PECARN
Pediatric Emergency Care Applied Research Network

PECARN

In a nutshell

Issue 1.3 Spring/Summer 2004

contentsinside

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

contactinfo

615 Arapeen Drive Suite 202
Salt Lake City, Utah 84108
Phone: (801) 587-7613
Fax: (801) 581-8686
www.pecarn.org

TBI Ramp-up Report

Brooke Millar, BS
Study Coordinator

For the first time ever in a PECARN history, the Traumatic Brain Injury (TBI) Study conducted a month long "ramp up period" prior to implementation of the study. The Nodal Administrators and CDMCC conducted site monitoring during the ramp up period to help sites roll out the study in compliance with the protocol. Individualized visits to study sites offer an opportunity to clarify study issues, talk with physicians, and address site specific issues. This effort has been very helpful in getting the study off to a strong start. During this month there was a lot of feedback gained through conference calls, site visits, and emails. Everyone involved learned a great deal about how to ensure that this study runs smoothly.

We learned several important lessons that should be integrated into future PECARN studies. One of the lessons learned is the importance of including RA in the planning and rollout of the studies. The RA have a unique perspective and can be valuable to the investigator and working group with their practical suggestions. Since they are the ones that complete many sections of the CRF, their input is essential. It was also evident during site visits that the Research Assistants (RA) have done a phenomenal job organizing this study and making it work at their respective institutions. The volume and complexity of this study is unprecedented and will require ongoing commitment from RAs.

We learned that there are many factors which affect the RA workload, and this is an important variable in conducting the study appropriately. HEDAs with high volume patients have had a more difficult time keeping up with patient enrollment than sites with lower patient volume. We also discovered that different ED tracking systems affect the workload. For instance, those hospitals with electronic based tracking systems and on-line charting seem to have an easier time flagging patients and searching for "missed eligibles". Nevertheless, hospitals with paper tracking systems have managed to a do great job at devising a searching method. Pre-labeling the CRFs is another factor involved in increasing the workload for the RA. Some sites have found it to be a time consuming process, but others have used it without problem. Pre-labeling all the pages is challenging, but remember that pre-labeling lessens the chances of forms and pages getting lost. Another issue which affects the workload is searching for the missed eligible patients. Ultimately, the TBI team has decided that the RA should look only at the primary diagnosis when searching for potential TBI patients.

Physician and nurse support is crucial to the success of the study. Many sites initially struggled with gaining compliance from doctors, while others have had amazing response and positive feedback about the study.

It also seems that the more the nurses are involved with this study, the easier it is to capture TBI patients.

Continued on page 3.

whoswho

Nathan Kuppermann, MD, MPH
Chairman of the PECARN
Nodal Principal Investigator
nkuppermann@ucdavis.edu

Jim Chamberlain, MD
Vice-Chairman of the PECARN
Nodal Principal Investigator
jchamber@cnmc.org

Ron Maio, DO, MS
Nodal Principal Investigator
ronmaio@umich.edu

Steven Miller, MD
Nodal Principal Investigator
szm1@columbia.edu

J. Michael Dean, MD, MBA
CDMCC Principal Investigator
mike.dean@hsc.utah.edu

Mike Shults, MA
ACORN Nodal Admin.
mbshults@ucdavis.edu

Tasmeen Singh, MPH, NREMT-P
CARN Nodal Admin.
tsingh@cnmc.org

Jennilyn Suhajda, RPh, MS
Great Lakes Nodal Admin.
jkleins@umich.edu

Helena Rincon, MA
PED-NET Nodal Admin.
hr2016@columbia.edu

Sally Jo Zuspan, RN, MSN
CDMCC Project Manager
sally.zuspan@hsc.utah.edu

Rene Enriquez, BS
CDMCC Data Manager
rene.enriquez@hsc.utah.edu

Jeri Burr, RNC, CCRC
Pediatric Pharmacology
jeri.burr@hsc.utah.edu

Richard Holubkov, PhD
Chief Biostatistician
rholubkov@hrc.utah.edu

Clay Mann, PhD, MS
Director of Research
clay.mann@hsc.utah.edu

Fu-Chih Cheng, PhD
Biostatistician
fu-chih.cheng@hsc.utah.edu

Stacey Knight, MStat
Biostatistician
stacey.knight@hsc.utah.edu

Amy Donaldson, MS
Biostatistician
amy.donaldson@hsc.utah.edu

Brian Gadoury, BS
Software Developer
brian.gadoury@hsc.utah.edu

Drew DeMarco
Computer Systems Analyst
andrew.demarco@hsc.utah.edu

Brooke Millar, BS
Head Injury Study Coordinator
brooke.roberts@hsc.utah.edu

Kym Brown, BA
Program Coordinator
kimberlee.brown@hsc.utah.edu

Janna Talbot
Office Assistant
janna.talbot@hsc.utah.edu

upcomingmeetings

The PECARN Steering Committee Meeting is scheduled for Wednesday, June 30 and Thursday, July 1, 2004 in Washington, DC. The meeting will tentatively begin at 9:00 a.m. each morning with a continental breakfast starting at 8:30 a.m. It is recommended that those outside of the Washington metropolitan area arrive on Tuesday, June 29, in the afternoon or evening.

The meeting is scheduled to end each evening around 5:00 - 5:30 p.m. On the evening of Wednesday, June 30th from 7:00 -9:00 p.m. a social dinner meeting will be held.

