PECARN
Pediatric Emergency Care Applied Research Network

PECARN In a nutshell

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## contactinfo

P.O. Box 581289
Salt Lake City, Utah 84158
Phone: (801) 587-7613
Fax: (801) 581-8686
www.pecarn.org
Editor Kym Call

# Bronchiolitis Closeout Visits

Rita Gerard
Site Monitor

The first randomized controlled trial in PECARN is coming to a close. Completion of this trial represents a huge accomplishment for the network. Our results will help answer important questions about treating bronchiolitis in infants. The network has much to be proud of. However, the events after active data collection can be just as important as data collection itself. After data collection phase is complete, the final step in site monitoring will be a site closeout visit. While this is a new type of monitoring visit, it does not differ greatly from previous monitoring experiences. This article will summarize the importance of a closeout monitoring visit and will help sites know what to expect from the closeout visit.

### Why perform a close out visit?

Closeout visits represent the "last chance" to correct/validate data. All data and regulatory questions must be answered before the data set is closed out or "locked". Once data is locked, data cleaning and analysis can begin. Therefore, the closeout visits should be scheduled as soon as possible after enrollment is complete.

Closeout visits also help to prepare the site for a possible audit. Yes, it is true: a site could be audited even after enrollment has been completed. Even after the study is over, it is possible for an external agency to request an audit. It is also possible that the PI could request a re-evaluation of the data if questions arise. The closeout visit will help each site to complete and organize documents so that they could be easily reviewed at a later date. Organized and accessible documents are vital to the completion of a positive audit.

### Closeout Visit Agenda:

- Informed consent form review
- Study drug reconciliation
- Review regulatory documents
- Review archiving plan

**ICF review:** Each consent form for season 3 will be reviewed and compared to source documents and regulatory documentation. The time of consent will be compared to randomization and drug administration in order to ensure that study procedures occurred after consent. The version of the consent will be compared to the IRB approval dates in your regulatory documents.

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# whoswho


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

**Peter Dayan, MD**
Vice-Chairman of the PECARN
Nodal Principal Investigator
psd6@columbia.edu

**Jim Chamberlain, MD**
Nodal Principal Investigator
jchamber@cnmc.org

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

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

**Emily Kim, MPH**
ACORN Nodal Administrator
egkim@ucdavis.edu

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

**Sherry Goldfarb, MPH**
GLEMSCRN Administrator
Goldfarb@umich.edu

**Valerie Stevenson, BAS, RRT**
GL Nodal Project Manager/Monitor
vwillis@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

**Rita Gerard, CCRP**
PECARN Site Monitor
rita.gerard@hsc.utah.edu

**Jeri Burr, RNC, CCRC**
CPCCRN Program Director
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

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

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

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

**Gabe Herron**
Head Injury Study Coordinator
gabrielle.herron@hsc.utah.edu

**Kym Call, BA**
Bronchiolitis Study Coordinator
C-Spine Study Coordinator
kym.call@hsc.utah.edu

**Cam Torres**
Executive Secretary
cam.torres@hsc.utah.edu


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**Drug reconciliation:** Remaining study drug will be physically reviewed and inventory reconciliation paperwork will be confirmed. If the pharmacy paperwork was kept in the pharmacy during the enrollment phase of the study, this paperwork should be collected and prepared for archiving with the rest of the study documents.

**Regulatory:** Complete regulatory documents for the life of the study will be reviewed. This includes full IRB applications, amendments and correspondence. This also includes a full record of site staff's human subjects protection training, medical licenses, etc. for the life of the study.

**Archiving:** The bronchiolitis protocol source documents, as well as the investigator's copies of the Case Report Forms, must be saved for 3 years after the grant is completed. This is a PECARN requirement and is common in research studies. Please be sure to comply with your institutional requirements also. Sites will be contacted once the grant is considered "complete". Location of all study records must be documented for future accessibility. It is essential that data and information are retrievable and stored in a secure and logical manner.

Each site will be asked to complete an archiving questionnaire which will be posted on eRoom. Some sample questions are listed below. The answers will constitute your archiving plan.

1. Please provide the location where the records will be stored.
2. How long will the records be securely stored in the facility/area?
3. Is the archiving location secure and HIPAA compliant?
4. Please describe the process by which the records are retrieved once they are archived.
5. How are the archiving boxes labeled?

## Timeline

Close out visits will be scheduled after enrollment ceases at a site. The visit timeline will be dependent on the course bronchiolitis takes this season. Close out visits will probably take place April-June 2006.

