predictors of acute kidney injury in DKA is “revise and resubmit” at JAMA Open. We are submitting two more manuscripts this week, and are completing several others. Our abstract regarding AKI in DKA was awarded "top 5" honors at the SAEM. Finally, the FLUID Public Use Dataset (PUD) is currently under final review.

SCIENCE

The SCIENCE study, designed to prepare PECARN Registry sites for participation in a large implementation trial improving guideline adherent care for children with sickle cell disease presenting with pain, continues its excellent progress. The first round of patient/family and care team interviews to determine barriers and facilitators to delivering guideline adherent care have been completed. The Round 1 interview data has been analyzed and we are prioritizing interventions across sites for a second round of interviews. The Round 2 interviews will provide intervention data for the subsequent implementation trial.

HIKO STEC

Hyperhydration to Improve Kidney Outcomes in Children with Shiga Toxin-Producing E. coli Infection (HIKO STEC): Planning a Multinational Randomized Clinical Trial has been funded by the NIAID for one year with a R34 planning grant. The goal of this phase III, embedded, cluster-randomized, crossover trial is to compare hyperhydration (e.g. early aggressive intravenous treatment) with conservative fluid management as treatment for STEC-infected children. This study has the potential to improve health outcomes in STEC-infected children. The study has been submitted to the NIAID as part of the Request for Consultation pathway towards over-the-cap and U01 approval.

Biosignatures I & II

The Biosignature I/II studies are evaluating the ability of the “RNA Biosignature” to distinguish febrile infants <60 days-old with viral versus bacterial infections. This technology has the potential for rapid and accurate diagnosis of febrile infants. Biosignatures II is assessing the stability of the RNA signature via sequential sampling. We enrolled 2,612 infants, with 306 sequential samples! We are focusing most of our efforts on the manuscripts for the Biosignature II studies. For Biosignatures I, we expect to submit the main manuscript on the accuracy of biosignatures to a major journal in the coming months. For Biosignatures II, our focus is to move forward with many analyses and manuscripts in addition to the sequential sample biosignature manuscript. Since the last newsletter, we published a manuscript in Hospital Pediatrics pertaining to the time to positivity for growth of true bacterial pathogens versus contaminants from the blood and CSF. We also published a manuscript about the characteristics of febrile infants with radiographic pneumonias in Pediatric Emergency Care. Most recently, we presented two “top 5“ award-winning abstracts at the 2020 virtual SAEM: 1) the risk of bacterial meningitis in febrile infants with UTIs, and 2) Validation of the PECARN febrile infant prediction rule. Manuscripts on both have been drafted. Several more manuscripts will follow including how the presence or absence of respiratory viruses affect the prediction rule! All of these studies will help facilitate a more expeditious, accurate and safer evaluation of the febrile infant.

HEADACHE

The Headache Assessment in Children for Emergent Intrancranial Abnormalities (HEADACHE) study aims to enroll 28,000 children across 18 sites 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. This information may safely reduce unnecessary emergency department neuroimaging in children with headaches, and decrease exposure to risks associated with neuroimaging, such as lethal malignancies due to ionizing radiation. The notice of award was received from NINDS late August, with study training planned for November and anticipated enrollment start in early December 2020.

BEEPER

The BEEPER study is in the start-up phase with the NOGA received Spring 2020 and initial IRB submitted. This study is a large multi-center prospective, observational cohort study of children ages 4 to 17 years old who have sufficiently high probability of pulmonary embolism (PE). This study design (45-day follow-up and 90-day for PE+) takes advantage of convenience sampling when enrolling and is the most logical required step in advancing PE detection in children. Starting in November, the goal is to enroll up to 4,030 eligible children over approximately 4 years.

PED SCREEN

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

C-SPINE

To date, the Development and Testing of a Pediatric CSI Risk Assessment Tool (C-Spine study) has enrolled 10,429 patients for the prospective observational portion of the study and 208 of these patients had cervical spine injuries. Additionally, we have completed user-centered design (UCD) activities at 6 sites. We are happy to report that thanks to the hard work of the Round I sites we are on schedule for the derivation of the rule even after a 2.5 month enrollment pause. We have begun enrolling with the Round II sites for the validation phase of the study! Lastly, the diversity supplement was awarded to support Dr. Jordee Wells' investigation into disparities amongst cervical spine injured patients!