The PECARN Steering Committee Meeting will be held at the J.W. Marriott Hotel on Pennsylvania Avenue. For more information regarding the logistics for this meeting please refer to the IQ Solutions eRoom. https://www.nedarcssl.org/eRoom/nddp/IQSolutions

J.W. Marriott Hotel
1331 Pennsylvania Avenue, NW
Washington, DC 2004
Phone: (202) 393-2000
Fax: (202) 626-6991

Bronchiolitis Wrap-up

Stacey Townsend, MD
Study Coordinator

As I gathered input from other sites about their end-of-study thoughts, it seems we've compiled as many questions as answers through our study of dexamethasone for bronchiolitis. Here are a few of your observations, the analysis of which may help in boosting next year's enrollment:

•One of the most common reasons for exclusion of potential subjects was a past medical history of wheezing, either bronchiolitis or asthma. This had the added effect of making the eligible population younger on average.

•Some sites noted a higher proportion of Spanish-speaking patients enrolling. This raises a number of questions about the cultural differences in attitudes about medicine and more specifically clinical research. For some interesting reading on the subject, see Dr. Kodish and colleagues' work published in the Jan. 28th 2004 issue of JAMA: http://jama.ama-assn.org/cgi/content/abstract/291/4/470.

•One site noted the most common reasons for refusal to participate were the potential side effects and perceived risk/benefit ratio (this includes a preference stated by several families for using a "known" entity such as Albuterol.) Perhaps we need to focus more on dexamethasone's long track record of safety and effectiveness in other disease processes.

•Some sites found that a lot of kids were receiving steroids from their PCPs prior to coming to the hospital and thus were ineligible.

•Many patients were hesitant to commit to the 4-hour period. Late night travel expenses were a concern. This was especially true of urban centers where patients used public transportation to come to the hospital. Some RA's felt that recruitment could be enhanced by offering a financial incentive to families for completing the telephone follow up. This would overcome some of the travel inconvenience.

•Site PI's have to continuously promote the study with their ED physicians and nursing staff to keep the enthusiasm going.

•There was a lot of variation in RDAI scoring when the kids' conditions did not seem to change that much. Many RA's had doubts about the RDAI inter-rater reliability, whether due to training differences or the interpretation of "wheezing."

There were many other useful observations made, but alas, I cannot fit them all in this article. Thank you so much for your efforts this year. All in all, it was a successful go of things, and I'm confident next year will be even better.

TBI Ramp-up Report Continued

Everything from pizza parties to financial incentives has been used in efforts to gain the doctors' and nurses' assistance. Many of the Nodal Administrators and Nodal Champions presented lectures on this study in efforts to enlist the doctors' support. At several sites the nurses actually assist with the screening during triage and may even slip CRF 1 into the chart for the MD to fill out.

During site visits, it was thrilling to see the pink cards in the doctors' pockets and the posters hung in the EDs. These seem to be a useful reminder and aide to the ED personnel.

We learned that it doesn't hurt to remind physicians of the following: (A lot of this will save RA work and headaches tracking down missing data)

"Dr. Nate Kupperman states:

a. Faculty/Fellows: remember, if the resident is completing the data form, the attending/fellow must participate in the clinical decision-making (section V) and sign the form.

b. We prefer that the attending or fellow (rather than the resident) completes the form.

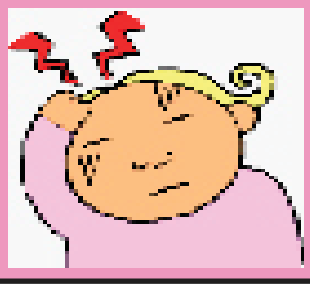
c. Complete Section VII (Course in the ED). In the vast majority of the cases, this just requires one check box for "No" (that you didn't observe the patient in the ED to determine whether or not to obtain a CT).

d. Hand out the study information sheet to every enrolled patient.

e. Complete the face sheet for ineligible patients / trauma patients who don't qualify. This requires just one check box and the patient's name plate.

f. Site PIs: please help the RAs complete the imaging form (form 4) if the patient has a positive CT. They may need some guidance/assistance until they get the hang of interpreting the radiologist's final impressions."

We learned that Nate's promise was accurate. Filling out form 1 really does only take 2 to 3 minutes! Best of all, we found that across the sites there is unanimous support for the need for this study. It is important to come up with a valid decision rule for childhood CTs. Good luck to all sites and keep up the amazing work!



Monitoring Workshop

A clinical research monitoring workshop was held on March 3rd at the Hotel Lombardy in Washington DC. We were honored to have two guest speakers with considerable clinical research experience. The first was Jill Steeley, BS, RTT, an independent clinical research monitor from New York. Jill has extensive experience monitoring all phases of drug development. The second was Jose Rosario, BS, CCRC. Jose is a Clinical Research Associate in the Hematomimetics Program at the Naval Medical Research Center (NMRC). He has extensive experience in emergency exception from informed consent requirements through his participation in research on blood substitutes.

The first presentation, "An Overview of Clinical Research Monitoring," has been posted in eRoom in the CDMCC Public Resources. It covers the who, what, where, when, why, and how of clinical research monitoring. It includes a brief history of human subjects regulations and a list of the International Conference on Harmonization (ICH) guidelines for monitoring.

Jennilyn Suhajda
Great Lakes
Nodal Administrator

The second presentation, "The Informed Consent Process," has also been posted in eRoom. It covers informed consent procedures in detail. The presentation describes the process used in obtaining an emergency exception from informed consent in the Hemopure® [hemoglobin glutamer - 250 (bovine), or HBOC-201] study, jointly conducted by NMRC and Biopure Corporation. This presentation may be of particular interest to those involved in the lorazepam vs. diazepam seizure study, for which PECARN is seeking emergency exception from informed consent.

