Why are some willing to participate in research while others refuse? This seemingly simple question led me to initiate a research project that is now in process in the Great Lakes node of PECARN.

One of my first duties as a research coordinator (RC) was to screen patients for the Bronchiolitis Study. Although I received extensive training from our research department, the pediatric ED offered unique challenges. Approaching parents of sick children in a busy emergency setting and asking them to consider enrolling in a research study was challenging. When parents declined participation, I often wondered why they said “No.” Was it something I said? Was it my timing? Did I stink? I could not ask parents such direct inquiries, but I was curious. My curiosity drove me to research the literature on the consent process in emergency medicine, only to find there were no satisfactory answers.

At the same time, it happened that Dr. Hoyle, our site PI, was developing a pilot study that required consent from parents in the ED. I presented Dr. Hoyle with my idea to survey parents on the factors attributing to their research decisions. He was very supportive and we eventually pitched the proposal to our nodal leadership team. Soon we were immersed in the PECARN study proposal process, consulting with scientists, statisticians and project managers.

As an experienced research coordinator I was able to envision how the study would work on the ground; however, this alone was not sufficient to push the study forward. My ideas were critiqued, the study goals were redirected and the protocol was revised. Finally, after a great deal of work, the project was approved and is now underway as a pilot in the Great Lakes node.

This experience awakened me to the complex PECARN review process that is necessary to develop a comprehensive study. Everyone I consulted with was encouraging, and the team effort and mentorship by Dr. Hoyle and others have made this an educational and rewarding experience.

I have learned it is one thing to ask a question and another to go the length to find a satisfactory answer. I never thought my simple question would grow into the monster it is now with a protocol, manual of operations, training session, IRB approvals, etc. In the end I hope to look back and say it was all worth it. So far it has been.
Good Clinical Practice Tip

Submitted by:
Kimberlee Call, BA, CCRP
PECARN Program Coordinator

Question: Must informed consent documents be translated into the written language native to study subjects who do not understand English?

Answer: The signed informed consent document is the written record of the consent interview. Study subjects are given a copy of the consent to be used as a reference document to reinforce their understanding of the study and, if desired, to consult with their physician or family members about the study.

In order to meet the requirements of 21 CFR 50.20, the consent document must be in a language understandable to the subject. When the prospective subject is fluent in English, and the consent interview is conducted in English, the consent document should be in English. However, when the study subject population includes non-English speaking people so that the clinical investigator or the IRB anticipates that the consent interviews are likely to be conducted in a language other than English, the IRB should assure that a translated consent form is prepared and that the translation is accurate.

Upcoming Meetings

- ACEP Advanced Pediatric Emergency Medicine Assembly April 14 - 16; Boston, MA.
- Pediatric Academic Societies Annual Meeting May 2 - 5; Baltimore, MD.
- 2009 SAEM Annual Meeting May 14 - 17; New Orleans, LA.
- NASEMSO Mid-Year Meeting June 8 - 9; Alexandria, VA.
- Annual EMSC Grantee Meeting June 9-12; Alexandria, VA.
- Agency for Healthcare Research and Quality (AHRQ) 5th Annual Practice-based Research Network (PBRN) Research Conference June 24 - 26; Bethesda, MD.

For links please contact Bethany McCunn BMccunn@cnmc.org

Who’s Who

Peter Dayan, MD, MSC
Chairman of the PECARN
PED-NET Nodal Principal Investigator
psd6@columbia.edu

James Chamberlain, MD
CARN Nodal Principal Investigator
jchamber@cnmc.org

Nathan Kuppermann, MD, MPH
ACORN Nodal Principal Investigator
nkuppermann@ucdavis.edu

Rachel Stanley, MD, MHSA
GLEMSCRN Nodal Principal Investigator
stanleyr@med.umich.edu