# TrialDB - Chosen for EDC in PECARN Studies

by Rene Enriquez, Data Manager

## Announcement

Starting this year the Central Data Management Coordinating Center (CDMCC) will use TrialDB to support new studies that will be conducted by the Pediatric Emergency Care Applied Research Network (PECARN). Historically, CDMCC has been developing databases on a study by study basis. This process required modifications to the database and form structures each time a new study was approved. To help simplify the development process, CDMCC chose TrialDB to capture, manage and report clinical research data.

## What is TrialDB?

TrialDB is a web-based electronic data capturing system (EDC) developed at the Yale Center for Medical Informatics, with support from the National Cancer Institute and National Center for Research Resources. It has been used in more than 90 trials, and is being used at Yale University, University of Alabama, Johns Hopkins and research sites around the world.

The combination of an Entity-Attribute-Value (EAV) design and a common library of data elements significantly streamlines the development process, allows for cleaner data, and adds velocity and capacity to our data management steps.

## TrialDB Key Features

- *Automatic Creation of Data Entry Forms
- *Reports to Monitor the Data Collection Process
- *Notification Messaging System
- *Scheduling and Patient Data Monitoring
- *Form-Specific and Web-Enabled Help
- *Exporting Data for Statistical Analysis and Reports
- *Data Element Library

For a complete list of features visit:
http://ycmi.med.yale.edu/trialdb/

### Automatic Creation of Data Entry Forms

The data entry forms (the electronic version of the case report forms) used to collect data for each patient are created automatically based on information in the data library. As a result, these forms can be readily modified and/or reused in different studies.

### Reports to Monitor the Data Collection Process

TrialDB can generate a number of reports to help monitor and manage the data collection process. These reports include listing, for each patient in a study, the forms for which data have been entered, and the status of each form, e.g., "complete," "incomplete," "not available," etc.

### Form-Specific and Web-Enabled Help

Mechanism to provide Web viewing of form-specific help from an HTML page created by the study designer for clarification on data entry issues (such as scoring, definition of terms etc.).

### Exporting Data for Statistical Analysis and Reports

For statistical analysis, Trial/DB "exports" its data in a format that can be input directly to statistical packages such as SAS or SPSS. This process creates the desired statistical data dictionary and makes it available to users through the Web browser. The data can also be exported to Excel or database applications such Microsoft Access or Oracle, for other types of analysis and reporting.

### Scheduling and Patient Data Monitoring

Trial/DB's "patient calendar" feature assists scheduling and workload planning in prospective studies. The calendar, in addition to creating a "to-do" list for study coordinators, also generates electronic form letters, complete with customizable institution or study-specific logos, or E-mails to patients if desired.

## What is Next?

There is much more work to be done, and a lot of it is aimed at making the system easier to use. In the next few weeks, CDMCC will be moving TrialDB from a test environment to a production server and conducting TrialDB training sessions.

This is an incredible milestone for the CDMCC. The use of a common database architecture to support a national research infrastructure is an exciting endeavor. CDMCC is counting on all PECARN members to help make this transition a success.

# upcomingmeetings

The PECARN Steering Committee Meeting is scheduled for Wednesday, February 1st through Thursday, February 2nd, 2006 in San Diego, CA. The PECARN meeting will begin at 7:00 AM on Wednesday and will adjourn at 6:30 PM. On Thursday the meeting will be from 7:15 AM to 5:30 PM. It is recommended that those outside of the San Diego area arrive on Tuesday, January 31st, in the afternoon or evening.

The PECARN Steering Committee Meeting will be held at the Holiday Inn on the Bay.

Holiday Inn on the Bay
1355 N. Harbour Drive
San Diego, CA 92101
Phone: (619) 232-3861
Fax: (619) 232-4924

The Summer PECARN Steering Committee Meeting is scheduled for June 22nd through the 23rd. The meeting will be held at Hotel Washington, Washington, DC.