Many thanks to Tasmeen Singh and the CARN node for their gracious hosting!

Bambi Bademosi, Leslie Fukushima and Mike Shults

Lily Daniali and Tasmeen Singh

George O'Gara, Emily Kim, Carl Brown and Helena Rincon

nodalnews

ACORN

• The Head Trauma grant was funded as of January 1st and data collection has begun. We would like to thank everybody for the great effort and hard work on this study.

• Leslie Fukushima has been promoted to Nodal Coordinator for ACORN.

• We would like to thank Stacey Townsend in Utah for her hard work on the Bronchiolitis Study.

• We welcome Kammy Jacobsen as the new Research Assistant at Primary Children's , Virginia Koors as the new Research Assistant at St. Louis Children's and Katie Webber as the new Research Assistant at Cincinnati Children's Hospital.

• Two of our wonderful Research Assistants will be leaving Acorn to continue their education. Kate Berz (Cincinnati Children's Hospital) will be leaving to attend medical school at Virginia Tech and Katarina Zoltan (Children's Hospital of Wisconsin) will be attending graduate school in Chicago. We wish them both the best of luck in their new endeavors.

CARN

• CARN welcomes Liz Jacobs, MD to the team as the new site PI for Holy Cross Hospital. Dr. Jacobs is already an active participant and nodal champion for the Mental Health Working Group within PECARN. See the "New Faces" section for more details about her.

GREAT LAKES

• The Great Lakes Node would like to welcome Joshua Kay, PhD from the University of Michigan Department of Physical Medicine and Rehabilitation. He joins us as an Associate Investigator with an interest in pediatric rehabilitation after brain injury.

• Dr. Prashant Mahajan's pilot study, "Procalcitonin in the Diagnosis of Serious Bacterial Infection," was approved by the Great Lakes Node and should begin this summer.

• Please join us in congratulating Mary Ann Gregor on receiving her DrPH from the University of Michigan and Jenn Suhajda on receiving her MS in Clinical Research Administration from George Washington University. Kudos to the graduates!

PED-NET

• Upstate Medical University received tentative approval to resume their Pediatric Emergency Medicine Fellowship Program beginning this year. In January 2004, Dr. Callahan welcomed several Syracuse University volunteers into the ED who have been assisting with patient enrollment for Bronchiolitis.

• Two PED-NET Research Assistants are moving on to bigger and better things this year: Christine Forgione (Morristown Memorial Hospital) will be attending Georgetown University Medical School, while Jami Rothman (Bellevue Hospital Center) will be attending graduate school at Harvard University. We'll miss them both!

• New PED-NET RAs include Neysha Fletcher at Harlem Hospital Center, Margaret Boyle at Upstate Medical University, and Haiping Qiao at Children's Hospital of Buffalo. New PED-NET Investigators include Fred Agre, MD at Harlem Hospital Center, Michael Bachman, MD at Newark Beth Israel Hospital and Susan Wojcik at Upstate Medical University. Arthur Cooper, MD, MS is the new site PI at Harlem Hospital Center and Lynn Cimpello, MD is the new site PI at the University of Rochester. Welcome to all!

Leslie Fukushima, Emily Kim, Katie Webber, Kammy Jacobsen, and Kate Berz

Amy Drongowski and Roxanne Piazza

There was a TBI RA training meeting held in New York City on April 23rd. Most of the RA's were in attendance and found the training very helpful to get the Head Injury Study up and running at each of their sites. Peter Dayan presented and Carl Brown coordinated the meeting. They did a wonderful job! We wanted to thank them for all their hard work and dedication.

pecarnupdate

Psych Working Group: The PWG Pilot Project, "Referral Patterns and Resource Utilization for Pediatric Emergency Department Patients Presenting with a Psychiatric or Mental Health Problem: The PECARN Psych/Mental Health Working Group Pilot Study" is underway. Data abstraction and entry is underway at all participating sites, and is slated for completion on April 30th. Derivative projects and grant development is planned for summer-fall 2004. A second project is near completion: a PECARN-wide survey of Psych/Mental Health issues in the ED. The survey will be presented to PECARN subcommittees for approval and prioritization in the coming months. A survey of ED physician perception of Psych/Mental Health training is next in line for development.

Prehospital Working Group: The working group hopes to conduct a survey of PECARN HEDA's to determine their level of interest and participation in EMS research. A proposal was submitted for PCRADS consideration June 2004. Additionally, the previously submitted c-spine proposal is currently being reviewed by the prehospital working group for resubmission to PCRADS. If you would like to be a part of the prehospital working group, please contact Tasmeen Singh at tsingh@cnmc.org.

Disparities Study: The purpose of this study is to measure racial and ethnic disparities in access to medical care (prior to ED arrival as well as in the ED) in patients with a delay sensitive condition such as appendicitis and asthma. A grant application was submitted to the NIH Oct. 1, 2003 with primary assignment to AHRQ and secondary assignment to NICHD. The grant was not funded. The review indicates a positive response to the study if measurement issues can be addressed. A re-application is thus planned.

Head Injury Study: The real deal began June 1st, 2004. After a one month trial period, all Head Injury Study team members were ready to begin collecting "real" data. The trial period is being labeled as "the hardest month of the study." It included trial and error, getting organized, site visits, changing forms, and modifications to IRBs, just to name a few. However, it looks like things are well on their way to settling down. TBI conference calls will begin happening every other week instead of once a week. In addition, RAs will begin having their own conference calls periodically. This excellent communication is what makes our network function so well. Dr. Nate Kupperman continues to thank everyone "for the great support and collaboration."