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

Mikhail Berlyant, BBS
PEDNET Nodal Administrator
mb2521@columbia.edu

Bobbe Thomas, BA, EMT-B
CARN Nodal Administrator
tbthomas@cnmc.org

Emily Kim, MPH
ACORN Nodal Administrator
emily.kim@ucdmc.ucdavis.edu

Kate Shreve, MPH
CARN Nodal Administrator
kshreve@cnmc.org

Rachel McDuffie, MPH
GLEMSCRN Nodal Project Manager / Monitor
rmcduffi@med.umich.edu

Sherry Goldfarb, MPH
GLEMSCRN Nodal Administrator
goldfarb@umich.edu

Sally Jo Zuspan, RN, MSN
CDMCC Program Coordinator
sally.zuspan@hsc.utah.edu
NRC Seeks Nominations for 2009 National Heroes Awards

The EMSC National Resource Center (NRC) is seeking nominations for the 2009 EMSC National Heroes Awards. These awards are presented to individuals who make an outstanding contribution to the EMSC Program. This year’s award categories include: EMSC Project Coordinator/Manager of Distinction, EMSC Provider Leadership, EMSC Family Representative Volunteer of the Year, EMSC Advisory Committee Member, Outstanding EMSC Research Project, State EMSC Policy Leader of Distinction, and EMSC Lifetime Achievement.

Nominations are due Friday, April 3, 2009. Winners will be announced at the 2009 Annual EMSC Program Meeting. Note that one person can make multiple nominations, and that the selection process for each awardee has changed.

The brochure/nomination form is available through the NRC website at:

Pediatric Medication Safety in the Emergency Setting Meeting: A Collaboration

The EMSC National Resource Center along with AAP and Duke University hosted the Pediatric Medication Safety in the Emergency Setting Meeting February 23-24, 2009 at Duke. The meeting convened a multidisciplinary group of ED health care professionals and representatives from the federal government, drug manufacturers, IT, pharmacists, patient advocates, and others to develop solutions to safely deliver pediatric medication with a focus on children in the ED. Dissemination of the meeting results is pending.

EMSC Program Celebrates 25th Anniversary

Happy Birthday, EMSC! In 1984 the EMSC Program was authorized and subsequently awarded the first four demonstration grants. Since then, the program has grown to having grantees in all 50 states, the five territories and District of Columbia. To celebrate, the NRC is planning a 25th Anniversary Bear, community events in Washington, DC and ways for others to celebrate this milestone.

2009 Annual EMSC Grantee Meeting Update

Plans are underway for this year’s Annual EMSC Program Meeting to be held June 9-12, 2009, in Alexandria, VA. June 9 is scheduled as a targeted pre-conference day. It will be held jointly with the mid-year Meeting of the National Association of State EMS Officials. Additional meeting information and registration are on the NRC website at:
www.childrensnational.org/emsc

Appropriations

Fiscal Year 2009: The EMSC Program is currently funded under a continuing resolution, which ends on March 6, at the 2008 Fiscal Year level of $19.454 million. Congress has indicated that they will take up the 2009 Fiscal Year appropriations bill after President’s Day recess.

EMSC Federal Legislation

The Wakefield Act has been reintroduced in both the House and Senate. HR 479 was introduced by Congressman Jim Matheson (D-UT) in January. It currently has nine cosponsors: Representatives Sanford D. Bishop Jr. (D-GA), Lois Capps (D-CA), Kathy Castor (D-FL), Gerald E. Connolly (D-VA), Gene Green (D-TX), Peter King (R-NY), and David Reichert (R-WA), Vic Snyder (D-AR), and C.W. Bill Young (R-FL). Passage of the Wakefield Act would reauthorize the EMSC program for five years, from Fiscal Year 2010 through FY 2014, starting at $25 million and ending at approximately $30.5 million.

