



Risk Assessment at the Site Level

*by Bobbe Thomas, BA, CCRP and Kate Shreve, MPH,
PECARN Nodal Administrators*

PECARN

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Risk Assessment at the Site Level

Simulation: An Example of Risk Review and Mitigation from the ESETT Trial.

By Bobbe Thomas, BA, CCRP and Kate Shreve, MPH, PECARN Nodal Administrators

In the environment of risk-based assessment (see page 8 of this newsletter on “risk assessment” to learn more about RA), simulation exercises can play an important role in identifying potential vulnerabilities of a research protocol that may place a research trial and its subjects at risk. Engaging the simulation program at a site at all stages of a study from the pre-protocol planning stage to study implementation can be invaluable, particularly for higher risk, low incidence studies (Chan S, Babcock L, et. al.) At Children’s National in Washington, DC, we have engaged the simulation team 3 times to date to conduct exercises to train/refresh study personnel on the ESETT protocol. This began as an exercise to help clinical research staff become familiar with, as well as to fine-tune, study enrollment workflow, (e.g., RC/physician/nursing/pharmacy interactions). More importantly this became an important tool to identify risks related to the study. In other words, simulation has become an important tool not only to eval-

uate research team competencies but also to evaluate the “real-world” feasibility of the protocol itself.

Risk identification

The simulations helped identify and address three general areas of weakness:

1. Study team roles and responsibilities
2. Accessibility of study materials/resources
3. The need for good study-related communication that is well-integrated into clinical communication

Risk communication

In response to these findings, the team developed tools to effectively communicate pathways to mitigate the identified risks (see chart below)

Risk review

Simulation also enabled us to re-evaluate risks over time to assess the effectiveness of the mitigation as well as identify additional risks.

Conducting a simulation exercise: How did we do it at Children’s National?

Prior to conducting the simulation exercise, the ESETT study coordinator (Vanessa Grant) developed a draft simulation script based on the ESETT protocol workflow, which detailed the roles of the RC, RN, MD and Neurologist in a theoretical ESETT enrollment scenario. Prior to the SIM exercise, the SIM team lead, Pavan Zavari, MD, PIs Kathleen Brown, MD and James Chamberlain, MD and the ED research team reviewed the enrollment scenario. In each simulation exercise, the team identified areas of vulnerability in the workflow (*Risk Identification*); conducted a de-briefing to review the identified risks; developed a communication plan to mitigate risk (*Risk communication/mitigation*).

Simulation #1: What could possibly go wrong?

- Who’s on first?—We learned that it was critical to clearly identify study roles and responsibilities. It is really important that RCs are clear about their roles and are confident communicating to the treating team (MD, nurse and pharmacy).
- Where are the study materials? The study workflow was significantly interrupted if items were missing from the study binders or not accessible (in the code bay or research office).
- There’s a study patient.... where’s the study team? The study team attends every “code blue” or “medical alert” called and is not likely to miss a patient who invites these alerts. The team also tracks every seizure patient on the electronic whiteboard. However, what if an eligible patient is seen in the ED and identified by a treating MD, how do they contact the study team? In some instances, these cases were missed because the unit clerk/ED nurse did not have im-