Bronchiolitis Study: A multi-center randomized trial: This study has taught us a tremendous amount about conducting a multi-center clinical trial. Though enrollment numbers have not been what we had hoped, we are encouraged by the way each site has worked to maximize enrollment. If it should become necessary to continue the study next year, we are confident that things will run more efficiently with some experience under our belts. Each patient enrolled takes us one step closer to answering this important clinical question. Keep up the great work!

Hypothermia Study: Chart abstraction is now underway. Fifteen sites are busy abstracting pediatric cardiac arrest cases occurring July 1, 2003 to December 31, 2004. Site investigators are looking forward to the PECARN meeting in Chicago, the site of their first face-to-face project meeting which will be useful in planning the hypothermia RCT proposal that will likely be submitted in Summer or Fall, 2005.

PECARN Core Data Project: Phase I (electronic data) are complete and cleaned. Phase II (electronic and chart review) are in and are being cleaned. As you may recall, we submitted six abstracts to the Pediatric Academic Societies' meeting and six abstracts for the Society for Academic Emergency Medicine, both in May. All six were accepted for PAS and four were accepted for SAEM. Come join us in San Francisco and Orlando as we present our first PECARN abstracts.

Bioterrorism Surveillance: Historical data has been sent to Children's Hospital of Boston and real time data transfer will begin soon. Additional PECARN sites are getting IRB approval or are in the early planning phases or are in the early planning phases.

Use of Lorazepam for Pediatric Status Epilepticus: A Double-blinded Randomized Diazepam Controlled Clinical Trial: The NIH issued a request for proposals (RFP NICHD-2003-10) under the Better Pharmaceuticals for Children Act (BPCA) for a contract to study the pharmacokinetics and efficacy of lorazepam for the treatment of pediatric status epilepticus. Lorazepam is a commonly used drug for pediatric seizures but is not FDA-approved for children under 18 years of age. The BPCA has a congressionally mandated list of such drugs that require pediatric study. The objective of this contract is to determine the pharmacokinetics and optimal dosing of lorazepam for pediatric use and to conduct a randomized controlled trial of lorazepam with a diazepam control arm for the treatment of status epilepticus. The lorazepam study was the first in a series of RFPs that will be issued by NICHD under the BPCA. Since status epilepticus is an emergency condition and informed consent is not feasible in the 5-min. therapeutic window, this protocol was submitted under an exception from informed consent using the community consent process. Five PECARN sites were originally submitted with a budget of $2.9. The NIH responded in Dec. 2003 informing CNMC that we were in competitive range for the contract and requested the addition of 6 sites. All of the PECARN nodes responded and a total of 11 sites were resubmitted in Dec. 2003 with a total budget of $4.6. Since that time, we have been negotiating with the NIH regarding the exception from informed consent process. The NIH has a unique relationship with the FDA under the BPCA and has been working with CNMC to conduct this study without an exception from informed consent, which is a long and labor intensive process. Negotiations are ongoing and the last conference call with the NIH was on May 14, 2003. Although a final award has not been determined for this contract, the intensity of ongoing negotiations and the official response from the NIH indicate a competitive proposal. If funded, this will be the largest external grant received by PECARN.

eRoom

PECARN Core Data Project: https://www.nedarcssl.org/eRoom/nddp/PECARNCoreDataProje
Hypothermia: https://www.nedarcssl.org/eRoom/nddp/Study-HypothermiaPlanningGrant
Bioterrorism Surveillance: https://www.nedarcssl.org/eRoom/nddp/Biosurveillance
Effectiveness of Oral Dexamethasone in Acute Bronchiolitis: A Multicenter Randomized Contro
Clinical Decision Rules for Identifying Children at Low and High Risk for Traumatic Brain Injuri

newfaces

Roxanne Piazza, RA

I am very enthusiastic as I begin my new adventure in the research end of medicine. I joined Wayne State University under Dr. Prashant Mahajan in the Department of Emergency Medicine at Children's Hospital of MI as his PECARN Research Assistant on January 1st. I've been in nursing for the past 24 years with a very diverse background in the Health Care Industry. I was born and raised in Michigan currently residing in Livonia. I'm blessed with 3 beautiful healthy children, Anthony 20, Ashley 17 ½, & Adam soon to be 16. I enjoy music, dance, theatre, outdoor activities in any season, and most of all my family.

Mohamed Badawy, MD

Mohamed Badawy, MD, a 1991 graduate of the University of Alexandria (Egypt), is a pediatric emergency physician at the University of Rochester. Dr. Badawy has developed a telephone outcome instrument for the assessment of children with mild traumatic brain injury and is currently working on its validation. His research interests include asthma, conscious sedation, crowding and length of stay in the ED.

Lily Daniali, RA

Lily Daniali is a recent addition to the CARN group. She joined us in January, and she is our first off site RA. She is based at Johns Hopkins Hospital and has been a liaison for CARN at Hopkins and University of Maryland Baltimore. Lily graduated from Johns Hopkins University with her bachelor's degree in Public Health Studies in May of 2003. She is very excited to be a part of the PECARN team!