PECARN Federal Program Officers

PECARN Federal Program Officers
HRSA/MCHB/EMSC Program:
Dan Kavanaugh, MSW, LCSW-C, (301)443-1321 dkavanaugh@hrsa.gov
Tina Turgel, BSN, RN, BC (301)443-5599 cturgel@hrsa.gov

Technical Assistance Liaison:
EMSC National Resource Center
Bethany McCunn, MPH (202)476-4927 bmccunn@cnmc.org

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

HRSA Grants Management:
Thais Díaz-Macaluso (301)443-0682 Tdiaz-Macaluso@hrsa.gov
**Biosignatures Study**

The year two training session, held in December, was a success and generated valuable comments and feedback from the sites. As a result some revisions were made to the study procedures, the Manual of Operations and the data collection worksheets. In addition, each site participated in an individual site training conference call to ensure understanding of the changes to the study procedures that occurred after the training session. Enrollment for year two began on Monday, January 26, 2009 and after 5 weeks of enrollment more than 70 samples have been collected.

**C-Spine Injury (CSI) in Children**

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,774 controls. Abstracts were submitted for the 2009 PAS and SAEM meeting; Predicting c-spine injury (CSI) in children: a case-control analysis, Age-related differences in risk factors associated with cervical spine injury (CSI) in children and Inter-observer agreement for clinical findings in children at risk of cervical spine injury. All were accepted. Two secondary analyses are being prepared: Utility of plain films in the diagnosis of CSI in children and Spine immobilization among children less than 2. Fifteen other abstracts/manuscripts are under consideration by the C-spine collaborators.

**IAI**

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The study will enroll over 10,000 children with blunt torso trauma, including over 800 with IAI. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Patient enrollment began in May 2007. As of February 4, we have enrolled 7,770 patients with a capture rate of 79.8%. This includes 492 patients with IAI. Second site monitoring visits began in January. In addition, the CDMCC continues to perform remote monitoring and regular queries through TrialDB to ensure top data quality. Patient enrollment is expected to continue through the end of September 2009. Please remember to remind your site physicians to enroll all eligible patients as we head into the busy spring and summer seasons.

**IAF Study**

The Intra-abdominal Fat and Appendix Visualization study is currently in study development. We are working on finalizing the protocol for distribution for IRB approval. We are also working on reconnecting with interested radiologists to ensure their continued interest in the study. We hope to have the protocol ready for site distribution by the mid March. Training and enrollment will begin in spring/early summer.

**EMS Focus Group**

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

**Patient Safety**

The investigators are proposing to conduct the HEDA Investigator survey of ED characteristics and the climate of safety survey on an annual basis. These surveys are currently being updated and revised. The second phase of the study is continuing to collect incident reports from 18 PECARN sites. Reviewers are analyzing and categorizing this incident reporting data into a database for further analysis. A grant proposal has been submitted to New York State Department of Health to implement pilot testing of the new protocol being reviewed. This grant proposal would incorporate the incident reporting data and medical chart abstraction of medication errors to develop and improve ongoing surveillance for medical errors in the EDs.

**PECARN Core Data Project**

PCDP Data for 2002 – 2007 are now available in the cubes. Please plan for 2008 data to be submitted to the CDMCC by April 1, 2009. We will be happy to help in any way possible to streamline the submission process. Reports for data validity checks will be generated after data submission. Please review your site’s report in a timely fashion.

A grant, “Risk-Adjusted Pediatric Emergency Medicine Outcome Measures Using an Electronic Medical Record Registry”, was developed with the input of the PCDP Working Group and was submitted in January for consideration of R01 funding to the NIH special section for Emergency Medical Services for Children. The overall goal of this proposal is to compare severity-adjusted quality measures of pediatric emergency care across different institutions by using data from a registry of electronic medical records.

For preliminary analysis of PCDP data, you can use the cubes or complete a data request form. The cubes can be accessed at [http://reports.pecarn.org/reportportal](http://reports.pecarn.org/reportportal). Contact Andrew.Demarco@hsc.utah.edu to obtain or reset your cube login and password. For any questions, please contact Libby Alpern at alpern@email.chop.edu.
**Performance Measures**

Work on the Performance Measures project continues. The initial pool of 333 measures has been reduced to 104 over the past year and our aim is to further reduce this number during the upcoming work group meeting to be held on March 5, 2009. Measures remaining after this meeting will be grouped and sent to EMSC stakeholders for further feedback.