## 10 Tips for Successfully Applying to Medical School: How your PECARN experience can help

Corey Atwell, Research Assistant

*As winter turns to spring, some of you will be preparing for that dreaded day in the middle of April; it's not tax day. Taking and performing well on the MCAT is part of a successful application to medical school. What you might not realize is that your experience as a PECARN RA can be a valuable addition to your application. Here are 10 things I wish I had known before I applied to medical school.*

*1. DO EVERYTHING EARLY!!!! From your letters of recommendation and preparing for the MCATs to writing your personal statement and submitting your secondary applications. The earlier you get each step of the application process done, the better your chances are. AMCAS opens June 15th – try to have your application ready by the 4th of July.*

*2. Getting meaningful letters of recommendation is really the first part of preparing to apply to medical school. Make sure you are confident in your relationship with the person you ask to write the letter before they do so because you don't want a generic letter even if it's from a bigshot - you want a great one.* ***Quick tip: Request a letter from your supervisor in PECARN. This will show the schools that you have been committed to your interest in research and medicine even when out of school by working in a position that will prepare you for your future career. ***

*3. Taking the MCAT is a stressful event for everyone. Look at your study habits in college and decide which method will help you most. Don't underestimate the amount of time required to prepare for this test. stress load while studying. I found it most helpful to take every practice test I could get my hands on. This will save you time and confusion on the real MCAT. It will also help you to pinpoint areas where you are struggling.*

*4. After the MCAT take a couple weeks to relax, then start working on your personal statement. Use this statement as a chance to tell the committee something about yourself, with an emphasis on your interest in or how you became interested in medicine. Like your letter of recommendation, showing the experience you have gained through PECARN will be an example of your commitment to this field. The hardest part of your AMCAS application is now complete!*

*5. The rest of the AMCAS application is fairly easy. The most time-consuming parts are entering all of your classes and your extracurricular activities. Remember that you can start working on your application online in May.*

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*Set a deadline for yourself of when to submit it and hold yourself to it.*

*6. The earlier you submit your AMCAS application, the earlier you will receive secondary applications! I suggest following the same plan with these as you did your personal statement and AMCAS application. Give yourself 1-2 weeks to complete each application from the time you receive it.* ***Quick tip: Make yourself sit down one night and write the essays because procrastinating can really slow you down here***

*7. The earlier you submit your application, the earlier they can invite you for an interview. Congratulate yourself if a medical school offers you an interview because it's the equivalent of your second interview for PECARN - it basically means they want you! The most important thing I had to keep telling myself was to control my excitement – a recommendation from Bobbe after asking her for advice based on her experience interviewing me for my position with CARN.* ***Quick tip: Try to think of things you have learned while interviewing interns or other RAs or during your own interview for your position at PECARN to help you out in your admissions interview***

*8. Prepare for your interview. Just like you did for your PECARN interview, learn some things about the school so that you know what you are talking about and can ask questions that show your interest. Go through practice questions so that you don't seem awkward when you meet with the Chairman of the surgery department or the Dean of Students. Don't forget to talk about what you learned doing research in PECARN.*

*9. Use your interview to learn everything you can about the school. Get as many different perspectives as you can. Key things I wanted to know: How early did students start interacting with real patients and how prepared did they feel? Did many students participate in study groups? If you already know what kind of doctor you want to be, what opportunities does the school offer for you to gain experience in that specific field before you have to start your residency applications? Many people change their mind, and you want to know BEFORE you spend your internship year doing something that you do not like.*

*10. If you don't get accepted, please don't give up! If you are really dedicated to becoming a doctor, you'll be able to show it through your work and activities - the flipside is, you may realize this is not what you want to do. DO constantly remind yourself that this is your goal, and make it your priority. You've already done a lot: PECARN is a great organization that gives you a solid foundation with experience in clinical research and background medical knowledge. Look at where you can improve, and realize that something will have to change in order for you to have a different result next year. I didn't even get a single interview the first time. But the second time around I paid more attention to the advice people gave me and I became more focused. And I got in – you will too!*





## Bioterrorism Surveillance:

Children's Hospital Boston continues to gather pilot biosurveillance data from Children's National Medical Center and is working with UC Davis and University of Michigan IT groups to set up processes to collect historical batches of data as well as set up daily data feeds. Howard County Hospital is the most recent hospital to join the project. For some, IRB continuing approval applications have already been submitted. Remaining sites are in various stages of working through IRB concerns. The study PI, Ken Mandl, submitted a 5-page pre-proposal to the nodal PIs for review (and either approval, or re-submission to PCRADS) at the end of November. The initial pilot work (3-4 months) of this proposed study can be performed without grant funding but Ken has identified possible sources of funding for the subsequent phases of the project, (6 – 18 months). The proposal itself holds two major objectives: 1. to take a leadership role and help coordinate current health information technology efforts among the American Academy of Pediatrics, the American Board of Pediatrics, the national Association of Children's Hospitals and Related Institutions, the Child Health Corporation of America, and the Centers for Disease Control and Prevention. 2. to build a robust dataset for use by PECARN researchers. Ken has identified two specific aims to address these objectives. 1. to develop a national demonstration project using evolving open architecture and information standards to develop a pediatric research network and 2. to leverage this network for use in biosurveillance, with an initial focus on influenza surveillance, at the national level. The completion of these two major objectives through the work under the two specific aims will accomplish the goal of establishing a Children's node within NHIN.

