



# In a nutshell

Issue 2.2

Spring 2007

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

## RA RIGHTS & RESPONSIBILITIES

RACHEL L. MCDUFFIE, MPH, GREAT LAKES NODE - PROJECT MANAGER/MONITOR

You've probably heard some of the horror stories: "Study coordinator sentenced for falsifying information" or "Researcher faces prison for fraud". The Federal Office of Research Integrity (ORI) releases case summaries of scientific misconduct investigations each month, and the results can be quite unnerving. Although the number is relatively low in proportion to the number of studies carried out, cases of research fraud are all too real to the research staff and subjects involved. However, it's important to remember that as an RA, there are two sides to protecting yourself and your site against this trouble - you have both a responsibility to follow the appropriate standards of Good Clinical Practice, IRB and sponsor requirements, as well as the right to complete your work in an ethical environment without fear of retaliation if you report practices that may threaten patient protections or data integrity.

Consider these **real** cases:

Robert Fiddes forced study staff to alter or destroy the medical records and health histories of ineligible patients so that he could reap the financial benefits provided by the sponsoring drug companies' enrollment incentives. Employees were regularly paid bonuses for providing their own blood and urine samples, so that they could be substituted for those subjects that did not meet inclusion criteria. Monitors and government audits did not detect this

fraud, most likely because the de-identified subject data made it all but impossible to link the specimens to the source. One study coordinator (who was fired immediately after protesting this unethical behavior) became a whistleblower and supplied evidence used to support her complaints to the FDA and FBI. After a lengthy investigation, Dr. Fiddes was ultimately sentenced to 15 months in jail, ordered to repay \$800,000, stripped of his medical license and deported. Two study coordinators were also debarred (banned) from working in clinical research for five years.

Although he was hired as a Research Assistant and did not complete medical school, Paul Kornak posed as a doctor and carried out entire research studies. Under his direct supervision, subjects that should have been excluded were placed at risk when their screening results were altered. Volunteers under the impression that they were ideal candidates were encouraged to enroll and continue dangerous study procedures; multiple subjects died after receiving experimental drugs. Kornak was convicted of negligent homicide, sentenced to nearly six years in prison, fined \$639,000 and received lifetime debarment from all federally sponsored research.

The FDA determined that Kornak's supervisor, Dr. James Holland, regularly delegated too much responsibility to multiple

study coordinators, failed to protect subjects and did not conduct/supervise the trials according to federal regulations. Additionally, there is an ongoing investigation into the hospital's research program; two pharmacists reported harassment and forced resignation after expressing concerns about unethical and dangerous research practices that took place even before Kornak was hired.

Study coordinator Anne Butkovitz was charged with falsifying case report forms, after documenting follow-up phone calls and information on serious adverse events without actually contacting parents of children enrolled in a vaccine trial. Butkovitz was sentenced to one year of probation, fined \$1,000 and permanently debarred from working on FDA studies.

These true stories may seem like "worst-case scenarios", but the reality is that sanctions have been issued by the federal government and even local IRBs for infractions that are far less dramatic. If you'd like to determine if you're on the right track, here are a few helpful questions to ponder:

**Are you in the loop?** - Although Good Clinical Practice guidelines are "tried and true", there are also many areas of detail that may change during your career as an RA. This can range from Manual of Operations updates for a particular study, to

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new staff training/certification requirements from your institution. Pay close attention to relevant newsletters, emails, and meeting minutes to stay informed of updates that may affect you or your site.

**Do you know the regs?** – Punishable offenses aren't limited to subject data. Occurrences of falsifying or fabricating information can also include things like misrepresenting certifications on a grant/IRB application and backdating training documentation for study staff. For example, the ORI report of the Kornak case contains an admission of falsifying an employment document, for failure to disclose a prior conviction of mail fraud during the hiring process. Make sure that you have easy access to Federal Regulations and Guidance, and be sure to reference them whenever you think you've stumbled one "gray area".