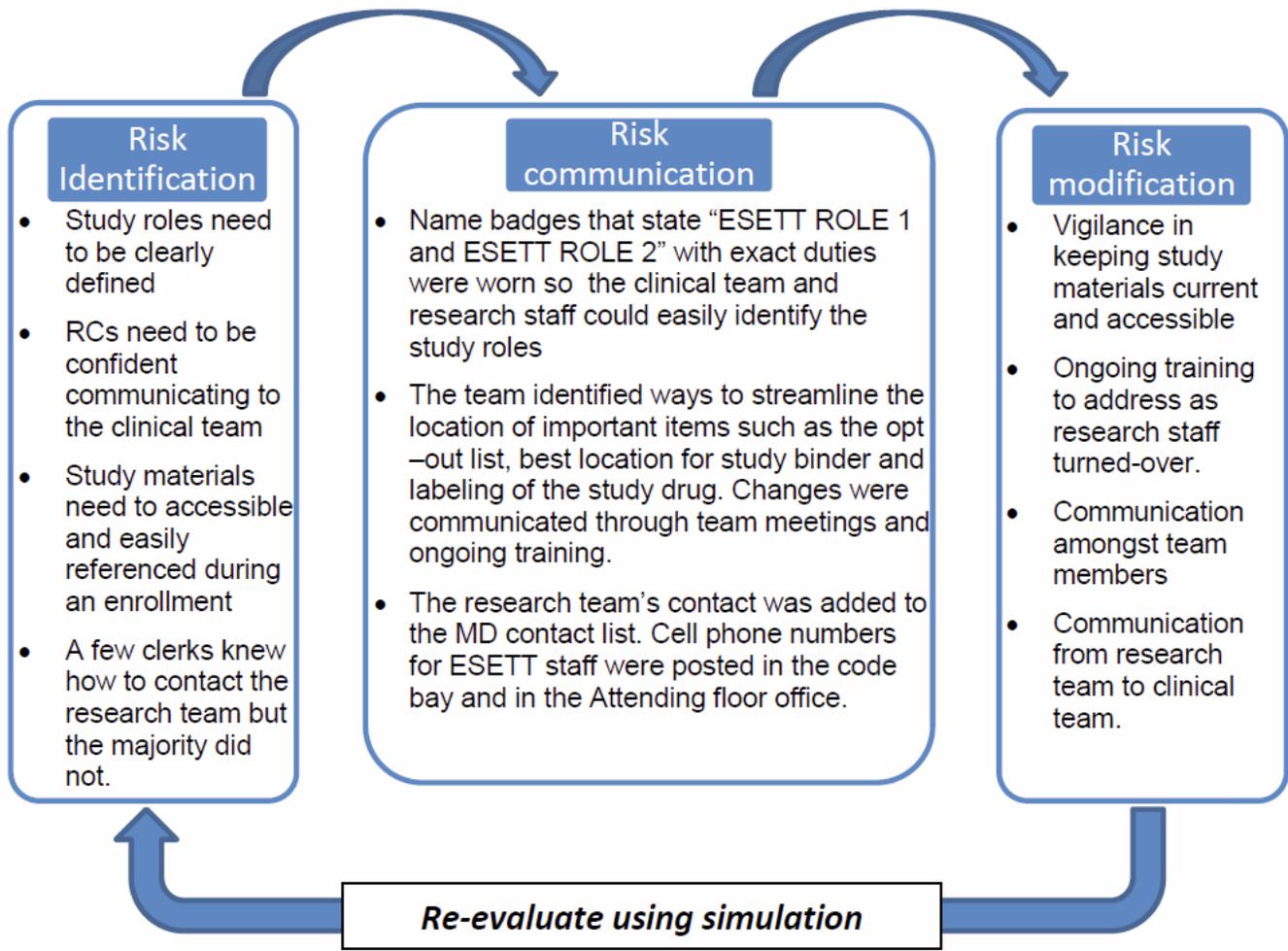


Table 1: Simulation Exercise: Risk ID Communication, Modification

mediate contact information for the research team.

So, what did we learn?

For complicated, high acuity, low incidence events like in the ESETT study, simulation gives us a degree of preparedness that we otherwise would not have. Overall, this iterative approach using simulation was very helpful.

Challenges:

- Difficult to train all ED staff on the protocol using simulation—ED staff are too busy and too numerous. In our case, we projected we would only be able to reach 30% of providers with our current simulation

team.

- Study staff turnover requires a train-the-trainer model, so the new staff are as prepared for the SIM as they can be. A “walk-through” is very different from the SIM but can offer valuable training to understand roles and responsibilities and give research coordinator a primer on how to speak to the clinical staff before the “real-world” SIM
- With a simulation exercise, we are really testing both the research team’s knowledge of the study as well as the “real-world” feasibility of a study and the varying interaction with

the medical treating team. This makes it difficult to truly evaluate the effectiveness of simulation as a training tool because the variables are changing with research team turnover. It may be more useful to evaluate its impact at the protocol development stage.