The Biosurveillance group continues to hold monthly conference calls. In the future, Ken will continue to work on assembling a biosurveillance working group and identifying nodal champions to help move this study through PECARN.

## Bronchiolitis Study:

Sites began screening patients for the third and final season of the bronchiolitis study on November 1, 2005. The University of Maryland and Boston Children's joined the study this season which brings our number of participating sites to 17. We had an early start on enrollment and current numbers exceed the number enrolled last year at this time.

## C-Spine Study:

All sites obtained IRB approval, and almost all sites completed their IT conference calls. In November, eight sites uploaded their case/control files and four sites officially entered the abstraction phase. The electronic data collection system (EDCS) was moved to a web-based platform for real-time data upload.

## Diagnostic Grouping system:

The ACORN DGS study, funded by an EMSC Targeted Issues Grant, convened expert panels at the September, 2004 and the January, 2005 PECARN Steering Committee meetings. Using electronic Delphi surveys and the Nominal Group Technique, the panel has developed a "Diagnosis Grouping System" that combines ED diagnoses in a clinically sensible fashion. Twenty two major groups with 72 subgroups were created using PCDP phase I data. The system was then applied to other data sets (the National Hospital Ambulatory Medical Care Survey and the Wisconsin and Connecticut State ED databases), where it was found to be consistent and comprehensive with regard to distribution and number of ED diagnoses. This work was presented at an Emergency Medicine platform session during the 2005 Annual Pediatric Academic Societies meeting in Washington, DC. The expert panel is currently creating a Severity Classification System, rating ICD-9 codes from the DGS with regard to the intensity of ED resources required.

## Head Injury Project:

There were more than 24,000 patients enrolled in "Childhood Head Trauma: A Neuroimaging Decision Rule" by November 2005. We now plan to enroll 30,000 patients (rather than 25,000) to compensate for the ~4 % of charts that are completed after CT review, data loss due to site study drop-out, and our somewhat lower-than-expected number of patients

eRoom

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

udyupdate

with GCS14-15 and our outcome of interest. Nonetheless, we are on target for reaching our enrollment target in March of 2006. Our overall enrollment capture rate remains ~ 78%, which is very good.

We have received approval and have the resources to continue to enroll patients through September 2006. These added patients will serve as our "validation set" to validate the decision rule we create with the first 30,000 patients. We have circulated a template letter for Site PIs to submit to their IRBs for continuing to enroll patients through September 2006 for purposes of decision rule validation.

During the last quarter, two sites have started participation in this study, and will stay with the study through its completion at the end of 2006. Both Children's Hospital Boston and Children's Memorial Hospital of Chicago are up and running and we welcome their addition.

## Hypothermia Study:

After data cleaning, 489 patients were entered into the hypothermia database. The data cleaning and query process is ongoing as of Nov 2005.

## PECARN Core Data Project:

The ongoing annual collection (2003-2007) of PCDP electronic data is now in progress. The deadline for the submission of 2005 electronic data to the CDMCC is April 1, 2006. The submission for 2003 data from all sites is complete and the data is being cleaned. We are incomplete for 2004 data from 3 sites; however, we working with these sites and are expecting this data soon. The PCDP working group is happy to help in any way to facilitate submission of data. Please direct any questions regarding this process to Libby Alpern at alpern@email.chop.edu.

The PCDP working group has developed a "PECARN Core Data Project - Request for Preliminary Data Analysis" form to help facilitate your request for data to be used for project planning. This form can be found in the eRoom at: https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_a670

The working group is available for assistance with this form or use of the cubes (also found in the eRoom) for your project development. Data from 2003-2004 should be available for the cubes in April 2006.

## Psychiatric Emergencies Pilot Project:

The group has been working on cleaning data and obtaining missing data elements from all five participating sites.

## Prehospital Working Group:

All sites should have submitted the template exemption letter to their IRBs by September 12, 2005. In October, a protocol was made available for those sites that required one (it is posted on eRoom). When you receive your exemption letter, please forward a copy to your Nodal Administrator and the CDMCC. Completed surveys were faxed or emailed to Tasmeen Singh (fax: 202-884-3573, email: tsingh@cnmc.org). The deadline for completion was December 15, 2005.

