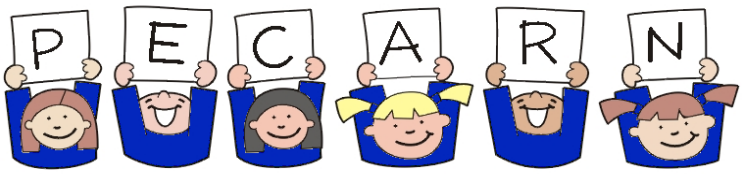
Winter 2009

PECARN NEWSLETTER

What's Inside?



In a nutshell

IRB Variation in Multicenter Research

Alexei Ku, Research Coordinator for CNMC

Institutional review boards (IRBs) are charged with protecting the rights of human subjects in research and must maintain a balance between this imperative and the goals of the research itself – namely, to improve medical care and eliminate useless or harmful treatment strategies.

Clinical research in the past few decades has increasingly taken the form of large, multicenter studies involving several local IRBs. Indeed, the number of citations for multicenter trials increased by 1.6-3 fold for each five-year interval between 1985 and 1999 (McWilliams, et al., 2003).

The proliferation of this format – in which identical study proposals are submitted to several IRBs – has provided an opportunity to investigate the degree to which local IRBs vary in their reviews and decision-making processes.

Recent studies have revealed significant variation in nearly all aspects of local IRB review, a finding that has led a growing body of clinical investigators and regulators to push for re-evaluation of the existing regulatory framework surrounding human protection. It has also prompted an increasing number of investigators to take steps toward more centralized options for multicenter IRB approval.

IRB variation alone is not inappropriate and is in fact predictable. Each board is granted broad latitude to interpret and apply federal regulations, and that each operate in unique local settings. Furthermore, the work of local IRBs is heavily intellectual, and the approach to interpreting regulations requires a high degree of ethical reflection and discretion. This often leads to inter-institutional variation as each member of an IRB provides a unique perspective.

However, when differences between IRB decisions are independent of local considerations and instead highlight variance in the degree of human protection afforded by local IRBs, impose an unnecessary burden on investigators, or indicate deviations from the original intent of federal regulations, they render the system ineffective.

In a survey of three institutions in the same city that received identical protocols for a minimal risk study, Hirshon et al. (2002) noted that one institution approved the protocol in 15 business days, the second approved the protocol with a waiver of written informed consent, and the third approved the protocol only after several months and three revisions.

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Alexei Ku, BS
Clinical Research Coordinator

PECARN
Pediatric Emergency Care Applied Research Network

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

Supported by Grant U03MC00008, Maternal and Child Health Bureau, Health Resources and Services Administration, Department of Health and Human Services

What is Bias?

Larry Cook, PhD

IAI Study Statistician

Bias refers to systematic error in the estimation or statistical testing process that causes results to regularly miss the truth. Bias can arise in any phase of a study, including patient enrollment, study design, data collection, and data cleaning. Study investigators, research coordinators, and the CDMCC can work collaboratively to reduce the chance that we obtain biased results in PECARN. For many studies it is important for us to gather information about missed eligible patients in order to demonstrate that enrolled subjects are an accurate representation of all patients.

Further, when studying an intervention, we randomly assign patients to either the intervention group, or a control group in order to determine that any effect seen is due to the intervention being performed rather than other unmeasured factors. Also crucial in preventing bias is collecting and querying data for patients that are negative for a study outcome. For instance, if we thought that femur fractures were associated with an intra-abdominal injury (IAI) we might decide to review the medical records of the IAI patients to ensure all femur fractures have been recorded.

However, by ensuring that we captured every femur fracture for the IAI group but not making similar efforts for the non-IAI group, femur fractures may actually appear to be a better predictor of IAI than they truly are. For this reason, many PECARN studies require the same data elements to be collected on all patients regardless of their status as a case or control. Similarly, we use the query system to identify inconsistencies in the data for all patients, regardless of final study outcomes. Through careful planning of the study design, patient enrollment, data entry, and data analysis we can reduce the likelihood that our studies will produce biased results. These efforts will help assure that PECARN study results are high quality and make meaningful contributions to pediatric emergency care.