References

In Situ Simulation to Mitigate Threats to Participation in a Multicenter Clinical Trial in High-Acuity, Low-Frequency Setting. Chan S, Babcock L, Geis G, Frey M, Robinson V, Kerrey B. *Simul Healthc.* 2018 Sep 13. doi: 10.1097/SIH.0000000000000328. [Epub ahead of print]

“ CONDUCTING HIGH PRIORITY, HIGH-QUALITY RESEARCH IN PEDIATRIC EMERGENCY CARE ”

PECARN Study Updates



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 currently has lead site IRB approval and plans to start with phase one (workflow analysis) and IT development in January 2019 followed by the implementation of the pragmatic trial in late 2019.

FLUID

The FLUID study enrolled ~1,800 children with diabetes: ~1400 with DKA and 400 without DKA. The primary objective was to evaluate the effect of different fluid regimens on neurological outcomes in DKA. The main analysis was recently published in the NEJM and demonstrated no significant differences between fast and slower fluid rates on neurological outcomes. This liberates clinicians to use their clinical judgment when hydrating children with DKA, and not be bound by misguided fluid restriction protocols. Several secondary analyses/manuscripts are nearly complete. Perhaps most importantly, we are evaluating the 1400 patients with and 400 patients without DKA to assess the effect of DKA itself on neurological endpoints.

ESSET

ESETT has enrolled 229 children. Enrollment is on hold while we await results of an interim analysis.

Registry

The PECARN Registry project is an emergency care visit registry from electronic health record data for pediatric patients at participating sites. The PECARN Registry currently contains data from all ED visits for calendar years 2012 through 2018. Each site transmits data to the DCC four weeks after completion of the calendar month to allow for maturation of the data. Comprehensive data quality assurance rules have been automated to assess data quality and validation of the transmitted data. The PECARN Registry Expansion project has completed onboarding of three sites additional to the original four. We are in the process of bringing in the next two sites, which would bring the current total to nine.

The PECARN Registry is used to directly populate stakeholder endorsed pediatric emergency medicine quality of care performance measures and has derived achievable benchmarks for each of the measures. Each month we successfully distribute over 475 provider-level and site level report cards.

Arginine

Findings from the original R34-funded Arginine study were incorporated into the phase III clinical trial grant, named the STArT trial, which has been submitted as a UG3/UH3 to the NHLBI, and is scheduled to be reviewed at study section on March 1, 2019. Additionally, the Arginine manuscript on IV fluid use in Sickle Cell Disease (SCD) has been accepted with revisions to Am Journal Hematology. Two additional Arginine manuscripts (Use of intranasal Fentanyl to treat pain in children with SCD and ED adherence to the 2014 NHLBI guidelines targeting analgesic therapy in the management of vaso-occlusive pain episodes in children with SCD) are currently being written in preparation for journal submission.

PED SCREEN

The PED SCREEN project 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.

ASSESS

ASSESS has been busy analyzing and manuscript writing! To date, six publications have been accepted; 2 manuscripts under review; 2 manuscripts invited for resubmission. The team is working on 2 manuscripts currently with plans for 4 more articles in 2019.

APPEND-X

APPEND-X is currently in a no cost extension. The study PIs and DCC have been refining the study protocol, based on reviewer and NIDDK feedback. NIDDK's DSMB will be reviewing the protocol in late January, with a U01 re-submission planned for March 2019. APPEND-X will determine the efficacy, complications, and health and cost utility of non-operative management for acute pediatric appendicitis, and has the potential to dramatically alter the treatment of this common condition.

PRoMPT

Sepsis affects more than one million Americans, including 75,000 children, and an estimated three million people globally each year. Septic shock is the most severe form with cardiovascular and metabolic dysfunction. This study seeks to simultaneously confirm (or refute) the benefits of balanced fluids (Plasmalyte or Lactated Ringer's solutions) over normal saline recently demonstrated in critically ill adults, and to extend (or limit) the generalizability from adults to children. If the hypothesis is confirmed, a paradigm shift in the use of lactated ringers will yield maximal benefits since current practice relies almost exclusively on normal saline in the pediatric ED. Findings from this study have the potential to save hundreds of children's lives every year in the US and thousands more globally. A single center pilot study has been completed at CHOP, with plans to submit the grant for the full PECARN study in June 2019. This trial has also received support from the Trial Innovation Network. In addition, we are discussing research partnerships for this study with the PREDICT (Pediatric Research In Emergency Departments International Collaborative) PEM research network in Australia and New Zealand and the PERC network in Canada.