## Seizure:

We have now enrolled 34 patients in the study and all sites are up and running. The following lists enrolled patients by site: CNMC 10, CHOM 7, CHOP 8, UC Davis 5, Buffalo 3, and U of Michigan 1. The study will be extended into 2006 due to low enrollment in the last few weeks. The end enrollment is approximately 60 patients. Funding for the RCT is contingent on completing enrollment in the current study. We are still working with NIH and FDA on the exception from informed consent for study 2.

## Sepsis:

The Sepsis group is submitting a proposal to PCRADS for the Jan PECARN meeting: The proposal consists of 1. A retrospective chart review which will identify current management of sepsis at selected PECARN sites and will compare these practices with the ACCM-PALS sepsis guidelines, 2. Focus groups of PECARN ED physicians and nurses to ascertain enablers and barriers to the treatment of pediatric sepsis according to the ACCM-PALS sepsis guidelines, and 3. A consensus group of experts who will use the results of 1 and 2 to identify interventions to be used in a future randomized controlled trial. The main goal of the randomized controlled trial will be to improve the management of pediatric sepsis within the network.

taProject
ant

ed Controlled Trial: https://www.nedarcssl.org/eRoom/nddp/BronchiolitisRCTProject
Brain Injuries after Mild Blunt Head Trauma: https://www.nedarcssl.org/eRoom/nddp/HeadTraumaStudy

# newfaces

## E. Brooke Lerner, PhD

E. Brooke Lerner is Assistant Professor and Director of Research for the Department of Emergency Medicine at the University of Rochester. She is also Assistant Professor in the department of Community and Preventive Medicine and directs the Center for Emergency Preparedness and Disaster Medicine at the University of Rochester. An injury epidemiologist by training, she is a nationally recognized researcher in emergency medical services. She has authored dozens of peer-reviewed research papers, and managed several large, federally funded research projects. Her primary research focus is secondary prevention of morbidity and mortality through appropriate utilization and treatment by emergency medical services. She has been conducting emergency medical services research for over 10 years and focuses mainly on the prehospital treatment of major trauma and cardiac arrest. She has co-edited a supplement on performing EMS research and co-directs an annual national pediatric EMS research workshop funded by the EMSC Program. Lastly she serves on the Board of Directors for the National Association of EMS physicians.

## Cam Torres

I moved to Utah 5 years ago from Arizona. My wife and I have 3 wonderful boys that keep us laughing and cleaning all the time. I come from a corporate background and I am glad that Sally Jo has given me this opportunity to do something so meaningful (and have fun while doing it). I am ecstatic to be working with the PECARN project I am also humbled at the opportunity to help in such an important task. I look forward to working with all of you.

## Jennifer Brady, RA

I attended Drew University in Madison, NJ where I received my Bachelors degree in 2005. While at Drew I majored in Biology with a minor in Psychology. I was also a part of the Circle K, Habitat for Humanity and Beta Beta Beta, the biological honor society. I am currently the Research Assistant at Morristown Memorial Hospital working under Dr. Michael Gerardi on the Childhood Head Trauma: A Neuroimaging Decision Rule study. I intend on going to graduate school for a PhD in Biology, with an emphasis in molecular/microbiology, in the fall of 2007. I also enjoy running, watching movies and going to the beach.

## Matthew Krugh

Clinical research is an endeavor I believe in. Though my earliest appreciation for it was genuine, it was also explicit and practical. My eyes have been opened. Within less than a year and a half's worth of professional research experience at CCHMC, including work on several PECARN studies I have realized the true essentiality of clinical research. Not only furthering medicine, thus bettering the physical health of people, through validation and evidence-based care, research demonstrates an intelligent passion and the progressive dedication toward a higher quality existence. Inspired by the innate, sincere compassion for one another, this sustainable idealism is testimony to the faith in our potential to change the outcome. I believe in research, for research is evidence of a collective belief in humankind and its propensity towards good will. Thank you CCHMC, PECARN, the public as study participants, and all involved, who I have learned from and who have helped me to realize this.

## Brook Hanna

I am the new research assistant for the PECARN group at CNMC. My BA in biopsychology was conferred in December 2004. Since then I have taken classes to prepare myself for physical therapy school, where I would like to get my doctorate and focus on pediatric care. I aspire to continue working on physical therapy related research throughout my career and eventually focus solely on the effect of self-efficacy on healing time for various injuries. I am thrilled to be a part of this team and hope to be a key player.

Q. Must an investigator gain IRB approval before implementing EVERY type of research change (except those to eliminate immediate hazards)?

## Good Clinical Practice Tip

A. An investigator must assure that he or she "will not make any changes in research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects."