Leslie Fukushima, RA

Leslie Fukushima joined PECARN in January of this year. She is working on the TBI project as a Clinical Research Coordinator at UC Davis. In December of 2003 she received a BS in Physical Anthropology with a minor in Communications. Prior to joining the PECARN team, Leslie worked as a tissue recovery assistant, procuring tissue from cadavers for transplant surgery, and also as a research assistant for a chest pain evaluation project. She loves winter for the snow-if it's on the ground, she's on the mountain. Otherwise, she likes to spend warmer months traveling and enjoying time with her family.

Brooke Millar, BS

Brooke Roberts is a new member to PECARN. She is working at the CDMCC as the Study Coordinator for the Head Injury Project. She graduated from The University of California, Davis in 2002 with a BS in Human Development and a minor in Exercise Biology. Before moving to Utah to join the CDMCC, Brooke worked at the UC Davis Medical Center as a Post Graduate Researcher. Her research interests include the use of informatics tools to improve patient safety, and pediatric emergency care. In her spare time she can be found running, or spending time with her new husband.

Elizabeth Jacobs, MD

Dr. Elizabeth Jacobs has newly joined the CARN network as the site PI for Holy Cross Hospital. Dr. Jacobs is already an active participant and nodal champion for the Mental Health Working Group within PECARN. Dr. Jacobs recently completed her fellowship in pediatric emergency medicine at Children's National Medical Center. She currently is the assistant fellowship director at CNMC and splits her time between CNMC and Holy Cross. Her interests are in psychiatric emergencies and burden of care issues related to patients presenting with mental health complaints.

Good Clinical Practice Tip

Q: What is "protected health information," or "PHI"?

A: Health information is defined as any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual. Health information is individually identifiable, and thus is considered to be PHI if there is any reasonable basis to believe that the information can be used to identify an individual.

Source: Good Clinical Practice: A Question & Answer Reference Guide June 2003, To order copies of this book visit the Barnett International Website www.barnettinternational.com

ct

lled Trial: https://www.nedarcssl.org/eRoom/nddp/BronchiolitisRCTProject

es after Mild Blunt Head Trauma: https://www.nedarcssl.org/eRoom/nddp/HeadTraumaStudy

Nominal Group Process

During the last PECARN Steering Committee meeting in Salt Lake City, UT, we participated in a Nominal Group Process (NGP) as the first step in generating a list of PECARN research priorities. The purpose of the NGP is to provide structure for a group discussion when the group is facing the challenge of reaching agreement on complex topics. NGP is a structured problem-solving or ideas-generating strategy in which individuals'; ideas are gathered and combined in a face-to-face non-threatening group situation. The process is practical for maximizing creative participation in group problem-solving, assures a balanced input from all participants and takes advantage of each person's knowledge and experience. It is useful for generating and clarifying ideas, reaching consensus, prioritizing, and making decisions on proposed alternative actions.

The Emergency Pediatric Research Priorities list, generated from existing research and steering committee members, was modified to contain 53 research priorities. Members were randomly assigned to one of six groups, who then worked through a cyclic step-by-step process of discussion, prioritization, limited discussion, and tallying of the priorities. Day 1 results are presented in Table 1. During Day 2, participants further quantified their determinations using the Hanlon Method of Prioritization. This process considered importance (number of people affected or how many incidences of the problem occur); seriousness (morbidity and mortality, disruption to society, or social importance); and practicality for PECARN (feasibility of intervention of the study, funding potential). Priority scores are presented in Table 2.

The next steps in this process are a conference call with interested participants on March 31st, an appeal to the general PECARN membership to propose any additional Priorities, and making writing assignments for the first draft of an initial process/results manuscript. Please contact Steve Miller at szm1@columbia.edu if you wish to participate.

Table 2. HEALTH PRIORITY SETTING WORKSHEET

Please score each item in the left column from one to ten with one being the lowest and tem being the highest.

A= Size or importance (number of people affected or how many incidences of the problem occur);

B= Seriousness (morbidity and mortality, disruption to society, or social importance.

C= Practicality for PECARN (feasibility of intervention of the study, funding potential); 1=low; 10=high.

Health Priority	A= Size or Importance	B= Seriousness or Social Importance	A+B Score Without C Weighting	A+B Ranking Score	C= Practicality for PECARN Research	D= Priority Score (A+2B)C	E=Final Score
Respiratory Illnesses / Asthma			394	2		5,376	1
Prediction Rules for High Stakes / Low Likelihood Disease			343	12		4,811	2
Medication Error Reduction			391	3		4,698	3
Injury Prevention			414	1		4,682	4
Urgency and Acuity Scaling			358	6		4,419	5
Race, Ethnic, Class Disparities in Health			351	8		4,296	6
Mental Health			347	10		4,272	7
Treatment of Infectious Diseases			349	9		4,263	8
Best Practices in patient care			362	4		4,203	9
Pain & Anxiety Management			352	7		4,138	10
Education / Training Outcomes			345	11		4,021	11
Development of Treatment Algorithms			361	5		3,991	12
Improvement in Health Outcomes for Cardiac Arrest			297	14		3,678	13
Practice Protocols			337	13		3,434	14
Seizure Management			260	16		3,112	15
C-Spine Immobilization			287	15		3,083	16

CDMCC Site Visits

"You want to see HOW MANY records?" "You're coming when?"

Sally Jo Zuspan, RN, MSN
CDMCC Program Manager

The idea of a site monitoring visit can strike fear in the heart of the most experienced researchers. But site monitoring in PECARN should be an educational experience, not a threatening one.