Probiotics

The main manuscript for the Probiotics study was published in the New England Journal of Medicine in November 2018. Our findings showed that among preschool children with acute gastroenteritis, those who received LGG did not have better outcomes than those who received placebo. These findings along with similar findings from a multicenter study using a different combination probiotic product in Canada published in the same issue of the Journal, underline the importance of conducting high quality studies prior to recommending therapies

SCIENCE

NHLBI guideline-based care for the timely treatment of sickle cell pain crises in EDs is infrequently followed. The SCIENCE study, an implementation science grant to improve timeliness of care, hit the ground running and aims to improve the acute care of children with sickle cell disease through both quality improvement and research. Using Registry data from 7 sites, we identified the sickle cell population of interest and validated the data to assess baseline compliance with opioid administration guidelines. We have central IRB approval for the lead site for the dissemination and implementation aims of the grant; other sites are completing IRB work for their approval.

TBI-KT

Manuscript “Implementation of a Clinical Decision Support System for Children with Minor Blunt Head Trauma Who Are at Non-negligible Risk for Traumatic Brain Injuries” was published in *Annals of Emergency Medicine* in December 2018. The study demonstrated that real-time provision of the risk of clinically important traumatic brain injury through electronic clinical decision support led to a modest and safe decrease in ED CT use for children at non-negligible risk of clinically important traumatic brain injuries.

SPEED

Creation of a Generalizable Anti-microbial Stewardship Program for the Emergency Department using EHR Clinical Decision Support (SPEED) is a study to develop EHR-CDS System for CAP and UTI antibiotic prescribing and a centerpiece for ED-based ASP. We are currently prepping for central data collection from each site and are hoping to have our guideline adherence algorithm ready in summer 2019, and our prototype EHR-CDS ready by next winter so we can start receiving automated provider feedback.

After-ED Fracture Outcomes (IMPROVE)

Enrollment is expected to open in early spring for the new After-ED Fracture Outcomes study. This comparative effectiveness study aims to optimize pain management among children with long bone fractures. We plan to enroll 14,000 children across 6 PECARN sites, with data collection done via text messaging and linking Registry data. This study has the potential to deliver generalizable results that define the most effective acute pain management practice in the ED and at home. Last month sites voted on the acronym IMPROVE for this project (Improving Measured Pain Related Outcome Via Electronic messaging), so look for that in the next newsletter!

C-SPINE

The Development and Testing of a Pediatric CSI Risk Assessment Tool (C-Spine study) is currently enrolling patients at six of the eight Round I PECARN sites. As of Jan 30th, we have enrolled 280 patients for the prospective observational portion of the study. We have gotten positive feedback from EMS providers who have completed the survey, as well as Emergency Department Physicians that have participated. We will be launching the simultaneous qualitative user-centered design portion of study in Spring 2019.

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. The PCDP database has complete data for 2002-2016 and is no longer accruing data. The Public Use Data Set request form can be found at <http://www.pecarn.org/study-Datasets/StudyDetails?-studID=2>.

ED-SAMS

Funding for the ED-Initiated School-based Asthma Medication Supervision (ED-SAMS) study was approved by the NHLBI in late August 2018. The study will supervise medication administration in children with asthma by a school health official, during school hours. Study protocol training was completed on December 6, 2018 in Tucson, AZ. Currently, participating sites are working with their school districts to get approval to conduct the study at their local schools. About 90 subjects will be enrolled, and recruitment is expected to begin in February and continue through March. Recruitment will resume the following school year.