TIC-TOC (TXA)

TIC-TOC is a pilot and feasibility trial of tranexamic acid (TXA) for children with hemorrhagic injuries. TXA has the potential to safely reduce blood transfusions, morbidity, and mortality in injured children. The study has received FDA and sIRB approval to enroll children using the federal exception from informed consent (EFIC). We have completed patient enrollment and will finish patient follow up in September 2020 for the TIC-TOC pilot trial. We submitted the TIC-TOC efficacy trial to NINDS in June 2020. Several manuscripts have been completed or are in draft.

STI

Sexually transmitted infections (STIs) are highly prevalent among adolescents. Despite established principles for STI control, clinical practices related to screening, diagnosis, treatment and prevention of STIs among adolescents are suboptimal. This study aims to determine the most clinically efficient and cost-effective ED STI screening method among adolescents who would otherwise not receive preventive healthcare. This study has the potential to improve diagnosis of asymptomatic STIs and decrease the time interval to treatment, consequently decreasing reinfection rates as well as decreasing healthcare costs. The STI study team completed data collection for phase one (workflow analysis) and is implementing the pragmatic trial at all sites July through December 2020. We currently have a manuscript that compares the cost-effectiveness of these two screening strategies based on literature estimates in press at JAMA Pediatrics, and a manuscript describing the results of the workflow analysis under review.

SPEED

The aim of this study is to develop a electronic health record clinical decision support (EHR-CDS) tool for outpatient antibiotic prescribing of pediatric urinary tract infections and community acquired pneumonia. Currently we are in the early stages of prototype EHR-CDS development, with incorporation of adapted guidelines and specified triggering mechanisms. EHR-CDS development will serve as the centerpiece for implementation of ED-based antimicrobial stewardship programs.

STArT

The STArT trial (**S**ickle Cell Disease **T**reatment with **Ar**ginine **T**herapy) has been approved for funding by NHLBI and is currently in study start-up. The phase 3 randomized controlled trial will investigate the efficacy and safety of IV arginine for the treatment of children with Sickle Cell Disease (SCD) and acute pain. Pain is the clinical hallmark of SCD, and is the leading cause of hospitalizations, emergency room visits, missed school, and is associated with an increased death rate. Arginine is a promising new therapy that could change the way we treat acute pain in children with SCD.

Probiotics

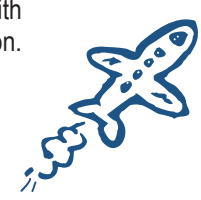
The Probiotics trial showed that LGG a commonly used probiotic was not better than placebo in improving outcomes in children 3-48 months of age with acute gastroenteritis. This landmark study, published in the NEJM, reverses previously held beliefs regarding the effectiveness of probiotics products, an industry worth 32 billion dollar per year globally. The probiotics investigators and the DCC continue analyzing this large database, including data from a parallel trial conducted by PERC in Canada, the Progut study, and publishing multiple sub-studies.

IMPROVE

This is a multi-center, longitudinal comparative effectiveness study combining Registry data with prospective outcomes data, which are collected via text messages. This study aims to provide evidence to inform optimal pain treatment for a long bone fracture. Enrollment has been open at all 6 sites since Summer 2019, with a brief enrollment pause from mid-March to May 2020 as a result of the COVID-19 pandemic. As of the beginning of August 2020, 886 subjects have been enrolled. Our target enrollment is 14,000 children over 4 years. Currently we are working to better understand the changes to ED arrival patterns resulting from COVID-19 and improve enrollment rates across all sites in order to reach this goal.

ED-STARS

To date, the ED Screen for Teens at Risk for Suicide (ED-STARS) has published five manuscripts and three are pending review. We are actively working on approximately eleven additional manuscripts with five MARFs in preparation.