**Pre-hospital Infrastructure**

Thanks to all the hard work of the PECARN investigators we now have data for over 74,000 runs from eleven EMS agencies. In an effort to be fair to those eleven agencies and everyone else who is waiting to use the data for study proposals or hypothesis generation, we will close the data submission process on March 2, 2009. At the writing of this newsletter, we believe we will obtain data from two to five more agencies before the study deadline. We continue to work on cleaning the data we have received and should begin data analysis shortly after the submission process closes.

**Seizure**

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) is currently ongoing with 9 of the 11 participating sites actively enrolling. Children’s Hospital Dallas has a site initiation visit scheduled for early February and Children’s Boston is awaiting final IRB approval; both sites are set to begin enrolling shortly. With a total of 54 patients enrolled, we have now met 22% of our projected enrollment numbers.

**TBI**

Eleven abstracts were presented at the 2007 and 2008 PAS, SAEM, ACEP and AAP meetings. Two more abstracts have been accepted to the 2009 PAS/SAEM meetings. The Scalp Hematoma abstract was voted best EM abstract at the 2008 AAP meeting. Two manuscripts were published in *Academic Emergency Medicine* (Inter-rater Reliability, Guardian Presence). The main Prediction Rule manuscript has been submitted for publication! Many manuscripts are being prepared from the studies already presented as abstracts. We anticipate completing several manuscripts over the next year, and submitting 3-4 TBI abstracts per meeting at the important national EM and Pediatric meetings over the next 1-2 years until all sub-studies have been presented (we are almost there!). Next TBI projects: 1) knowledge translation of the prediction rule, and 2) progesterone for serious TBI!

**THAPCA Trials**

THAPCA Trials: Drs Moler and Dean were notified that NHLBI plans to fund these trials. The funding mechanism was changed from R01 to U01. The study design has been modified to have an 18 month feasibility phase-in period of 15 ‘Vanguard sites’. If successful, 4 ½ additional years with 30 total sites we be supported.

---

**Site Monitoring Visits**

*Submitted by Jennie Wade BS, Clinical Research Coordinator*

The IAI Study is just over halfway through their second round of site monitoring visits. The monitors have been impressed with the sites once again. Below is a list of sites and the date of the visit:

**January:**
- Children’s National Medical Center - Jan 5
- University of Maryland - Jan 6
- Children’s Hospital of Buffalo - Jan 8
- University of Rochester - Jan 9
- Boston Children’s Hospital - Jan 12
- Jacobi Medical Center - Jan 13
- Children’s Hospital of New York - Jan 14
- Bellevue Hospital Center - Jan 15
- Children’s Hospital of Philadelphia - Jan 16
- Hurley Medical Center - Jan 22

**February:**
- Howard County General Hospital - Feb 2
- University of Michigan - Feb 4
- Primary Children’s Medical Center - Feb 10
- Children’s Hospital of Michigan - Feb 12
- DeVos Children’s Hospital - Feb 20
- Medical College of Wisconsin - Feb 25

**March:**
- Washington University - Mar 9
- University of California Davis - Mar 24
- NationWide Children’s Hospital - Mar 30

Thank you all for your cooperation and participation. We appreciate it!
**Does that *Really* Need to Go In My EDB??**

*Submitted by Jennie Wade BS, CCRP, Clinical Research Coordinator*

The Essential Documents Binder (EDB) can often become “the forgotten binder”: a binder assembled at the start of a study, and left to collect dust as the study progresses. Then the monitor comes along, wants to review your EDB, and panic sets in. A few questions may come to mind… Why is an EDB necessary? What are essential documents? And who decides what is essential?

EDBs are necessary to house all essential documents within one place. According to Good Clinical Practice Guidelines, the EDB confirms the validity of the trial conduct and the integrity of data collection. Having an up-to-date EDB can also help maintain successful management of the trial by the CDMCC and help your site monitoring visit go smoothly.