*21 CFR 312.66*

# nodalnews

## ACORN

● ACORN would like to congratulate Joe Zorc and family on the recent birth of beautiful twin girls. Julia (5lbs 6oz) and Sarah (5lbs 9oz) were born on November 3rd. Everyone is happy and healthy. Congratulations!

## CDMCC

● The CDMCC welcomes Cam Torres as the new Executive Secretary. We are very happy to have Cam with us and look forward to working with him.

## PED-NET

● PEDNET welcomes four new co-investigators/consultants. Ellen Crain, M.D., Ph.D., is a Professor in the Department of Pediatrics and the Director of Pediatric Emergency Services at the Albert Einstein College of Medicine in New York. Dr. Crain is distinguished as a clinical researcher in the management and reduction of morbidity in pediatric asthma. E. Brooke Lerner, PhD, is an Assistant Professor in the Departments of Emergency Medicine and Community and Preventive Health at the University of Rochester and will provide leadership in the conduct of prehospital research. From Columbia University we welcome Dale Hesdorffer, PhD an Assistant Professor of Epidemiology in the Mailman School of Public Health and Emilia Bagiella, PhD, Assistant Professor of Clinical Biostatistics in the Herbert Irving Comprehensive Cancer Center and Psychiatry. Drs. Hesdorffer and Bagiella enhance the research infrastructure of the RNC.

● Congratulations to Margaret Boyle (RA from Upstate Medical University) on her acceptance to the University of San Diego School of Nursing!

# Great Lakes EMSC Research Network Retreat

On December 12, 2005 the GLEMSCRN node held its first nodal retreat at Domino Farms in Ann Arbor, MI. The meeting was attended by 22 members from our node including members of the Scientific and Pre-hospital advisory committees. The goals of the meeting were as follows:

- To facilitate effective and productive collaboration among GLEMSCRN investigators, staff, committees, and consultants
- Provide essential information about PECARN and GLEMSCRN
- Define the missions of the subcommittees
- Identify areas of research in which our node can excel
- Delegate specific tasks and develop deadlines for participants
- Explore ways to foster the development of research proposals by junior nodal investigators

Dr. Ronald Maio reviewed the GLEMSCRN history, his vision for the future of the node the goals, and responsibilities of each committee. Dr. Rachel Stanley's presentations included an overview of the early work within the network, and the rationale, function, and format of the nodal report cards. Break out sessions were built in for each subcommittee during the retreat. This was a great opportunity for the committee members to meet face to face and solidify plans for each committee. Each committee provided a report to the group at the end of the sessions. A meeting for the RAs was held in parallel to the subcommittee meetings. During this meeting we reviewed GCP basics as well as items specific to our node. RAs were also provided time to discuss issues important to them and provide feedback on the node.

Drs. Mahajan and Stanley discussed the study proposals in preparation for submission to PCRADS. Discussions centered on the age groups, use of technology, and study design, and possible utilization of the current treatment protocols. The presentations allowed all the members present to give input to each investigator to make for even stronger proposals.

Arguably, the highlight of the retreat was a genomics and proteomics presentation provided by Dr. John Younger. Dr. Younger is the Director of Research for the UM Emergency Department, and has done extensive research in this area. Dr. Younger discussed strategies for funding projects, costs associated with various laboratory techniques, and ways to collaborate with GLEMSCRN/PECARN. Dr. Younger offered his willingness to support future GLEMSCRN endeavors.

Dr. Maio expressed his pleasure over the success of the meeting. Our goal is to hold a similar meeting in six months at a location to be determined.

# Federal Corner

by *Isabelle Melese-d'Hospital, Ph.D.*
EMSC National Resource Center

**EPSES Update:** The purpose of the Emergency Pediatric Services and Equipment Supplement (EPSES) is to characterize the pediatric preparedness of US hospitals to provide pediatric emergency services and determine if there are explanatory variables associated with preparedness. The EPSES 2002-2003 data report will be submitted to a journal and will be published as an Advance Data Report in February 2006. The CDC/NCHS will repeat the EPSES survey in 2006 and add 25 children's hospitals to the sample.

**New Research Network:** The NICHD/NCMRR reported that the National Collaborative Pediatric Critical Care Research Network has two active studies. One of these is on critical pertussis, through the National Vaccine Program Office at the DHHS/Office of the Secretary. This study will look at clinical critical care course, resource utilization, and child health and development outcomes. Five other studies proposed by Network scientists are in development.