ED-STARS

The final follow up phone calls for ED-STARS are winding down with the last call ending in February 2019 for the PECARN sites, and March 2019 for the Whiteriver site. A number of ED STARS baseline manuscripts are being written and routed through GAPS, most recently “A Computerized Adaptive Screen for Suicidal Youth (CASSY): Derivation in the ED-STARS National Sample.” Three manuscripts have been submitted to peer-reviewed journals, and data analysis is continuing for the remaining three manuscripts. An additional 6-8 manuscripts are planned for 2019. Many thanks to all for their amazing work up until the last enrollment day!

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. To date 2377 infants have been enrolled, with 259 sequential samples! We are making progress enrolling the most important cohorts: bacteremia, bacterial meningitis, and UTIs. We are also continuing to publish manuscripts from Biosignatures I with the febrile infant prediction rule using procalcitonin as a biomarker.

TIC-TOC (TXA)

The Traumatic Injury Clinical Trial Evaluating Tranexamic Acid (TXA) in Children (TIC-TOC) is a pilot and feasibility trial of TXA for severely injured children being conducted at four PECARN sites. TXA has the potential to safely reduce blood transfusions, morbidity, and mortality in injured children. Enrollment is on hold while awaiting IRB approval for the use of Exception from Informed Consent (EFIC). We are currently updating the Manual of Operations and other study tools with guidance for enrollment using EFIC and continuing work on manuscript writing plans.



Good Clinical Practice Tip

“See the data. We often focus on the next milestone (e.g., first patient in, all sites activated, database locked, inspection preparation), and we forget to pay attention to the indicators that might show when a problem is coming. Only collect the metrics that are actionable—move beyond the data specific to recruitment and data cleaning status to the data that are timeline-provoking. Finally, learn to implement your pre-determined action plans when the data starts to stray from the norm.”

- CRISSY MACDONALD, PHD,
EXECUTIVE DIRECTOR, THE AVOCA GROUP



PEDIATRIC EMERGENCY CARE
APPLIED RESEARCH NETWORK

Federal Corner

EMSC releases Targeted Issues Grant Opportunity

The EMSC program has released the Notice of Funding Opportunity (NOFO) for the Targeted Issues grant program. This program will provide funding for investigator-initiated research to demonstrate the link between system readiness improvements within hospital and prehospital emergency medical systems and improved clinical care and better health outcomes among pediatric patients. There will be 4 grants awarded at \$325,000 a year for 4 years. There are two categories of awards:

1. Readiness of Emergency Departments (EDs) to Care for Children. These projects will focus on how adoption of these guidelines within EDs is associated with changes in the quality of pediatric clinical care and improved health outcomes.
2. System Readiness Improvements in EMSC Performance Measures and demonstrate the impact on delivery of optimal clinical care and improved pediatric health outcomes.
 - o Pediatric Emergency Care Coordination in Pre-Hospital Settings (EMSC Performance Measure 02): The presence of a designated individual or combination of individuals responsible for key coordination roles focused on improving pediatric care within a local EMS agency.
 - o Hospital Recognition for Pediatric Medical Emergencies (EMSC Performance Measure 04): Hospitals with an ED that are recognized

through a statewide, territorial, or regional standardized program as able to stabilize and/or manage pediatric medical emergencies

The NOFO is available to download from: <https://mchb.hrsa.gov/fundingopportunities/?id=31632f4a-4257-4e53-b706-8a2b-29f4c2e2>

Agency for Healthcare Research and Quality (AHRQ)

The AHRQ Evidence-based Practice Center (EPC) program is collaborating with NHTSA Office of EMS on an Evidence-based Report “Pharmacological management of Acute pain by EMS in the prehospital setting.” AHRQ will seek public feedback during the draft report review process in the Spring 2019 and will focus on the comparative effectiveness and harms of the initial analgesic agent treatment for achieving reduction in moderate-to-severe acute-onset pain level when administered by EMS personnel in the prehospital setting. It will also look at in patients whose moderate-to-severe acute-onset pain level is not controlled following initial analgesic treatment, what is the comparative effectiveness and harm of switching the analgesic regimen compared to repeating the initial treatment. For more information see: <https://effectivehealthcare.ahrq.gov/topics/acute-pain-ems/protocol>. The final report is expected to be published in summer 2019. It will be used to update the Evidence-based Guideline for prehospital analgesia in trauma, including the addition of clinical guidelines on non-traumatic pain management. The EBG will then be promoted for incorporation into State and local EMS protocols and practice guidelines.