In PECARN there are two types of site visits: Specific study monitoring and more general Central Data Management and Coordinating Center (CDMCC) visits. Study specific site monitoring visits help assure the study protocol is being followed, validate patient safety and protection of human subjects, and to assure data validity. A CDMCC visit is more informal with a focus on getting to know the individual HEDA. Sometimes we combine CDMCC visits and study specific visits simply because it makes logistical sense. Many of you have already had a visit from your Nodal Administrator or CDMCC personnel related to the PCDP or Bronchiolitis study, and some sites have also had a CDMCC visit as well.

If you haven't had a PECARN site visit, get ready! With the rollout of the TBI study, nearly every site should expect a visit from a nodal administrator or CDMCC to help get your site ready for collecting head injury data. What to expect? In general, monitoring should be done as a collaborative effort to help individual sites do the best job possible. At the visit, your NA or CDMCC will most likely:

- Verify all regulatory documents are in place (IRB approvals etc.)
- Review the protocol, case report forms (CRF), and study logs
- Provide the site with a contact if questions arise
- Review the Essential Document Binder
- Discuss study procedures

The CDMCC may also visit your site for a variety of reasons. The CDMCC is the data center for most PECARN studies, and it is important for us to get to know the HEDAs and site personnel. It is helpful for us to know how your site operates, what resources you have, and how we can help you carry out research. The CDMCC can provide educational presentations for your clinical staff on a particular study, help work though problems that have come up at your site, or brainstorm with you on ways to solve problems. While visiting a site, we like to see the emergency department, meet with research staff and discuss any concerns you have. We can help answer your questions about regulatory issues, study specific problems, internal issues, or study ideas. We may also want to see patient files on an ongoing study, or regulatory documents. We will send you a letter prior to any visit letting you know how to prepare. We also welcome your suggestions on what we can do differently when planning or implementing a study. Since PECARN is a relatively new network, we are constantly learning lessons about how to implement studies more effectively and your input is helpful to us in improving the network. We look forward to seeing you at our next visit.

Table 1. Day 1 Results – Priority Ranking

Point Value	Priority
123	Mental health
117	Medication error reduction
110	Prediction rules for high stakes/low likelihood diseases
91	Education/Training outcomes
89	Injury prevention
83	Race, ethnicity, & class disparities in health
76	Asthma/Airway Management (Airway management, Asthma)
73	Pain & anxiety management
73	Seizure management
69	Development of treatment algorithms
67	Treatment of infectious diseases
66	C-Spine immobilization
62	Urgency & acuity scaling, adjust case-mix severity
61	Practice protocols
60	Improvement in health outcomes for cardiac arrest
57	Best practices patient care (efficiency ED flow, overcrowding)
46	Respiratory Illness
46	Cost of care, cost-effectiveness
39	Improve access, foster appropriate use
38	Medical Informatics
33	Adolescents, especially access to care, transition to adulthood
30	Strength quality measurement/improvement
30	Access to care, ED waiting times
29	Acute care
27	Utilization of hospital services, ancillary tests
23	Appendicitis treatment
22	Biosurveillance
22	Pediatric equipment and training in non-pediatric facilities
21	Qualitative research methodologies
19	Link epidemiologic studies to population-based sets
18	ED and 911 utilization
18	Use and linkages of IS to coordinate patient care
16	Special health care needs
14	Abused and neglected children
7	Training and education

CDMCC Query Management Tool

Rene Enriquez, BS
CDMCC Data Manager

CDMCC is in the process of defining and implementing a Query Management tool that will allow us to streamline the "data cleanup" process. We know queries are never fun, however, such activities are an important part of Good Clinical Practice (GCP) and essential to the capture and delivery of quality data for analysis and publication.

Figure 1 is a general model for query generation and resolution. CDMCC will generate data queries automatically by linking the study database to a data validation rules engine. The Query Management process will be handled electronically via a web user interface. After the RA/Monitor logs on to the query system, there will be a message that indicates whether there are outstanding queries. The RA/Monitor clicks on the query link and all outstanding queries are listed. We expect query turnaround time to be minimized and data forms can be locked immediately, allowing for cleaner interim analysis and shortening the time to database lock.

Figure 2 illustrates how the Query Management system may work. There will be four types of queries; 1) System Query – will be generated when there are missing, out of range and/or illogical data elements that require event explanation or justification. 2) Monitor/CDMCC Query – when the monitor or CDMCC queries the site and is waiting for resolution. 3) Pending Approval by Monitor/CDMCC – when the RA has replied to a query and is waiting for the Monitor/CDMCC to respond. 4) Resolved/Approved – when the query has been approved or fully resolved.

CDMCC is committed to using tools that allow for more efficient data and study management. We expect this tool to streamline the data management process by decreasing the time to database lock and statistical analysis.

Table 1

Table 2

PECARN
Pediatric Emergency Care Applied Research Network

Central Data Management Center
Query Management
Query Management Report

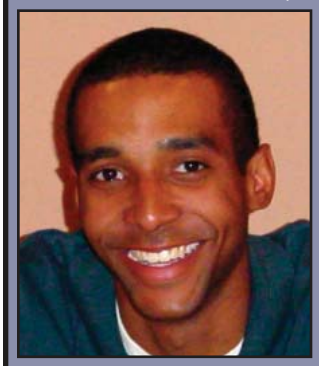
Search
Subject
Query ID
Status
Pending Queries
Search Reset

Study: Head Injury **Site #: 77** **Subject: 1111**

Query ID	Form Name	Field	Discrepency	Entry Date	Query Detail	Status
100	ED Data Blunt TBI	LOC Sa	Missing, report given	6/1/2004	View	System Query
101	ED Data Blunt TBI	Mental Status GCS	Intubated Yes - reported GCS NA	6/1/2004	View	System Query
102	Imaging Data	CT Note	Radiologist final impression unclear, please verify	6/4/2004	View	Monitor/CDMCC Query

spotlights

CARL BROWN, RA (PED-NET)



As Research Coordinator at the Children's Hospital of New York-Presbyterian, I'm busy supervising and training student volunteers on several PECARN and non-PECARN research studies. My ultimate goal is to become a physician, so remember this face because some of you will be seeing it again attached to a medical school application. When I am not working, I coach and play baseball in New York City. I recently traveled to South Africa with a Harlem Little League baseball team to help build interest in baseball in the country.