NodalNews

ACORN would like to welcome Andrea Quinn (HEDA RC), Jonathan Gagai (Regulatory Specialist) and Jamie Chalfin (Biosignatures RC) at Cincinnati Children's. Congratulations to Emily and Isaac Kim on the birth of their daughter, Ella.

CDMCC Jennie Wade recently took the Society of Clinical Research Associates (SoCRA) exam. SoCRA established the certification program for clinical research professionals in order to create an internationally accepted standard of knowledge, education, and experience by which clinical research professionals will be recognized by the medical research community. Jennie passed the test with flying colors and she is now a Certified Clinical Research Professional (CCRP).

GLEMSCRN John Hoyle, M.D., HEDA PI, Helen DeVos Children's Hospital, received a promotion to Associate Professor, Michigan State University. Kelsey Hines, Research Coordinator, at Children's Memorial Hospital, Chicago, passed the Association of Clinical Research Professionals Clinical Research Coordinator Certification Exam. Elizabeth Duffy, Research Coordinator, Children's Hospital of Michigan, passed the Society of Clinical Research Associates (SoCRA) Certified Clinical Research Professional (CCRP) exam. CONGRATS to them all!

Mark your calendars

Steering Committee Meeting, *Philadelphia, March 3-4, 2009. Post meeting training March 5th*

Steering Committee Meeting, *Salt Lake City/Park City, Utah September 30 – October 1, 2009.*

NRC Welcomes New Staff Members

The NRC would like to welcome the following staff members:

Jeffery Barbers, Resource Coordinator jbarbers@cnmc.org
Jessica Weber, Research Assistant III jeweber@cnmc.org
Anita Patel, Project Assistant apatel@cnmc.org
Rinal Patel, Project Assistant ripatel@cnmc.org

HRSA Funds Four New EMSC Targeted Issues Grants for 2008

The Health Resources and Services Administration (HRSA) is pleased to announce that four new EMSC Targeted Issue grants were funded in fiscal year 2008. Awards range up to $250,000 per year for up to three years. The newly funded Targeted Issue grants are:

- Connecticut Children's Medical Center; Efficacy of Driving Simulator Training for Novice Teen Drivers; Principal Investigator: Brendan Campbell, MD, MPH;
- Children's Hospital Boston Center for Biopreparedness; REUNITE: A Novel Imaging System for Children Separated during Disaster. Principal Investigator: Michael Shannon, MD;
- Michigan State University Kalamazoo Center for Medical Studies; Michigan Pediatric Errors and Excellence Discovery with Simulation (MI-PE2DS); Principal Investigator: Richard Lammers, MD, FACEP;
- Children's Research Institute of Children's National Medical Center; Family Presence during Pediatric Trauma Team Activation: Measuring the Effects of a Multidisciplinary Approach to Patient-Family-Centered Care; Principal Investigator: Karen O'Connell, MD.

Reauthorization Update

As you may recall, the House of Representatives approved HR 2464, the Wakefield Act, by a vote of 390-1 earlier this year. The Senate has yet to consider S60, the Senate's version of the bill; however, there are currently 13 co-sponsors.

You may recall that in order for a reauthorization bill, such as HR 2464, to become law, both the House and the Senate must vote on, and pass, their respective versions of the bill.

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Funding Update

Fiscal Year (FY) 2008 ended on Tuesday, September 30, and FY 2009 began on Wednesday, October 1. Congress, however, did not enact several of the FY 2009 appropriations bills before the beginning of the new fiscal year, including the FY 2009 Department of Health and Human Services-Labor-Education appropriations bill, which funds the EMSC Program.