**Are you a "neat freak"?** – Although you may only want to reduce clutter, getting rid of what seems like "old stuff" can actually be a very dangerous practice. Missing records are a red flag, and can even suggest fabricated data in some cases. For example, trashing expired medical licenses in favor of the current copies in your essential documents binder may seem like a good idea, but this makes it difficult to verify that the investigator was authorized to complete certain procedures throughout the entire study.

The NIH has previously cited investigators for scientific misconduct when it has been discovered that reported findings are inconsistent with earlier data (or if original data were not retained at all). It may not be your intent to deliberately destroy records or falsify information, but even sloppy records and/or overzealous housekeeping can lead to an ORI sanction for the most well-intentioned study team.

**Something on your mind?** – If something doesn't seem right to you, don't be afraid to speak up! Remember, the Fiddes fraud remained undetected by several independent monitors and government audits; the scheme was only ended after one brave study coordinator came forward and provided the evidence needed to support a full investigation. Be sure to follow your instincts; you

should never feel or accept any pressure to obliterate or misrepresent information. Even if you catch (or make!) an honest error, don't be embarrassed to bring it to your PI's attention – you can save your site a lot of uncomfortable scrutiny by appropriately documenting and correcting the mistake, instead of keeping quiet and having a monitor discover it later.

If you feel threatened, harassed or treated unfairly after reporting a violation or refusing to participate in inappropriate conduct, know that laws exist to protect you against this type of retaliation. Check with your institution's human resources and research departments for specific guidance on handling complaints and grievance procedures.

These tales of research "gloom and doom" aren't intended to frighten, only to serve as a reminder that as an RA, each of you are a vital part of PECARN. It is important not to lose sight of your rights and protections while working to fulfill the expectations placed on such a valuable role. By taking simple precautions and remaining vigilant, you can be confident that you are setting a positive example and encouraging your entire site to maintain accountability.

#### The Office of Research Integrity

<http://ori.dhhs.gov/>

#### The Whistleblower's Bill of Rights

[http://ori.dhhs.gov/misconduct/Whistleblower\\_Rights.shtml](http://ori.dhhs.gov/misconduct/Whistleblower_Rights.shtml)

#### FDA Good Clinical Practice Guidance

<http://www.fda.gov/oc/gcp/guidance.html>

#### Office for Human Research Protections (OHRP)

<http://www.hhs.gov/ohrp/>

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# Federal Corner

## EMSC Program Website

Reminder: The EMSC Program's recently launched a new website (<http://mchb.hrsa.gov/emsc>). The website is an excellent resource for the EMSC community and includes many new features such as toolboxes on special topics and a products and resources database search.

## Targeted Issues Grant Guidance

The EMSC Guidance for Targeted Issues (TI) demonstration grants competition was closed on April 16, 2007. For successful applications, the award date will be September 1, 2007 for a project period of September 1, 2007 – August 31, 2010.

## National Heroes Awards

The EMSC National Resource Center (NRC) currently seeks nominations for the 2007 EMSC National Heroes Awards. These awards are presented to individuals who make an outstanding contribution to the EMSC Program, including Outstanding EMSC Research Project. Nomination forms are due May 1, 2007. For more information and nomination materials, please contact the NRC at 202-884-6818.

## Health IT Toolbox

The EMSC Program recently launched a health information technology "toolbox" for EMSC grantees and stakeholders, in collaboration with HRSA's Office of Health Information Technology (IT) and the AHRQ National Resource Center for Health IT. This health IT toolbox will provide for online collaboration, resource sharing, and links to resources of interest to the EMSC community. The toolbox is currently in the development and testing phase.