## Past Meetings

### *Interagency Committee on EMSC Research (ICER) Meeting September 9, 2005*

Dr. Brenda Korte, Ph.D. is the program director for the Sensors and Microsystems division at the National Institute for Biomedical Imaging and Bioengineering (NIBIB). She was the featured speaker at the September ICER meeting, discussing NIBIB's mission and research funding priorities. The grantee base primarily consists of physical scientists and engineers. NIBIB also has an emphasis on discovery research and often partners with other agencies such as the NSF to develop funding initiatives. NIBIB's total budget is $298 million and the 2005 payline was 20%. NIBIB supports a wide range of grant mechanisms, including R01's, SBIR's, and Centers. They also have a strong training program. The basic funding mechanism is an R-01, but NIBIB began a new program called New Investigators, targeting researchers who have not received prior significant (i.e., R-01) NIH funding. Many use smaller grants called R-21 for high-risk, exploratory work.

During the ICER meeting, Dr. Theresa San Agustin of NIDRR announced that her agency will implement a model system competition on Spinal Cord Injury (SCI) in 2006, but without a separate focus on children. She suggested that EMSC researchers submit applications for SCI in children and youth. NIDRR will have new selection criteria and proposed funding level is $450,000 per year for 5 years; also a separate SCI collaborative projects competition would be funded at approx. $800,000 per year. In 2007, TBI and Burn Model Systems will be re-competed, $7,000,000 for TBI and $1,500,000 for Burn which include Pediatric Burn Center. Currently, there are 16 TBI and 4 Burn centers. Funding information is available at Department of Education website: http://www.ed.gov/fund/grant/apply/nidrr/index.html

### *AHRQ Priority Populations Seminar: Emergency Medical Services for Children: Responding to Mass-Casualty Events and Ensuring Long-Term Quality and Safety. October 17, 2005*

EMSC Director Dan Kavanaugh and PECARN PI Jim Chamberlain from CARN presented updates on the EMSC program and current PECARN studies. After additional presentations there was discussion on how to further implement research projects in the area of EMSC and some funding issues and ideas, which Dr. Chamberlain brought back to the PECARN leadership.

### *Considerations in Emergency Preparedness: A Two Track Conference December 13 – 15, 2005*

The National Center for Disaster Preparedness (NCDP) hosted a consensus conference in 2003 to develop guidelines for addressing needs of children in disaster planning. This 3 day conference funded by AHRQ and EMSC resulted in two reports, "Pediatric Preparedness for Disasters and Terrorism" and "Advisory Panel Report for Atropine Use in Children after Nerve Gas Exposure." In 2004, NCDP received a grant from AHRQ to lead a consensus process in updating the pediatric guidelines and developing guidelines for emergency planning and response for persons with disabilities. This ongoing revision and development process concluded with the December 2005 "two track" conference held in Washington, D.C.

### *Best Pharmaceuticals for Children Act, Emergency Research in Children: Ethical, Regulatory, and Clinical Challenges Workshop January 12-13, 2006*

This workshop, held in Bethesda, Maryland, was hosted by the National Institute on Child Health and Human Development (NICHD). PECARN was represented at the meeting by Nate Kuppermann, Jim Chamberlain, Dan Kavanaugh, and Tina Turgel. The agenda and related materials will be posted on eRoom when available.

## Upcoming Meeting

### *The 2nd Annual Interagency TBI conference: March 9-11, 2006*

This conference, sponsored by NIDRR, will be at the Bethesda Hyatt. Presentations will include a special section on children. http://www.tbi-interagency.org/pdf/tbi-inter_brochure.pdf

**PECARN Federal Program Officers:**

**HRSA/MCHB/EMSC Program**
Dan Kavanaugh, MSW, LCSW-C
301-443-1321
dkavanaugh@hrsa.gov

Tina Turgel, BSN, RN-C
301-443-5599
cturgel@hrsa.gov

**HRSA/MCHB/Research Program**
Hae Young Park, MPH
301-443-2127
hpark@hrsa.gov

# spotlights

## Doug Nelson

I have served as the ACORN PI for Primary Children's Medical Center in Salt Lake City for about a year. I admit that I am just starting to recognize all the network acronyms. I have the enviable advantage of being near the CDMCC, allowing me to pester them with questions: "Rene, what do these numbers mean?" They don't tell me how much they like this, but I see it in their eyes that they do. Especially Sally Jo.

My day job consists of serving as the Medical Director of our ED, and Associate Chief of our Division of PEM. I also chair the hospital's Pharmacy and Therapeutics Committee, earning me the enviable title of Drug Czar.