Therefore, on Wednesday, September 24, the House of Representatives approved HR 2638, the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, by a vote of 370-58. Under this measure, existing federal agencies, programs, and activities are funded at the FY 2008 level through March 6, 2009 or until the relevant FY 2009 appropriations bill is enacted. The Senate approved this measure by a vote of 78-12 on Saturday, September 27 and the President signed it into law on Tuesday, September 30. Congress has indicated that they will not take up appropriations bills again until the new Administration takes office.

This means that the EMSC Program is receiving stopgap funding at the FY 2008 level of $19.454 million for the next few months. Prior to March 6, Congress will have to pass an FY 2009 appropriations bill that covers the EMSC Program for the remainder of the fiscal year.

Save-the-Date: 2009 Annual EMSC Grantee Meeting

The EMSC National Resource Center is pleased to announce that next year's Annual EMSC Grantee Meeting will be held June 9-12, 2009, in Alexandria, VA. June 9 is scheduled as a targeted pre-conference day. It will be held jointly with the mid-year Meeting of the National Association of State EMS Officials. Additional meeting information and registration instructions will be forthcoming in the next few months.

Abdominal Fat Study

This study, CT Scan with IV Contrast Alone: The Role of Intra-abdominal Fat (IAF), will evaluate whether a patient's appendix is more easily seen on CT if the patient has more IAF and whether the adequacy of IAF can be determined by patient age and weight. Radiologists will review abdominal CTs from the intra-abdominal study to determine the presence of the appendix and adequacy of IAF. The study results will help determine whether certain patients can forego drinking oral contrast prior to CT. Study activities should begin in early 2009.

C-Spine Injury in Children

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,776 controls. Preliminary analysis resulted in four abstracts that were presented at the spring academic meetings: two at PAS and two at SAEM. The comparative analysis to identify pediatric specific risk factors to CSI, the Kappa analysis for the chart review and two secondary analyses are being prepared for the spring academic meetings. Several other abstracts/manuscripts are under consideration by the C-spine collaborators.

EMS Focus Group

This aspect of the study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed at limiting immobilization to those children who are at non-negligible risk for C-spine injury. Focus groups and focused interviews with all echelons of EMS leadership were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, DC and Baltimore. We are now concentrating on completing interviews with experienced researchers. Preliminary analysis and report development are underway.

Febrile Illness & Biosignatures

All sites have completed data entry and query resolution for year one. Remote monitoring and site monitoring visits have been completed at all sites. A training session was held on December 9th in Washington DC prior to the Steering Committee Meeting. Enrollment for year two will begin following the training session.

IAI

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The study will enroll over 10,000 children with blunt torso trauma, including over 800 with IAI. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Patient enrollment began in May 2007. As of November 5, we have enrolled 6,801 patients with a capture rate of 79.1%. This includes 455 patients with IAI. Site monitoring has been performed at all participating sites. In addition, the CDMCC continues to perform remote monitoring and regular queries to ensure top data quality. Patient enrollment is expected to continue through October 2009.

Patient Safety

The manuscript for Patient Safety: Phase 1A, "Pediatric Patient Safety in Emergency Departments: Emergency Department Characteristics and Staff Perceptions", has been accepted for publication in *Pediatrics*. The second phase of the study, which involves transmitting incident reports to the CDMCC, is still in the data collection phase. A new database has been created to effectively classify the ED events into a categorization scheme developed by the study PIs using a consensus process. The investigators intend to submit a proposal to the special NIH review panel in January. This proposal will cover the expenses of submitting and analyzing these incident reports and will convene expert consensus panels to determine how to make incident reporting systems more useful for patient safety.

PECARN Core Data Project

Data from the 2007 PCDP has been added to the cubes. Please plan for 2008 data to be submitted to the CDMCC by April 1, 2009. The data center will be happy to help to streamline the submission process. The PCDP working group has developed the "PECARN Registry" project. The overall goal of this proposal is to demonstrate the ability to utilize data from a registry of electronic health records to evaluate and compare severity-adjusted quality measures of care across different institutions. The full protocol will be voted on in December and we anticipate a submission of the grant in January.