## Partnerships with National Organizations

The EMSC Program has funded several national organization projects related to clinical research and guidelines:

National Association of EMS Physicians: *NAEMSP was provided funding to implement a national Pediatric Emergency Care Research Workshop, which was successfully conducted in January 2007 with fellows, faculty members, and EMS providers as participants.*

American College of Emergency Physicians:

*The Nakamoto Group, Inc. was provided funding to partner with ACEP in the development of clinical guidelines for the use of adjunctive agents and critical issues in administering sedation to pediatric patients in the emergency department.*

In May 2007 the EMSC NRC will host a meeting for the American Academy of Pediatrics and ACEP to update the joint policy statement "Care of Children in the Emergency Department: Guidelines for Preparedness."

## National Resource Center Update

The NRC is currently working on a 3-year strategic plan for the EMSC Program. The plan will focus on objectives and funding priorities for the EMSC Program for fiscal years 2008 to 2011. Members of PECARN will be asked to participate in focused discussions on the EMSC Program strategic plan.

## EMSC Federal Legislative Update

### Fiscal Year 2007 Appropriations

On Thursday, February 15, the President signed into law a continuing resolution, HJ Res 20, making further continuing appropriations for fiscal year 2007. The bill provides level funding for most federal agencies, programs, and activities through the remainder of the fiscal year (ending September 30, 2007), including \$19.8 million for the EMSC Program.

### Fiscal Year 2008 Budget

The EMSC NRC has received a number of questions regarding the Bush Administration budget for fiscal year 2008 (October 1, 2007 to September 30, 2008). This budget does not request funding for the EMSC Program. However, the release of the administration's budget -- which is non-binding -- is simply the first of several steps in the annual federal budget and appropriations process. Final appropriations are often altered considerably by Congress after consideration of the proposed presidential budget.

For more information, contact the EMSC NRC's Policy Analyst at [kbelli@emscnrc.com](mailto:kbelli@emscnrc.com).

## Meetings

*Interagency Committee on EMSC Research (ICER).* ICER met on April 10, 2007. Dr Zorc presented the PECARN bronchiolitis study to the group.

*American Trauma Society Conference:* April 27 – 28, 2007, Arlington, VA. This conference will teach health care professionals the art of communicating with families of trauma patients and help shape the future of the trauma profession.

*ACEP Leadership and Advocacy Conference:* April 29 – May 2, 2007, Washington, DC. This conference will focus on providing emergency medicine professionals the knowledge and skills needed to

increase their impact as leaders and advocates and shape the agenda for emergency medicine.

*Ambulatory Pediatrics/Pediatric Academic Societies Annual Meeting:* May 5 – 8, 2007, Toronto, Canada. The Pediatric Academic Societies Annual Meeting is the largest international meeting focusing on research in child health and provides a unique venue for interdisciplinary scientific interactions. EMSC grantees will present study results at this meeting.

*Academic Emergency Medicine: Knowledge Translation Meeting (AEM/SAEM):* May 15, 2007, Chicago, IL. The mission of the AEM Consensus Conference on Knowledge Translation is to stimulate the development of a research agenda and a coordinated initiative within emergency medicine aimed at finding optimal routes into clinical practice for consistent and reliable implementation of evidence-based interventions.

*American Pediatric Surgical Association:* May 23 -27, 2007, Orlando, FL. The American Pediatric Surgical Association Annual Meeting is designed to cover the breadth of pediatric surgery and is intended to acquaint attendees with the latest research findings, clinical discoveries, and trends that influence the day-to-day practice of pediatric surgery.

***EMSC Grantee Meeting: June*** 19 – 21, 2007, Silver Spring, MD. The EMSC Program will hold its annual grantee meeting from Tuesday, June 19, 2007 until noon on Thursday, June 21, 2007, in Silver Spring, MD. Each of the four NDDP cooperative agreements and the CDMCC must send two representatives to this meeting as a condition of their EMSC Program grant funding. Information on meeting logistics and online registration is available at [www.mchb.hrsa.gov/emsc](http://www.mchb.hrsa.gov/emsc). The meeting will feature sessions on federal funding opportunities as well as other research related topics.