SHIREEN ATABAKI, MD, MPH (CARN)

Dr. Shireen Atabaki is the site PI for the Traumatic Brain Injury Study at Children's National Medical Center. She completed her general pediatrics training and fellowship in Pediatric Emergency Medicine at Children's National Medical Center. She received her Masters in Public Health at the George Washington University School of Medicine and Health Sciences. She has been the recipient of several grants and awards for research in traumatic brain injury, including the 1998 National Heroes Award for Excellence in Research from the Emergency Medical Serves for Children of the Maternal and Child Health Bureau. She is currently a co-investigator on a grant funded by the CDC for outcome measurement of mild TBI in children and adolescents. She is also co-investigator on a study of neurodevelopmental outcome following TBI prior to age 1. She has developed a clinical pathway for ED management of mild TBI.

JENNILYN SUHAJDA RPh, MS, (GR LAKES)

I am delighted to join PECARN as the new Great Lakes Nodal Administrator. I've been a pharmacist for the past 10 years, most recently at Mott Children's Hospital at the University of Michigan. I became interested in clinical research when a friend, a CRA, asked me to help monitor some of her sites. I was born and raised in and around Boston, spent a couple of years in Atlanta, and landed in Michigan in 1999. My husband Dan, a native Detroiter, is also a pharmacist. I will receive my Master's in Clinical Research Administration this spring.

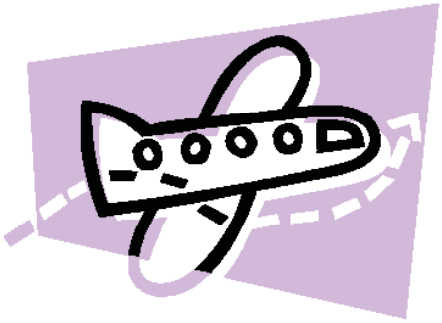
EVALINE A. ALESSANDRINI, M.D., M.S.C.E. (ACORN)

Dr. Alessandrini is an attending physician in the Division of Emergency Medicine at The Children's Hospital of Philadelphia (CHOP) and an Assistant Professor of Pediatrics, Emergency Medicine and Epidemiology at the University of Pennsylvania School of Medicine. She has her Master's degree in Clinical Epidemiology. Dr. Alessandrini is the principal investigator of an EMSC Targeted Issues grant entitled "Creating a Diagnosis Grouping System for Child ED Visits". She will collaborate with PECARN members and use the PCDP to create this grouping system. Other research interests include the effects of health insurance on child ED use and predicting ED reliance in under served pediatric populations.

PCDP Abstracts

Abstract	Objective	Conclusions
1. The PECARN Core Data Project: Epidemiology of a Pediatric Emergency Medicine Research Network.	To identify epidemiological information about pediatric ED patient visits within PECARN.	Data on >745,000 pediatric visits from a large EMSC research network revealed a diverse group of patients; most discharged from the ED and the majority seeking care for infectious causes. Comparison to other data sets is warranted to determine if PECARN is nationally representative.
2. Availability of Pediatric Emergency Visit Data from Existing Data Sources	To determine the availability and completeness of selected data elements from administrative and clinical sources for emergency department (ED) visits in a national pediatric research network.	Data elements important in EMSC are frequently missing in existing ADM and MR sources; completeness varies widely across EDs. Researchers must be aware of these limitations in the use of existing data when planning studies.
3. Practice Pattern Variation in Ancillary Diagnostic Testing for Acute Asthma Exacerbations in Emergency Departments	To compare ancillary diagnostic testing for pediatric patients with acute asthma exacerbation by different provider types and in different emergency departments (EDs).	The rate of ancillary diagnostic testing for children with acute asthma is higher when patients are treated by emergency physicians compared to pediatricians and PEM specialists. Testing rates may be higher for children treated in EDs at general hospitals and in EDs treating small numbers of children. There is no association between ancillary diagnostic testing and hospital teaching status.
4. Factors associated with practice pattern variations in the use of analgesia for long bone fractures.	To compare analgesia and sedation practices between physicians with different training/certification and between Children's hospital and non Children's hospital EDs.	In this study of long bone fractures treated in 25 hospitals, there was improved documentation of pain on records with pediatric-only trained clinicians. Future studies should address whether patients presenting to children's hospitals are more severely ill or whether triage practices at these hospitals promote greater consideration of pain.
5. The PECARN Core Data Project: Benchmarking Hospitals in a Pediatric Emergency Medicine Research Network.	To demonstrate the concept of using clinical research data to support hospital benchmarking efforts in emergency departments.	Benchmark statistics may be useful to assist clinical process improvement in participating hospitals in PECARN, based on data collected as an integral part of the PCDP research project
6. Racial Disparities in Pediatric Emergency Care: A preliminary Analysis.	To identify and describe disparities in management of selected conditions by race among children seen in hospital emergency departments (EDs).	Substantial disparities were detected in various aspects of management of children with asthma, long bone fractures and other traumatic injuries. Future research may identify causes for these disparities and tools to reduce or eliminate them.