Essential Documents are part of the Good Clinical Practice Guidelines set forth by regulatory authorities that are part of the ICH Guidelines. Essential Documents are those documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements. To assist you with knowing which documents are “essential”, the CDMCC has created study specific lists of documents to help each site maintain their EDB. These are available in the eRoom™. It is a good idea to review the list on a regular basis or before your monitoring visit.

The Binder is a valuable tool to help PECARN run quality studies. Each EDB should be a guide to how a study runs at your site. Remember, when updating your EDB, ask yourself, “Could I re-create my study using just what’s in the Essential documents Binder?” If the answer is yes, then you should have a complete binder.

---

**NodalNews**

**ACORN**
The ACORN node would like to congratulate Leah and Chris Tzimenatos on the birth of their son, Jack, on Christmas day! *(See picture on Page 8)*

**GLEMSCRN**

*Bema K. Bonsu, M.D., Nationwide Children’s Hospital, Columbus, GLEMSCRN, is now an associate editor of* Academic Emergency Medicine.*

*Susan M. Fuchs, M.D., FAAP, Children’s Memorial Hospital, Chicago, GLEMSCRN, was awarded the Jim Seidel Distinguished Service Award for 2008 by the AAP Section of Emergency Medicine. The Seidel Award recognizes an individual who has made outstanding contributions to the field of pediatric emergency medicine.*

**CDMCC**

Congratulations to *Marci Fjelstad* who recently took the Society of Clinical Research Associates (SoCRA) exam and passed the test with a very high score! She is now a Certified Clinical Research Professional (CCRP).

*Lydia Dong, CDMCC statistician, gave birth to a baby boy on January 31st, 2009. His name is Andrew and he weighed 9lbs 9 ounces. Lydia will return to work in April.*

**PED-NET**

Thanks to our innovative RC at Bellevue, Mollie Marr, the PEDNET RCs convened our first quarterly nodal conference call on January 26, 2009. It was an hour well spent updating each other about our individual sites and sharing good tips for current studies.
As we all know, communication is a major challenge in clinical trials. In PECARN, we must communicate critical information about multiple studies, across multiple sites, and to multiple investigators. As the facilitator of this communication, the CDMCC is investigating and what we can do to improve communication within PECARN.

At the December 2008 PECARN meeting, the CDMCC asked RCs to complete a feedback form identifying communication preferences. Thirty-one RCs completed the form and provided valuable insight. We wanted to share what we learned in this effort. (For more details, please ask Marci Fjelstad.) The majority of respondents preferred email as the main form of communication with the CDMCC. **See Figure 1 for results**

In addition, we asked several open-ended questions; here are some selected responses.

**Regarding least effective communications with the CDMCC:**

"...the least effective form of communication is when an email goes only to my PI. I think my PIs assume that I get the email and fail to follow up or forward it to me."

"RC Conference calls: they are often a colossal waste of time & ever so frustrating!!"

"Conference calls can be a difficult means to ask specific questions."

"When placing ‘important’ or dated materials in eRoom, nightly notifications the information can be overlooked. There is so much info not pertinent you or your respective site that the things that are sometimes go unnoticed."

"Study updates are often long reports sent as attachments with deadlines and relevant info buried in the body."

The CDMCC will continue to use email as our primary mode of communication, limiting conference calls. We will ensure that emails get sent to the correct people and that key information and deadlines are clearly indicated. To help us make sure that the correct people get the right emails, please keep us updated on staff or e-mail changes.

To help enhance eRoom communication, remember that the red arrows next to an item (as opposed to clear arrows) mean that something is new or changed. If you have questions about eRoom (including turning notifications on/off, using eRoom alerts, and finding items), please contact any CDMCC coordinator.

**Regarding most effective communications with the CDMCC:**

"Of course in-person communication is always most-effective but when it is not feasible I really appreciate emails -- specifically those that contain links to eRoom with further information."

"When mass emails are sent they are clear and informative; Phone: they {CDMCC staff} are always available for questions or concerns."

"Phone calls directly w/CDMCC: Able to troubleshoot & solve in real time & clarify concerns or misunderstandings."