I am originally from the East Coast, having trained in Pediatrics at St. Christopher's in Philly and in PEM at Boston Children's. My wife and I have lived happily in Utah for 13 years. Our two children, Rose (11) and Isaac (8) have been skiing since they could walk. Either would be happy to serve as your guide if you find yourself at Alta Ski Resort.

Life out west continues to be a great adventure. We recently purchased some mountain land covered with aspens and wildflowers. We erected a 27-foot diameter yurt with a crack crew of pediatricians and dentists. Surprisingly, no workers were injured in the process. The yurt is where I go to get away from the responsibilities discussed above. Except Sally Jo, no need to get away from her, she never stresses me out, nope, never.

# Scientific Grant Writing Workshop

## for PECARN Faculty and Fellows

### Need Help Writing Your NIH Grant?

When : August 23-25, 2006

Where : Swissotel Chicago

Registration : www.nedarc.org

RegistrationDeadline : July 1, 2006

The National EMSC Data Analysis Resource Center (NEDARC) is inviting PECARN faculty and fellows to its Scientific Grant Writing Workshop this August 23 - 25, 2006, at the Swissôtel Chicago.

This is an excellent opportunity to have dedicated grant writing time and to receive vital feedback that could save you weeks in the writing process!

The workshop will be lead by distinguished NEDARC/PECARN faculty who will instruct and assist you as you write your NIH-funded grant.

Over the course of the workshop, you will draft each section of your grant application on your laptop computer (Specific Aims, Background and Significance, Preliminary Studies, Research Design and Methods) while receiving continual feedback from faculty.

This workshop is for experienced and inexperienced grant writers seeking to improve their skills on research-oriented grant writing.

There is no charge to attend the workshop or for the workshop materials; printers will be available on site. Attendees are responsible for their travel and lodging.

The registration deadline is July 1, 2006. Be sure to sign up soon as space is limited. Go to www.nedarc.org and register for the Scientific Grant Writing workshop. If you have questions, please contact Jennifer Hulse at jennifer.hulse@hsc.utah.edu or at (801) 587-7554. We hope you will join us!

# Benefits of Multiple Coordinators at Site

Marlena Kittick, MPH
Research Assistant

*Over the last 2 years, CHOP has increased the number of Study Coordinators from one to three. This has resulted in the development of a cohesive team unit that works in unison to carry out the multiple PECARN studies being conducted at CHOP.*

*Marlena Kittick is in charge of the Head Injury study, which is time consuming in that there is a high volume of enrollment. In order to keep up with the constant follow-up calls, data entry, and other duties that are required, she needs to spend a lot of her daily time on this particular study. She also spends time weekly screening for Missed Eligibles and sending emails to doctors to remind them that they missed a patient. But what about the Seizure and Bronchiolitis studies? Luckily she has two fellow Study Coordinators to help out!*

*Amber Chew is the Study Coordinator for the Bronchiolitis study. She spends a good portion of her day screening the ED for potential "Bronchiolitics" and paging the Academic Associates (university students in charge of helping enroll patients for various studies in the ED) to make sure they haven't missed a potential patient. She also works hard to make sure there are no protocol deviations on the forms, and makes follow-up calls to parents.*

*Katie Lamond is the Study Coordinator for the Seizure study. She works tirelessly on this study, and is able to handle the meticulous details that are required with ease. She carries her pager with her wherever she goes, and is willing to come in at any hour of the day in the hopes of enrolling a patient. She also finds time to do data abstraction for the Head Injury study.*

*While each Coordinator is the best source of knowledge about their particular study, they work together to help out with the other studies as well. Both Amber and Marlena take the Seizure pager one weekend per month and one night a week to give Katie a break from being on call. All three Coordinators help each other in conducting follow-up calls for the Bronchiolitis and Head Injury study and they all screen for patients in the ED for each of the studies. During vacations and sick days, the Coordinators are there to help each other out on any tasks that need to be done for each of the studies.*

*By having three Coordinators, the stress of having to take care of all the little intricacies that a study brings has been minimized so that each Coordinator can focus on their specific study. Through this collaborative effort, the work environment that they have created has helped to maximize study enrollment, increase team work and promote a happy workplace.*

## PECARN On the Road...

### September:

**TBI Visits:**
Holy Cross
Howard
University of Maryland

### October:

**TBI Visits:**
Bellevue
CHONY
Syracuse
Rochester
Buffalo

### November:

**TBI Visits:**
Boston
Chicago
University of Michigan

### January:

**C-Spine:**
Washington U
University of Maryland

**Bronchiolitis:**
University of Maryland