WBCARN Intern Training Pilot Study

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Over the past 8 years, Children’s National has trained research interns and staff on techniques to properly gain informed consent/assent from research participants and their legal guardians. The training curriculum has evolved to incorporate suggestions from the DCC and examples of Good Clinical Practices (GCP), and has been adapted to better suit those with little/no research experience who have not consented a research subject. Although the current training program is rigorous and provides interns time to shadow senior research staff, the outcomes of interns varied and the trainings were based on experience than a comprehensive, formalized plan. Therefore, the Washington, Boston, and Chicago Applied Research Network research coordinators decided to conduct a pilot study to see if there is an effective way to measure the effectiveness of informed consent (IC) and to create a valid training tool for this process.

BACKGROUND: In research, the IC process requires staff to disclose appropriate study information to a competent patient or legal guardian, so that he or she may reach a voluntary conclusion to accept or refuse participation in a research study. The IC originates from the legal right a patient has to full autonomy over treatment, and from the ethical duty of the research staff to include the patient in the decision-making process. Participants must make an informed decision after full disclosure of study aims, procedures, potential risks and benefits, and alternatives to participation. Research conducted in an Emergency Medicine setting presents unique challenges to the IC process. Families approached in the Emergency Department (ED) are asked to make hurried decisions amid multiple stressors. The consent process is often interrupted to allow clinical care to proceed, which may inadvertently blur the distinction between research and clinical care. Even when families have adequate time to read the consent form, they may not fully comprehend the IRB-mandated language used in the document. As a result, true IC is probably an ideal that may be difficult to achieve in the ED setting.

Our current model of consent training for study staff is largely classroom-based. New team members attend mandatory training sessions where the senior staff reviews principles of GCP and all relevant study material. All trainees then must pass a written assessment and complete a simulated consent that is subsequently reviewed and critiqued. New team members shadow a full consent in the ED, and finally, approach a patient under guidance of senior staff. Only when the senior staff feels confident that a trainee can correctly obtain IC are they allowed to approach a patient without supervision. Ongoing refresher training and assessment of competence have not been provided on a regular basis.

To improve our hospital’s training program, we intend to implement a comprehensive curriculum using video, modeling, and assessment. In a short pilot study, our team will enroll new staff in the program, which requires trainees to complete multiple simulated consents while being video recorded. The staff will then review each recording with the trainee. Our hypothesis is that this process will better prepare new staff to obtain IC from study participants.

AIMS & METHODS:
Aim 1: To measure the validity of a consent assessment checklist.

Approach: Trainees will be required to complete a series of filmed mock consents. These will be evaluated using a checklist drafted by senior research staff. The checklist will grade the trainee on task completion (e.g., did the trainee mention all required elements under the Risk/Benefit section) and overall effectiveness. Task Completion will be graded on a Yes/No basis, and Effectiveness will be graded on a seven point scale ranging from “Not Effective” to “Extremely Effective.” Senior staff members will be required to evaluate each video in order to validate the assessment tool. To obtain validity of the checklist, we propose no greater than a 15% discrepancy on all Yes/No answers. We will use the interclass correlation coefficient to evaluate discrepancies on the Effectiveness Scale. Checklist items with poor inter-rater reliability will be discarded, and it will be revised accordingly. This may take several cycles of iterative development to achieve a satisfactory checklist.

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Upon completing the video reviews, we will create a database to analyze the collected assessments. This will allow us to determine the plateau, i.e. the mean number of video reviews it takes for a new study staff member to achieve maximum comprehension with respect to the consent procedure. Alternatively, if there is large variation between trainees, we can use this plateau effect as a measure of achieving competence for each individual, recognizing that some will achieve competence more quickly than others.

Remote Monitoring Success
Author: Amy Watson BS, CCRC, Project Manager—PECARN Data Coordinating Center

Site monitoring for data quality, regulatory, and protocol adherence is an important part of maintaining a successful clinical trial. In addition, monitoring is important to ensuring PECARN’s commitment to high priority and high quality research in pediatric emergency care. Recently, industry and academic researchers have begun to explore ways to conduct effective, cost efficient clinical trial monitoring. A novel approach is to replace or supplement physical, onsite monitoring with remote monitoring via electronic access to files and electronic health records (EHR). Remote access monitoring refers to a specific monitor who accesses specific subject records for the purposes of verifying trial data. PECARN has made steady progress in exploring this novel program in the past year.