For preliminary analysis of PCDP data, you can either use the CUBES or complete a data request form. The CUBES can be accessed at http://reports.pecarn.org/reportportal

Contact andrew.demarco@hsc.utah.edu *to obtain or reset your cube login and password. The data request form can be found in eRoom at:* https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_a670. *For any questions please contact Libby Alpern at* alpern@email.chop.edu

Performance Measure

The PEM Performance Measure grant progress is on target. Prior to our last PECARN meeting, working groups met to delineate the 25 performance measures each would like to put forth for final consideration for the Quality Report Card. To date, we have 105 performance measures combined from the Effectiveness, Safety, Efficiency & Timeliness and Equity & Patient-Centeredness groups (obviously, each group could not limit themselves to 25!). Of these, approximately 50% represent process measures, with the remaining evenly divided between outcome and structure measures. Nearly 50% of measures are general measures that apply to every ED visit with the remaining addressing a particular condition or cross-cutting conditions (e.g. pain or sedation). Our group will meet again after the PECARN meeting in March.

Prehospital Infrastructure

Thanks to all the hard work of the PECARN investigators and research coordinators who have worked so hard on the EMS study. We have partnered with 21 agencies, seven of whom will likely be unable to contribute data. To date, eight agencies have submitted data totaling 66,000+ unique patient runs! We are working to clean and categorize these data and report back to agencies and sites as necessary. Six additional agencies are close to data submission. We continue to work with sites and agencies to work out existing obstacles to data submission. Additionally, we have begun the qualitative portion of the study (key interviews focusing on barriers and enablers to the study) with the sites and the agencies who have submitted data so far. These interviews are going well and providing much insight into the study.

Psychiatric Working Group

The PECARN manuscript entitled "Referral and Resource Utilization Patterns for Psychiatric Related Visits to Pediatric Emergency Departments" will be published in Pediatric Emergency Care. The working group had a recent conference call to discuss future directions, including a potential proposal from Jackie Grupp-Phelan.

Seizure

The Pediatric Seizure Study continues to enroll patients. As of November 1 we exceeded 35 patients. Our goal is approximately 240. A unique aspect of this study is a provisional analysis at 50% enrollment to adjust the final sample size based on the actual differences between groups rather than on historical data. An interim safety analysis after 24 patients showed no safety concerns from the DSMB. No parents have expressed anger or dismay at being enrolled without consent. Manuscripts from Study 1 (the pK study) are being written and submitted.

THAPCA

The THAPCA Trials Scientific (Moler PI) and Data Coordinating Center (Dean PI) applications were resubmitted to NHLBI for the 11/5/08 cycle. If funded, a total of 30 sites from two research networks (PECARN and CPCCRN) will enroll children who had cardiac arrest in or out of the hospital setting to determine the efficacy of therapeutic hypothermia to improve neurobehavioral outcome.

Traumatic Brain Injury

Patient enrollment ended in September, 2006 after successful enrollment of 34,000 patients for the derivation phase of the study and an additional 9,000 patients for the validation phase. Data cleaning and query resolution continued through 2007, and is now finished (until we start working on more sub-studies!). Eleven abstracts have been presented at the 2007 and 2008 PAS, SAEM, and AAP meetings, as well as the 2007 ACEP meeting. Three more abstracts will likely be submitted to the 2009 PAS/SAEM meetings. The Scalp Hematoma abstract was voted best abstract at the 2008 AAP Section of Emergency Medicine Meeting in Boston. We have approximately 10 more abstracts to prepare and present over the next year or so, making this project a highly visible, and highly productive one for PECARN. One manuscript has been published in *Academic Emergency Medicine* (Inter-rater Reliability), and another is in press at the same journal (Guardian Presence). The main Prediction Rule manuscript has been drafted, is circulating among collaborators, and will be submitted before the December PECARN meeting! Manuscripts are being prepared from the studies already presented as abstracts, and others not yet presented. We anticipate completing several manuscripts over the next year, and submitting 3-4 TBI abstracts per meeting at the important national Emergency Medicine and Pediatric meetings over the next 1-2 years until all a priori sub-studies have been submitted as abstracts (we are more than half-way there!). Next TBI projects: 1) knowledge translation, and 2) therapeutic intervention for serious TBI! We met with our Canadian colleagues of the PERC network in November to discuss these issues.