National Quality Trauma Metrics Project

The National Quality Forum (NQF), with support from the Department of Health and Human Services, has assembled a multidisciplinary group of experts to identify population-based benchmarks for trauma outcomes. These experts represented emergency medical services, general and orthopedic surgery, and general and pediatric emergency medicine. This work is ongoing, but in the initial scan of potential measures, over 300 measures and concepts were included.

These measures included timeliness of transport to trauma centers, assessment and treatment of pain, and sharing of data between facilities. In addition, the group identified over 60 potential instruments or scales that can be used to measure patient-centered outcomes for trauma survivors.



National Emergency Medical Services Information System (NEMSIS)

The NEMSIS 2017 Public-Release Research Dataset is now available and includes Version 3 EMS activations submitted by 4,016 EMS agencies serving 35 states and territories. A total of 7,907,829 EMS activations are included. A Data Request Form and 2017 Data User's Manual is available at: <https://nemsis.org/using-ems-data/request-research-data/>. They will soon roll out the NEMSIS V3 Data Explorer, which will include nearly 30 million V3 EMS activations submitted to the National EMS Repository during 2017 and 2018. This tool will provide a web-based, user friendly approach to using National NEMSIS data.



Clinical Pediatric Emergency Medicine (CPEM) EMSC Special Edition

The September, 2018, volume of CPEM (<https://www.sciencedirect.com/journal/clinical-pediatric-emergency-medicine/vol/19/issue/3>) focused on Emergency Medical Services for Children. Edited by Kate Remick and Charles Macias, the volume includes several articles on pediatric readiness, performance measures, quality improvement tools that can be used in hospitals and prehospital settings, and collaborative relationships between EMSC grantees, including PE-CARN, NEDARC, and State partnerships.



Naloxone Evidence Based Guidelines (NHTSA)

NHTSA and HRSA EMSC are supporting the National Association of State EMS Officials (NASEMSO) via a Cooperative Agreement to develop the Naloxone EBG. In addition to the EBG, NASEMSO is creating additional products – 1) An EMS protocol for Naloxone administration in the National EMS Model Clinical Guidelines; 2) Naloxone Performance Measures; and, 3) a basic training course for law enforcement, fire service and EMS. NASEMSO will also publish the EBG and manuscript in Pediatric Emergency Care in Spring 2019.



Upcoming Scientific Grant Writing Workshop

The National EMSC Data Assistance Resource Center (NEDARC) holds an annual scientific grant writing workshop targeting pediatric emergency clinicians/ researchers. The next workshop is scheduled for August 27-29 in Chicago. Information and materials from previous sessions are available at: <http://www.nedarc.org/workshops/materials/grantWriting.html>

NEDARC



New Division Director joins HRSA, MCHB



HRSA

Health Resources & Services Administration

Sara Brett Kinsman, MD, MSCE, PhD

Director of the Division of Child, Adolescent, and Family Health

The EMSC Program welcomes Sara Brett Kinsman, MD, MSCE, PhD, as the new Director of the Division of Child, Adolescent, and Family Health. Dr. Kinsman served as the Director of the Division of Maternal, Child and Family Health (MCFH) in the Philadelphia Department of Public Health. In that role, she helped provide services, promoted education, and supported policies to promote optimal child

development and resiliency.

Prior to joining the Philadelphia Department of Public Health, Dr. Kinsman was an Associate Professor of Clinical Pediatrics at the Children's Hospital of Philadelphia and Director of Inpatient Adolescent Services. In that role, Dr. Kinsman co-authored and co-edited: *Reaching Teens: Strength-based Communication to Build Resilience and Support Healthy Adolescent Development*, which was awarded First Place by the American Medical Writers Association in the Health Care Professionals Category in 2014.