In June 2014, all PECARN sites were surveyed regarding their ability to allow remote access to the EHR for purposes of quality monitoring and response was varied. Children’s Hospital of Pittsburgh successfully piloted remote-access monitoring in the MAGIC trial, and this led to additional exploration of remote monitoring for the PECARN FLUID trial. The 13 FLUID study sites were asked to implement the initial steps to provide remote access monitoring to a Data Coordinating Center Project Site. These aims will allow us to complete a secondary study using the validated assessment tool and threshold number to evaluate the effectiveness of the new training program. We will compare this new curriculum to the traditional training program, and we believe students trained on the comprehensive curriculum will improve their approach to obtaining informed consent.

This project is being developed within the WBCARN node and we anticipate beginning to collect pilot data by Summer 2015.

Federal Corner

Continuing Education & Training Opportunities
Highlighted below are details on recent EMSC webinars that might be of interest including 2 archived and 1 upcoming educational event. Continuing Education credits are available to nurses, physicians and EMS providers.

Using Quality Improvement to Maximize Pediatric Emergency Care in Your State
Charles Macias, MD, MPH; Kate Remick, MD; Jane Brice, MD, MPH
This educational training opportunity reviewed the importance of quality improvement (QI) in pediatric emergency care, provided a QI framework, and illustrated the application of QI methodologies in improving pediatric trauma care. EMS providers may view the archived webinar to receive 1.5 CE credits for up to three years through the Continuing Education Coordinating Board for Emergency Medical Services sponsoring agency by accessing the link, viewing the archived event, and completing the evaluation at the end.

Pediatric Readiness Data: An Opportunity to Improve Quality of Care in Your Emergency Department
Charles Macias, MD, MPH; Kate Remick, MD; Evelyn Lyons, RN, MPH
This online educational product will soon be available with CE credits for physicians and nurses. The original webinar defined quality improvement (QI), highlighted key components of the QI process, and examined how to apply essential QI methodologies to improve pediatric emergency care using the National Pediatric Readiness data. When available, EMSC grantees and stakeholders will receive a special announcement.

An Introduction to the Updated Recommendations for Equipment on Ground Ambulances: Pediatric Equipment & Its Use in Prehospital Emergency Care
This is the 1st webinar (now archived) in a two-part series on the updated Joint Policy Statement: Equipment on Ground Ambulances. It provided an introductory overview of the recommendations, described essential pediatric equipment and how it is used in the prehospital setting, and discussed strategies for implementing the guidelines at the state and local level. This webinar targeted EMSC program managers, directors, family representatives, and others who have limited EMS field experience.

Building a Foundation for Pediatric Emergency Care: Equipment for Ground Ambulances
Mary Fallat, MD, Aaron Reinert, NREMT-P, David Byson, EMT-B
Save the Date: February 17th, 2015 at 4pm Eastern
As the 2nd webinar in the series on the updated Joint Policy Statement, it will address the rationale for the development of ambulance equipment guidelines and their importance to children, explain guideline changes and contributing factors, and discuss guideline implementation. It is intended for EMS leaders, including service directors, medical directors, managers, education specialists, EMS providers and program managers, state depts. of health regulatory staff, and hospital emergency care leaders interested in pediatric emergency care in the prehospital area. Continuing education will be available to nurses, physicians, and EMS professionals. https://emscnrc.adobeconnect.com/equip2/event/registration.html
Updated PECARN Acknowledgement

HRSA has recently updated the federal PECARN acknowledgement for manuscripts, abstracts, posters, newsletters, brochures, etc, as detailed below:

Acknowledgement: This project is supported in part by the Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), Emergency Medical Services for Children (EMSC) Network Development Demonstration Program under cooperative agreements U03MC00008, U03MC00001, U03MC00003, U03MC00006, U03MC00007, U03MC22684, and U03MC22685. This information or content and conclusions are those of the author and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

For an electronic copy of the acknowledgement please visit the Publication Resources eRoom or the PECARN Grantee Portal on the EMSC NRC website.

EMSC Federal Legislative Update

The federal government has been operating under a series of continuing appropriations bills that provide level funding—or funding at the fiscal year 2014 level—for all federal programs, including the EMSC Program, through Dec. 17th. To fund the federal government for the remainder of the fiscal year, Congress recently approved and the President signed into law H.R. 83, the Consolidated and Further Continuing Appropriations Act of 2015. This bill provides $20,162 million for the EMSC Program, a decrease of $51,000 from the fiscal year 2014 level of $20,213 million. This total amount, however, will be prorated for the time period Dec. 16th, when H.R. 83 became law, through Sept 30th, the end of fiscal year 2015.

EMSC Liaison Report

Each quarter, EMSC News, the EMSC Program’s official liaison report, is published. The report includes an update on: projects of national significance, program partnership efforts with federal agencies and national organizations, and EMSC grant program highlights, including the State Partnership, State Partnership Regionalization of Care, PECARN, and the Targeted Issues grant programs.