PECARN
Pediatric Emergency Care Applied Research Network

(cont'd from front cover)

A similar study cited a range of number of days between protocol submission and approval of 12-960 days (Newgard, et al., 2005).

For another example, a survey that looked at IRB processes for the same multicenter study at 68 U.S. intensive care units during 2001-2002 concluded that, based on federal criteria, the study qualified for expedited review. However, 14 of 68 hospitals considered the study exempt from review and 12 of 68 hospitals required full board review (Larson, et al., 2004).

Oftentimes, IRB variability is due to vagueness in federal guidance. For example, federal regulations allow for a waiver from informed consent in studies that present "no more than minimal risk." Such requirements are often applied inconsistently by local IRBs; therefore, gaining IRB approval for multicenter trials involving minimal risk can be particularly onerous.

The Unitarian model

The Institute of Medicine (IOM), the National Bioethics Advisory Commission (NBAC), and the Department of Health and Human Services (HHS), all have noted that duplicative reviews of multicenter protocols on a local level can actually detract from subject protections by diverting time and resources from more effective uses; they have also suggested streamlining review through the use of alternative models. As early as 1998, the deputy inspector general called for the reform of IRBs, citing their inability to deal with the ongoing shift in clinical research from small, single-institution studies to larger multi-institutional studies.

Federal regulations do permit unified IRB review of multicenter studies, with approval from the Office for Human Research Protections (OHRP). Both OHRP and FDA have responded to the increasing number of multicenter trials by clarifying that existing regulations permit institutions to use joint review, rely on another qualified IRB, or make similar arrangements to avoid duplication of effort for cooperative research. Indeed, such unified approaches – which use cooperative, reciprocal, central, and national review boards – have taken on increasing importance in recent years, with each format varying in the degree to which a single IRB is given responsibility for approving multicenter protocols and monitoring ongoing research.

Advocates point out that these formats increase efficiency and review standardization, while opponents believe a "one size fits all" approach is likely to hinder patient protection, as this depends heavily on the sensitivity of local IRBs to the state laws, institutional policies, professional and community standards, and population differences of each study site.

Types of Unified Review

At one end of the spectrum, *cooperative review* allows the chairs of more than one local IRB to coordinate meetings with one another to jointly address single research projects. In this format, each local IRB retains the bulk of its review responsibilities; however, cooperation among IRBs reduces redundancies and variation. In *reciprocal review*, a single IRB of record conducts a full review, and the remaining local IRBs conduct administrative reviews of the approved protocol. This means that while the protocol is approved via full review by a single IRB, each local IRB is given the opportunity to ensure that local issues have been addressed and amend the protocol accordingly. A *central review* also designates a single IRB to review and approve the study protocol, with local IRBs given veto power over the central IRB. In this scheme, however, local IRBs typically are not permitted to modify an approved protocol and sites are sometimes lost to veto.

Slow on the uptake

Many institutions are hesitant to adopt a unified review model. According to an Association of American Medical Colleges (AAMC) survey, those who have not used centralized IRBs did not do so because of concerns about liability, additional costs, absence of local representation, and inability to assess the quality of the services.

Regardless of the advantages offered by centralized review, federal regulations require that research review boards have "sensitivity to such issues as community attitudes," and many institutions emphasize that local review remains an essential component of ethical research.

PECARN IRB experience

PECARN has experienced many of the issues described above in its seven-year history. However, PECARN investigators have been remarkably successful in working with local IRBs. The success of this collaboration is evident by the number of PECARN projects that have been reviewed and approved within reasonable time periods by individual site IRBs.