"Specific details, questions, clarification made in natural discussion. Emails can confuse. How about a twitter feed or instant messaging? (I would not want to be on the receiving end of this suggestion.)"

The CDMCC will continue to investigate ways to improve communication including one-on-one phone calls, utilizing PECARN meeting time, and the possibility of tools like instant messaging.

**Regarding email specifically:**

"Email has been most effective because it can be referred back to at future points."

"I am checking my email all day long & can respond in just moments if need be. "I look @ all my emails and when I see an email from someone from the CDMCC, I consider it priority."

"All forms have been effective but I have found emails to be rude at times"

"Too many email messages. Perhaps restricting emails to urgent action items would limit load."

Email can be a very challenging communication medium. It is useful to provide complete information along with additional resources, and we all like the ability to refer back. Getting the tone of an email can be tricky; sometimes a direct statement may come across negatively or bossy, when it was not intended that way. We continually discuss this issue at the CDMCC and strive to make our messages clear and appropriate.

We will continue our email improvements by using subject lines that indicate deadlines and other pertinent information. Additionally, we make every effort to respond to your emails within 24 hours. If something is urgent on your end, you could indicate your deadline in the subject of the email to help us triage. If we realize you are waiting for something from us, we will react quickly. We also do our best to keep email volume down, but study changes can happen fast and often many communications are necessary.

**Figure 1**

Which method of communication did RCs prefer regarding:

<table>
<thead>
<tr>
<th>Deadline, due dates, and requests for work</th>
<th>82% prefer email</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB submissions, questions, or approvals and renewals</td>
<td>79% prefer email</td>
</tr>
<tr>
<td>Issues (data quality issues, process issues) that may exist only at your site</td>
<td>58% prefer email</td>
</tr>
<tr>
<td>Changes to a study MOO or PECARN process</td>
<td>41% prefer email</td>
</tr>
<tr>
<td>Which method of communication is most effective?</td>
<td>58% reported email</td>
</tr>
<tr>
<td>Which method of communication is least effective?</td>
<td>30% reported eRoom</td>
</tr>
<tr>
<td>The CDMCC communicates just enough, too much, too little</td>
<td>90% reported “Just enough”</td>
</tr>
</tbody>
</table>

And a final note:

“Thank you CDMCC – you guys are awesome!”

Thank you, too.
PECARN CDMCC would like to introduce Charles Casper, PhD, Statistician. Dr. Casper is Assistant Professor of Pediatrics and biostatistician for the Data Coordinating Center at the University of Utah. He is currently involved in the design, implementation, and analysis of clinical trials and other projects for PECARN. More than anything, he enjoys hanging out with his family (wife and two boys, one more kid on the way). He also enjoys fishing (obviously), golf, other outdoor activities, and music.

Angie Marchant (pictured below on the right), MStat, Statistician for CDMCC. Ms. Marchant works under the supervision of Dr. Holubkov. She has provided statistical support for PECARN projects for over one year. She provides statistical input and analysis to PECARN studies, during the development and implementation stage, and is currently working on the Biosignatures study. She enjoys practicing yoga and spending time with her nieces and nephews.

A few BRAND NEW faces in PECARN:

Leah and Chris Tzimenatos’ son, Jack (born Dec 25, 2008)

Lydia Dong’s New addition - baby boy Andrew (born Jan 31, 2009)
Andrew was born at 5pm on Jan 31 and weighed 9 lbs 9 ounces

Congratulations!

PECARN Home
Contact Us

PECARN, the Pediatric Emergency Care Applied Research Network, is the first federally-funded pediatric emergency medicine research network in the United States. PECARN conducts high-impact, multi-institutional research on the prevention and management of acute diseases and injuries in children and youth of all ages.

PECARN is supported by cooperative agreements between four academic medical centers and the Health Resources and Services Administration / Maternal and Child Health Bureau / Emergency Medical Services for Children Program / USDA / NARR / ERCC.

See THIS Edition of the PECARN Newsletter online at: www.pecarn.org

Also:

PECARN Updates...
... Helpful Resources
Current Research ...
... and MORE!