New PECARN Funding Opportunity Announcement

The 2015-2019 PECARN Funding Opportunity Announcement (FOA) has been released and applications are due April 2nd, 2015. A technical assistance call is scheduled for 1:00-2:00PM (Eastern) on February 13th, 2015. FOA: http://www.grants.gov/view-opportunity.html?oppId=271868

Who are Your PECARN Health Resources and Services Administration and National Resource Center Contacts?

Are you unsure who to contact when you have a PECARN-related question?

Health Resources and Services Administration (HRSA)

Elizabeth Edgerton, MD, MPH (eedgerton@hrsa.gov)

She remains the primary contact for any scientific issues or questions related to PECARN.

Diane Pilkey, RN, MPH (dpilkey@hrsa.gov)

She is the HRSA project officer for PECARN cooperative agreements, and is the person to contact with questions related to grants reporting, the Electronic Handbook, or upcoming FOA.

Emergency Medical Services for Children (EMSC) National Resource Center (NRC)

Sametria McCammon, MSPH (SMccammo@childrensnational.org)

She serves as the liaison for PECARN projects, providing assistance with research dissemination and facilitation of virtual meetings.

Barbara Mitchell-Swain (bswain@childrensnational.org)

She provides logistical support for PECARN’s on-site meetings.

NIH Announces Multi-site Single IRB

In an effort to hasten the initiation of research and streamline processes in multi-institutional studies, the National Institutes of Health (NIH) has issued a draft policy to promote the use of single institutional review boards (IRBs) in multi-site clinical research studies. Comments may be submitted the following ways:

1. Email: SingleIRBpolicy@mail.nih.gov
2. Fax: 301-496-9839

National Pediatric Readiness Project...Moving Forward

The next phase of the National Pediatric Readiness Project (Peds Ready) is well underway. The committed partners of this initiative (EMSC, AAP, ACEP and ENA) with the assistance of additional stakeholders will continue their work and collaborate on next steps to assist hospitals to improve their pediatric readiness and capabilities to provide optimal emergency care to children. In early November 2014, The Checklist of Essential Pediatric Domains and Considerations for Every Hospital’s Disaster Preparedness Policies was published and widely disseminated. The “Checklist” is a tool to help hospital administrators and leadership incorporate essential pediatric considerations into existing hospital disaster policies. It is available in both interactive and non-interactive pdf versions and is based on gaps identified in the Peds Ready data indicating that fewer than 50% of hospital’s that participated in the assessment have disaster plans that incorporate the specific needs of children.

Planning has started with partners for an April 9th, 2015 Peds Ready Stakeholder Meeting, the purpose of which will be to bring partners together to re-engage and help define next steps and how each of the partner organizations can contribute based on gaps identified by the Peds Ready data. For more information about the Peds Ready, visit http://www.PediatricReadiness.org.
PECARN Registry

The PECARN Registry project is designed to progress in a multi-staged approach from 1) developing an emergency care visit registry from electronic health record data for pediatric patients at participating sites; 2) using this registry to collect emergency care performance measures for important pediatric conditions and deriving achievable benchmarks for each of the performance measures, and; 3) providing reports to providers and sites and test the hypothesis that providing performance measure feedback will improve performance and decrease variation among clinicians and sites.

To date the study has established the electronic health record (EHR) registry (stage 1 above). Currently the registry contains data from all visits from the sites from 2012, 2013, and 2014. Currently, data is being transmitted monthly to the DCC from all sites. The study has designed and produced timely data reports to assess data quality and validation of the transmitted data. This registry has been used to directly populate stake-holder endorsed pediatric emergency medicine quality of care performance measures and has derived achievable benchmarks for each of the measures (stage 2 above). An expert panel convened on February 24th, 2014 during which they reviewed the achievable benchmarks of each performance measure derived from data within the registry. The expert panel meeting also reviewed the draft design of site- and clinician-level Quality Performance Measures Report Cards, making important recommendations on the format and structure of the cards.

These recommendations have been taken to finalize the design of the site- and clinician-level report cards. The Registry is being used to derive the Quality Performance Measures from the data and produce site and individual provider report cards. Distribution of monthly report cards (site and provider level) to four of the seven sites in the staggered time series has begun and further roll out in two-month intervals is anticipated.

PECARN Core Data Project

The PECARN Core Data Project (PCDP) is an observational descriptive study to identify basic epidemiological information on all ED visits from each participating hospital in PECARN. These data have been instrumental in hypothesis generation and grant acquisition for PECARN. The PCDP database has complete data for 2002-2013.