Good Clinical Practice Tip

A reminder from Marci Fjelstad, MPH, MBA Clinical Research Coordinator

Question: Why are source documents so important?

Answer: Source documents are legally valid raw data hard copies that support a study's findings. CRFs and source documents *must* match, data point to data point. A source document (e.g. a medical record) should support the data on the CRF, which should support the data listings and results of the study. Source documentation is the beginning of a clean, verifiable audit trail.

Role of the CDMCC Coordinators in PECARN Studies

Sally Jo Zuspan RN MSN, CDMCC Program Coordinator

Marci Fjelstad, Kym Call, Heather Gramse
(Jennie Wade not pictured)

You hear from them daily. They want you to do something, send something, or resolve something: the **CDMCC Research Coordinators**. The job of the data center is to support PECARN studies by providing regulatory guidance, statistical support, and study coordination. The CDMCC Research Coordinators have a major role in organizing PECARN studies, and their responsibilities have become more complex over the past few years.

Kym, Heather, Jennie and Marci manage many aspects of each PECARN study including tracking all IRB documents, maintaining eRoom, and helping to assure data quality for PECARN. They are responsible for working with PIs to plan new studies and to use past "lessons learned" to make sure study protocols are clearly written, well organized and meet all regulatory requirements. They organize, write, update and study the Manual of Operations, send study reports, conduct training sessions, and write FAQs. They are the major "communicators" of the study and are a resource for all aspects of study conduct. After enrollment is complete they work with the PI to finalize and clean data, close-out the study and assist with publication.

In addition, CDMCC coordinators now conduct regular remote monitoring. We know that even an error rate of 1% can have an impact on study results. Some data errors cannot be detected by the query system, therefore, the coordinators must verify data remotely. To demonstrate the magnitude of this task, consider that in recent remote monitoring activities, each CDMCC coordinator has reviewed over **6,000** individual data elements, comparing source data to database entries. They also communicate results to sites, and verify that missing or erroneous data are corrected. These efforts, along with the hard work by the site research coordinators, go a long way to making PECARN study results more robust.

Who's Who

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The nursing manager has become an important member of the CARN team. CARN is pleased to highlight:

Jennifer Hinrichs MSN, RN, the Advanced Practice Specialist and Research Nursing Consultant for CARN located at Children's National Medical Center (CNMC). Jennifer also serves as adjunct nursing faculty at Catholic University of America where she is working to develop Peds BKAT exam. She has also developed successful ED and PICU new graduate orientation programs at other institutions. At CNMC, Jennifer is responsible for nursing clinical outcomes, project management, and for implementation of ED policies and procedures. In her prior positions as a Clinical Nurse Specialist in a Pediatric ICU and ED she has implemented and evaluated research protocols for CARN/PECARN. Jennifer is responsible for training and education of nursing and paraprofessional personnel for all aspects of CARN/PECARN studies. She is also responsible for continuing nursing education and soliciting feedback from ED staff regarding research protocols. On the FUN side (not that PECARN is not fun), every Christmas she spends countless hours making homemade candy: caramels, peanut butter cups, fudge, and buckeyes. Jennifer is an avid runner averaging 2 ½ marathons per year and she loves movies that make her cry. She is a Mom to 2 teen-age kids and an adorable 8 lb puppy. When not doing PECARN research, she is busy going to gymnastic meets, football games, baseball games and wrestling meets.

New**Faces**

Annie Walker

The Great Lakes node welcomes Annie Walker, a research assistant for the Emergency Medicine department at Nationwide Children's Hospital in Columbus, Ohio. Annie graduated from Denison University in Ohio with a B.S. in Biology and is originally from Charleston, West Virginia. She enjoys volunteering with children & adolescent advocacy groups and enjoys living in Columbus. We are very excited to have Annie on our PECARN team!

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