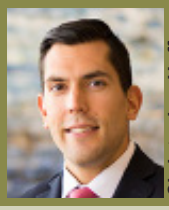
NEW FACES & NODAL NEWS

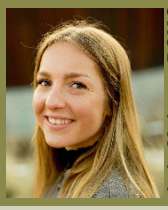
PRIME Node

Congratulations to **Tiffani Johnson** who was named this year's cohort of CAMPOS Faculty Scholars at UC Davis. Awarded by the Center for the Advancement of Multicultural Perspectives on Science (CAMPOS), their mission is to support the discovery of knowledge through an inclusive environment that is diversity driven and mentorship grounded. This prestigious award includes $100,000 of salary support annually for 5 years to promote the scientific and academic endeavors of the awardee. **Nate Kuppermann** received the 2020 Hibbard Williams Extraordinary Achievement Award, which recognizes a broad range of activities in public service, teaching and health research. In addition to exceptional teaching, he earned the Williams award for advancing the school's mission in ways that go well beyond education and research. While SAEM took place virtually, two presentations from Biosignatures (Nate Kuppermann and Prashant Mahajan lead authors) and one from Fluid (Sage Myers lead author) studies received honorable mentions as best abstracts.

Welcome new staff!!!


Erin Hyer -CHOP
March 2020 - HEDA PI


Christopher Hoffman
CHOP
August 2020 - RC


Jade Mulvey - PCMC
September 2020 - RC

SPARC Node

Mark Zonfrillo, MD, MSCE is the new HEDI PI for Hasbro Children's/Brown University, taking over for Jim Linakis, PhD, MD, who previously served in this role prior to his retirement.

Claudia R. Morris, MD was promoted to Professor of Pediatrics and Emergency Medicine, became the Co-Director for the Emory & Children's Center for Clinical and Translational Research, and was also awarded the Wilbur Fish Glenn Jr. Distinguished Faculty Chair for Clinical and Translational Research.

Reshika Mendis, MBBS was named as the Lead PECARN Coordinator for the Emory/CHOA arm of the SPARC node.

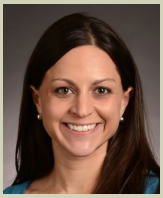

Mark Zonfrillo MD MSCE
HASB - HEDA PI


Nicholas Slater - UCSF
September 2020 - RC

HOMERUN Node

September marked an exciting transition for HOMERUN! Lynn Babcock MD MS is our nodal PI. We are thrilled to have Lauren Riney DO as our new EMSA PI along with Danny Thomas MD MPH and Tara Rhine MD as HEDA PIs for Wisconsin and Cincinnati, respectively. Brad Sobolewski MD MEd is our Dissemination PI. Rich Ruddy MD, David Brousseau MD MS, David Schnadower MD MS, Hamilton Schwartz MD MEd will act as scientific advisors.


Danny Thomas MD MPH
MCWI
March 2020 - HEDA PI


Tara Rhine MD - CINC
September 2020 - HEDA PI


Brad Sobolewsski MD
September 2020 -
Dissemination PI

WPEMR Node

Welcome new Research Coordinator!!!


Jasman Kaur - SEAT
June 2020 - RC

PEM-NEWS Node

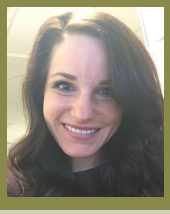
Welcome new Co-nodal Administrator!!!


Yakira Nolasco
June 2020 -
Co-nodal Administrator

GLEMSCRN Node

Welcome new staff!!!

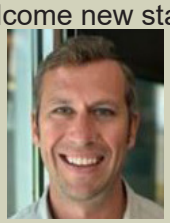

Vincent Cervantes - MICHR
March 2020- RC


Katie DiCostanzo - NWCH
May 2020 - RC Team Lead


Krista Wheeler -
June 2020 -
Co-nodal Administrator

DCC

Welcome new staff!!!


Taylor Mathie
January 2020-
Project Manager


Renee Kuhn
April 2020 -
Project Manager


Katie Lewis
February 2020-
Statistitian

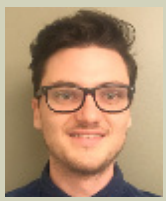

Justin Wheeler
June 2020 -
Statistitian


Deveree Partridge's
baby Shilo Brett Taylor -
June 22, 2020


Cynthia Jones
July 2020-
Project Manager


Rachel Codden
June 2020 -
Statistician


Caleb Bracken
March 2020-
Clinical Data Manager


Regan Jackson
April 2020 -
Clinical Data Manager


Heather Gramse's baby
Ruby Reese Gramse -
February 12, 2020

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