PCDP Demographic Reports are available for the 2009-2013 data through SharePoint at https://sp.utahdcc.org. Study personnel may use their Active Directory account login and password to access SharePoint. There are 2 reports currently available:

1. PCDP Demographic Data - Site Totals
2. PCDP Demographic Data - Study Totals

PCDP cubes have also been updated with 2009-2013 data and can be accessed at https://www.utahdcc.org/reportportal. For assistance, sites can contact Melissa Metheney (melissa.metheney@hsc.utah.edu) at the PECARN DCC. Information on using the cubes is available in the eRoom. For PCDP data analysis requests, please complete the PCDP Data Analysis Request Form, found in eRoom.

IAI (Intra-Abdominal Injury)

The last of the manuscripts from the IAI project are being published. The IAI project enrolled 12,044 patients with blunt torso trauma. Eight manuscripts have been either published or accepted for publication. An additional four manuscripts are currently under review at various journals.

Patient Safety

The Patient Safety study group has completed analyses of safety events. Investigators are working on completion of the last of the study manuscripts.
**THAPCA**

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continues to recruit only In-Hospital subjects. In February 2014, the study expanded to the UK, and seven additional sites in England were brought on to the study. The lead UK Principal Investigator is Dr. Barney Scholefield from Birmingham Children’s Hospital. In 2014, the THAPCA sites enrolled 60 In-Hospital subjects and 10 of those subjects came from the UK. To date, the In-Hospital enrollment total is 323. The Out of Hospital trial ended on December 31, 2012 and the paper is under review for publication. Thanks to all THAPCA sites for their hard work and dedication to this project.

**FLUID**

The FLUID study is pleasantly advancing through the tide! This NICHD-funded study will enroll approximately 1,400 children with DKA and 400 non-DKA patients over five years at 13 PECARN centers. Enrollment is close to reaching 1000 DKA patients! Also, half of the expected non-DKA comparison patients (~200) – children with type 1 diabetes who have never had DKA, have been enrolled. All sites are currently enrolling in one/both arms of the study and doing a great job! The “Methods” manuscript was published in *Pediatric Diabetes*, and a list of papers of interest for when enrollment is completed is being generated. Enrollment completion is anticipated for mid-2016. Two abstracts from ancillary study preparation were presented at the May 2014 PAS meeting in Vancouver and are currently being drafted into manuscripts.

**BIOSIGNATURES STUDY**

Investigators and DCC personnel are busy preparing manuscripts and continued microarray analyses are being performed. One abstract, pertaining to a prediction rule for serious bacterial infections, was recently submitted to SAEM. Work on the second paper continues with subsequent GAPS and journal submission expected soon. Study PIs plan to visit the DCC in the Spring for further manuscript writing and planning. The Biosignatures II grant was submitted in October 2014 and will be reviewed in May.

**PROBIOTICS**

The Probiotics Study has completed year 1 enrollment meeting the goal of 80 patients on time. The initial DSMB was held January 26th, 2015 and the study was approved to continue as planned. Enrollment re-opened at all sites February 1st. Follow-up is going very well with a rate of 96% at the initial Daily time point, 98% at Two Weeks, and 96% at 1 Month. Both pharmacy and remote access monitoring is planned to begin in the spring of 2015. Additionally, manuscripts are being developed with 15 Manuscript Analysis Request Forms (MARFs) to date and on-going discussion with the DCC to develop Manuscript Analysis Plans (MAPs) and confirm analysis plans.

**QUALITY OF CARE**

The PECARN Quality of Care study is currently in the data analysis and manuscript preparation phase. This AHRQ-funded R01 recently closed at the end of 2014. This study is evaluating an implicit review quality of care instrument and evaluating the association between a variety of care factors and quality of care. The chart reviews of 620 patients are complete. The first manuscript (evaluating the consistency, reliability and validity of the implicit review instrument) has been reviewed by co-authors. Subsequent analyses and manuscripts will focus on hospital, ED, physician, patient and presentation level factors and their associations with quality of care.

**SEIZURE**

Lorazepam update: Currently, there are no updates to share since the September 2014 PECARN Steering Committee meeting. The primary manuscript has been published and several secondary manuscripts are currently in progress. Labeling determination remains pending from the FDA.

**ASSESS**

As of January 10th, 4,790 patients have completed baseline ASSESS activities. Baseline activities include completing a survey in the Emergency Department regarding alcohol and drug use, teen sexual activity and violence. 10 sites have completed their enrollment and we expect several others to complete enrollment early in 2015; getting us to our goal of 5,000 participants enrolled! Thank you to all the sites for their hard work. In regards to the follow-up procedures, 1 week follow-up has been completed with 195 participants completing the follow-up survey (68% completion rate). 390 participants have completed the 1 year follow up survey to date (72% completion rate). The two year follow-up procedures begin in May 2015.