Dr. Kinsman received her medical degree from the University of Pennsylvania School of Medicine, and completed her General Pediatric Residency and Adolescent Medicine Fellowship at the Children's Hospital Of Philadelphia. Dr. Kinsman completed a PhD in Sociology with a focus on adolescence and the family and a Master's Degree in Clinical Epidemiology at the University of Pennsylvania. She has received grant funding from The Robert Wood Johnson Foundation, the Maternal Child Health Bureau, the Centers for Disease Control and Prevention, and NICHD.

Risk Assessments: Every study needs one

by Deveree Partridge, PECARN Project Manager, DCC

A shorter version of this article also appeared in the RCAC Winter Newsletter, Volume 4, Issue 2.

Surely, you have heard the terms “risk assessment”, “risk mitigation”, and “risk-based monitoring” floating around lately. Following the ICH GCP E6 (R2) guidelines, and as PECARN continues to grow with new and exciting trials, the DCC has been incorporating risk assessments for each project.

Risk assessments are done by first identifying risks to the study which could affect patient safety, data integrity, or regulatory compliance. Once identified, the impact to the study and the probability of occurrence for each risk is rated (Low, Medium, or High). The study’s primary outcome is weighted heavily when determining the impact to the study. The detectability of each risk is rated as well (Easy, Medium, or Difficult). For example, detecting that the number of subjects entered into the database is accurate is difficult for the DCC. Detecting the number of surveys completed during follow-up is easy. Using the impact, probability, and detectability ratings each risk is then given an overall risk score.

Conducting the risk assessment allows us to then develop plans and procedures to help mitigate these

risks. Risk mitigation happens in several ways, including but not limited to: study trainings and simulations, queries, monitoring visits, and adjustments to study procedures and workflows.

The DCC will also devise study reports based on data that need to be closely monitored in order to identify critical risks early on. Study reports include such things as enrollment numbers and follow-up rates. For example, number of days pain-free after ED discharge might be the primary outcome in a study. This outcome would have to be collected via follow-up surveys; making a low follow-up rate a risk to the study. Working with the study PI and study statisticians, we would come up with a threshold to determine an acceptable follow-up rate for the study. In this example, a follow-up rate of 85% might be appropriate. Anything below that would be a potential risk to the study’s integrity. Setting this threshold, informing sites of it, and sharing follow-up rates on the study’s monthly conference calls would be the first part of risk mitigation. The second part would be working directly with sites whose follow-up rates dip below that threshold to develop site specific

improvement strategies.

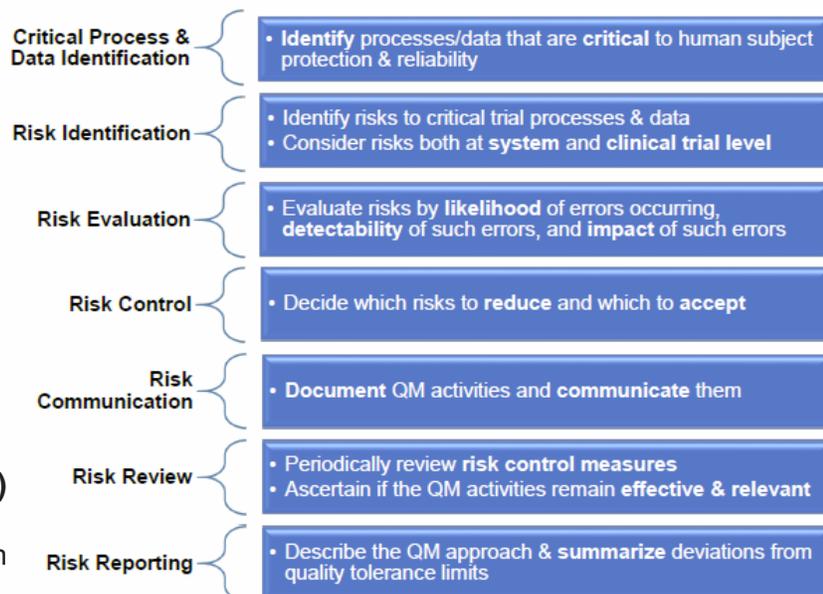
These risk assessments also guide our monitoring plans. Risk-based monitoring means that emphasis is placed on reviewing the study procedures or data with the highest overall risk scores.