CDMCC on the Road...



CDMCC hit the road, or should we say the air, in the past couple months to visit several HEDA. In March, Kym Brown and Sally Jo Zuspan toured Children's National Medical Center (CNMC) in Washington, D.C. and Children's Hospital of Philadelphia (CHOP). We were also fortunate to spend time with Bambi Bademosi from Howard County (CARN). Brooke Millar and Sally Jo visited Children's Hospital of Wisconsin and Cincinnati Children's Medical Center. In May, we visited Morristown, Newark Beth Israel, Upstate, Rochester, CHONY, and Harlem Hospital.

We were extremely impressed with CNMC and CHOP, both of which had high numbers of screened patients for the bronchiolitis study. We were impressed with the organization of CARN, and Kate Shreve who seems to be everywhere all the time teaching, enrolling and assuring extremely high quality at every step. At CHOP, Emily Kim is nothing short of miraculous; she oversees all study activities, supervises students, organizes the study rollout, helps out with Hypothermia, all in one of the highest volume sites in the network.

At the Children's Hospital of Wisconsin, we toured their nice facility and had our first look at their rollout of the TBI study. Katarina Zoltan and her crew are incredibly organized, and best of all used a recycled bread box for their TBI completed forms. Cincinnati was equally impressive as Kate Berz showed us how she had the TBI study organized. Registration clerks assisted in enrolling patients by placing a TBI CRF in patients' charts as they arrive. Combined with the triage nurses also identifying head injuries, Cincinnati has a nice system for capturing TBI patients.

At Newark Beth Israel Hospital, we managed to slow Teresa Hoffman-Bauer down long enough to have her show us her innovative approach to the study. She has won over the ED nurses at her site and has set up an incentive program for identifying head injury patients. Dinner for two goes to the nurse who identifies the most TBI charts; this has motivated the nurses to participate in this study—and they are happy about it. Morristown Hospital is lucky to have Christine Forgione. Her office is located directly in the ED; in fact sometimes patients get parked in front of her door, trapping her in her office. But being in the ED should help find TBI patients. We know she has things under control because during our tour we saw pink cards poking up from every physician's pocket. Morristown and Newark both have the same comprehensive, impressive ED tracking system that is very useful in tracking head injured patients in real time.

At University of Rochester, we found George O'Gara loves his computer and has come up with some great tracking forms to follow TBI patients. He also designed a Hypothermia tracking form that is efficient and amazing. He handles TBI and Hypothermia without breaking a sweat. He even designed the TBI form collection box in ED, placing it under counter so as to not take up desk space.

During a short visit to CHONY, Carl Brown duct taped Sally Jo to the chair while she helped him sort out TBI issues. Once she got loose she was able to see their busy ED and the gorgeous CRF collection boxes with beautiful lettering. Carl's was an awesome site as he shamelessly followed the physicians around "strongly encouraging" them to complete their CRFs.

At Upstate in Syracuse, we had a great tour of the ED and enjoyed meeting with Susan Wojcik. We saw beautiful essential document binders, and noted that their TBI enrollment was already quite high. They have established a very organized approach to capturing TBI patients and are on track with TBI data collection.

At Harlem Hospital, we met Nyesha Fletcher and welcomed her to the network. She is just getting things organized at her site but already had a good grasp on the head injury project.

Overall, we noted the continuing commitment from PECARN investigators and physicians who were willing to spend time and energy enrolling eligible patients. Most important, we saw the tireless efforts of the RAs who supervise, encourage, educate, organize, track, decipher, interpret, nurture, that precarious process called research. They are all a little short on sleep by now; perhaps they can get some sleep this winter when head injury slows down!

Double or Triple Data Entry...or Not!

Clay Mann
Co-Investigator

Estimating the value of double or triple data entry is not a straightforward equation, for several reasons. First, the process of multiple data entry can be implemented in several ways...some good, some not so good.

The most rigorous form of multiple data entry is blinded, independent and third-person "adjudicated". That is, double data entry (for example) is performed by two different persons using the same data entry forms (CRFs) where each person works "independently" and is "blinded" to the work of the other. A third person (the adjudicator) decides which entry is correct (if any) in the case of a discrepancy between the first and second entry.

More commonly, two people enter the same data but the second person identifies discrepancies between the first and second entry. This process is significantly less stringent since the second data entry person is biased to their own entry. Several recent papers question the cost efficiency and necessity of double data entry.[1,2] One should remember that double data entry is concerned solely with digit errors when transcribing information from the CRF into the database. More efficient methods for identifying and correcting these types of errors (and other errors) may include electronic range checks and other validation strings built into the data entry screen.

If double data entry is to be used, focus resources only on variables to be used in the analysis! CRFs often collect too much data, not germane to the primary hypothesis. Also, consider the value of verifying only a sample of records, commonly referred to as a "continuous sampling plan". In short, consistent data handling over time, across subjects and between sites is probably a far better approach to ensuring good quality data. Thus, consistent adherence to detailed SOPs may be the best medicine! Spending scarce resources ensuring "clean" data should not compromise our focus on "important" data.

1 King DW, Lashley R. A quantifiable alternative to double data entry. Controlled Clinical Trials, 2000;21(2):94-102.

2 Day S, Fayers P, Harvey D. Double data entry: what value, what price? Controlled Clinical Trials, 1998;19(1):15-24.