**MAGIC (Magnesium in Crisis)**

Data analyses and manuscript writing are currently in progress. Two abstracts related to this study were recently presented at the American Society for Hematology conference in Dec. 2015. Investigators continue to be impressed by the tremendous accomplishment of completing the study with such high enrollment numbers! A summary of study results is currently being prepared for dissemination to the study network.

**Public Use Data Sets**

To enhance the public health benefit of completed PECARN studies, public use data sets are available to qualified researchers. PECARN public use data sets are generally made available after study completion in accordance with PECARN policy. Data set creation and distribution will be performed by the data coordinating center. There are currently 15 public use data sets available for request. Interested investigators can obtain more details at [http://www.pecarn.org/studyDatasets/index.html](http://www.pecarn.org/studyDatasets/index.html).
The PRIDENET Node is alive and growing! We are pleased to announce the hire of our newest UPMC RC, Rose Azrak. Rose graduated from the University of Pittsburgh in 2012 with her Bachelors of Science in Nursing. She has worked as a staff nurse in the ED at the Children's Hospital of Pittsburgh of UPMC for the past 2 years. She spends most of her spare time at the dog park with her Australian Shepard puppy named Vailyn.

HASB welcomed their first Emergency Medicine Research Intern (EMRIntern), Taylor, this past October. Taylor Ahlborn a senior at Providence College, double majoring in Biology and English. Taylor enjoys cooking, exercising, and traveling.

Speaking of growing, we would like to extend warm, heartfelt CONGRATULATIONS to Hasbro RC Rosalie Berrios Candelaria on her recent marriage to Juan Carlos Gomez!!

Daniel Ostermayer, MD, became CHaMP’s new Houston Academic Advisor. Dr. Ostermayer is Assistant Professor of Emergency of Medicine at UT Health, University of Texas Medical School at Houston. He trained in Emergency Medicine in Los Angeles at Harbor-UCLA Hospital. Focusing on prehospital airway management, his research at Houston Fire Department investigates the use of supraglottic devices for pediatric respiratory failure.

The PRIME node would like to congratulate Mira Henien on her acceptance to medical school next fall! Mira has made excellent contributions to our FLUID study, both at Boston Children’s Hospital and at CHOP. Thanks Mira and good luck! The PRIME node would also like to congratulate Nate Kuppermann, who was recently named the winner of the third annual EMSCO/PEMSoft Achievement Award by the American College of Emergency Physicians for his contributions to evidence-based medicine in pediatric emergency care.

Shilpa Patel, MD, MPH—will be the ED-STARS Site Principal Investigator at Children’s National. Dr. Patel is an Assistant Professor of Pediatrics in the Division of Pediatric Emergency Medicine at the George Washington University School of Medicine. Dr. Patel received her B.A. in Biophysics from Johns Hopkins University; her M.D. from Penn State University and an MPH in Epidemiology from George Washington University. She completed her pediatric residency, served as pediatric chief resident and completed her PEM fellowship training at Children’s National Medical Center. Raised in Arizona, Shilpa moved to the east coast for college, where she met her husband, Anand. She joined CNMC as a community track resident and stayed on as a chief resident. Before coming back to CNMC as a fellow, she was lucky enough to spend a year in Old San Juan, Puerto Rico. While her husband clerked for a judge, she enjoyed the island as a new mom and amateur photographer -- she took over 15,000 pictures in one year!! Dr. Patel’s primary research interest is in ED surveillance and screening and their influence on the prediction of disease using geospatial and other risk factor data available in the electronic medical record. She hopes that someday in the near future, real time analysis and feedback from data in our EMR will impact provider decisions, resource utilization and allow for timely targeted public health prevention. Shilpa, Anand, and their daughters Ashvini and Nayathi live in Bethesda, MD.

Farewell to Andi Thomas!
It is with bittersweet emotions that the DCC says farewell to Andi Thomas. Andi began working with the DCC as an administrative assistant in March 2011 and moved over to PECARN full-time in late 2013. She has been our “go-to-gal” for so many tasks, especially with her expertise and creativity in Latex (aka, formatting protocols and MOOs), Moodle presentations, and the semi-annual PECARN newsletter. We will greatly miss working with her bubbly personality and her resilient positive attitude, but wish her the best in her future endeavors toward a career in nursing! We wish you the best of luck Andi!!