What does this all mean at the site level? For starters, much of the work we’re doing related to risk assessments at the DCC has a direct effect on the trainings, study workflows, and the MOO. However, risk assessments should be happening at the site level too! The site-specific study workflow should be assessed for risks. To help sites do this, the DCC includes questions like “What’s the risk? What could go wrong?” on workflow templates. For example, while working through the site-specific workflow, a site might realize that study drug can only be prepared by the research pharmacist. There is risk of delayed or missed study drug administration when only one person is able to prepare it. To mitigate this, the site may work with their research pharmacy to change this policy, to identify additional staff members who can act as backup, or to devise a plan to ensure the research pharmacist is notified with ample time to prepare the drug.



Use the **ICH GCP E6 (R2)** as your guide for risk assessment and mitigation at your site.

Risk-Based Quality Management



DCC Node

The DCC would like to welcome Zach, Hailey and Jesse!

Zach Mitchell is our new PE-CARN Project Manager. He started on November 19, 2018.

Hailey Jensen joined the Biostatistics team on December 19, 2018 and **Jesse Norris** joined the Biostatistics team on January 7, 2019.



WBCARN Node

Gina Nauman and **Sam Eddy** recently joined WBCARN as Clinical Research Coordinators.

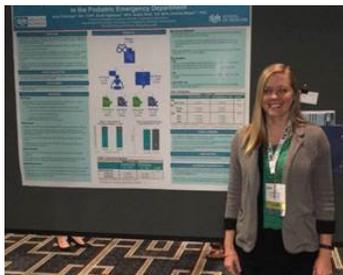
Lena Faisel is a new Clinical RA, who splits her time with CNMC and the Goldberg Clinic.



SW Node

Ginny Stasinski, SW-Nodal Administrator, was chosen as a teammate for the Dana-Farber Marathon Challenge team to run Boston Marathon 2019. While putting in the miles for training, Ginny's goal is to raise \$12,050 for Dana-Farber Cancer Research Institute. This fundraiser is personal for Ginny as she has lived through cancer twice, 12 years ago and 2018. If you would like to give a donation to Ginny's fundraiser you can go to [http://danafarber.jimmyfund.org/goto/Ginny Stasinski](http://danafarber.jimmyfund.org/goto/Ginny_Stasinski)

Also, **Amy Pottenger**, RC at the University of New Mexico, presented a poster at the Society of Clinical Research Associates (SOCRA) Annual Conference in New Orleans, LA in September 2018. This poster was comparing in-person study recruitment with phone recruitment for a pediatric mild traumatic brain injury study that is being conducted at UNM Children's Hospital.



NEW FACES & NODAL NEWS

PRIME Node

On the publication front, ACEP highlighted the DKA Fluid paper by **Nate Kuppermann** and colleagues in N Engl J Med as one of the top papers in 2018. A recent publication led by **Leah Tzimenatos**, "Accuracy of the Urinalysis for Urinary Tract Infections in Febrile Infants 60 Days and Younger" was chosen as one of the practice changing papers of the last 12 months by the editors of Pediatrics. Congratulations to Leah and team!

PRIME welcomes a new member to the PECARN family with the birth of **Benjamin Vong (Rebecca Kim-UC Davis RC)**. Benji was born on October 13 at 4:31pm, weighing 7 lbs., 14 oz., 21 inches long.



PEM-NEWS Node



Stacey Quesada joined PEM-NEWS as our EMS for Children Program Manager on November 15, 2018.

Also, in RCAC news, **Julie Ochs** was chosen to serve as the Quality Control Coordinator.

GLEMSCRN Node

Erin Fisher Kenny, **Dan Cohen**, **Rachel Stanley** et al. have a manuscript accepted to the Clinical Simulation in Nursing Journal for their work "Using High-Fidelity Simulations to Train Emergency Department Staff in Preparation for a Clinical Trial."

Jessica Saunders, **Sally Jo Zuspan**, and **Melissa Metheny** have presented their work titled "Risky Business: Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency in an Emergency Department Setting" to the ACRP Salt Lake City Chapter and will be presenting at the ACRP national conference in April.



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