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## PECARN Study UPDATE

### C-Spine Injury in Children

Since the January Steering Committee meeting, the sites have completed a tremendous amount of work. Currently, there are 368 cases completed and approximately 160 eligible cases have been identified in prescreening bringing us very close to our enrollment goal of 550. All sites have received all years of prescreening data and the majority has completed all prescreening work. The new target deadline for completion of data abstraction is April 30, 2007. Almost 1,500 queries have been sent and 64% have been resolved. Several more query rules are in development and are scheduled to be sent in the coming weeks. Sub-contracts were re-issued to the sites for year three.

### Diagnostic Grouping System

The investigative group is currently working with the CDMCC to make the Diagnosis Grouping System available to researchers and others interested in grouping diagnosis codes. The system will be available on the PECARN website and will allow researchers to "look up" ICDQ codes and map them to diagnoses group. More importantly, researchers will be able to use either an Excel or SAS program to group diagnoses from their own data sets. Also, the Severity Classification System was accepted as a platform presentation in the Health Services Research Session II at the Pediatric Academic Societies meeting.

### Bronchiolitis Study

The first manuscript has been submitted for publication and is under consideration.

### Traumatic Brain Injury

Participant enrollment ended in September, 2006 after successful enrollment of 34,000 patients for the derivation phase of the study and an additional 9,000 patients for the validation phase. Data cleaning and query resolution is still in progress now and all sites are responding to ongoing queries. The study PIs continue to travel frequently to the CDMCC for data cleaning and analysis. We sub-

mitted two abstracts for the PAS and SAEM meetings - one abstract on the epidemiology of TBI in PECARN and another on the inter-rater reliability of variables for the decision rule. Both were accepted from presentation. We look forward to completion of data analysis for the decision rule and will share final results with the group as soon as we are able.

### Psychiatric Emergency Pilot Project

The data have been analyzed, an abstract has been submitted to the PAS (2007), and the manuscript is in preparation.

### Prehospital Working Group

At the upcoming PECARN Meeting, the Working Group will discuss progress of the EMS (Lerner) study, survey results, and future EMS studies and collaborations with the group.

### Intra-abdominal Injury

On February 22, 2007 PIs and RAs from the 19 participating sites as well as representatives from the CDMCC attended the IAI training session in Washington, DC. Data Collection Forms and the Manual of Operations were finalized in early March and most sites completed training of their participating ED staff. As of mid-March, sites are continuing to prepare for study start up towards the end of the month. Enrollment is scheduled to start in April for a run-in period at those sites with IRB approval, with the remaining sites joining the study as they receive final IRB approval.

Pulling from the lessons learned during the TBI study, a number of improved quality assurance methods and data quality management strategies are already in place. Thank you to all sites for your outstanding responsiveness in preparing for the study start and special thanks to those sites who have submitted site specific tools to be shared among the group.

### PECARN Core Data Project

We now have final and locked 2002-2005 PCDP data. Data cubes are in a new, more flexible format and include all available data for 2002-2005. For preliminary analysis of PCDP data, you can either use the cubes or complete a data request form. The cubes can be accessed online. Contact Andrew.demarco@hsc.utah.edu to obtain or reset your cube login, password, form and address. The deadline for submission of 2006 data was April 1, 2007. If you have not already made this deadline and submitted data, please submit data as soon as possible. The 2006 data are currently being processed. Please help us finalize the 2006 data quickly by responding to questions and reports from the CDMCC in a timely manner. For any questions, please contact Libby Alpern at Alpern@email.chop.edu. We had two recently accepted manuscripts to add to our published manuscripts from the PCDP data:

Lack of Agreement in Pediatric Emergency Department Discharge Diagnoses from Clinical and Administrative Data Sources. *Academic Emergency Medicine*, in press.

Variation in Ancillary Testing Among Pediatric Asthmatics Seen in Emergency Departments. *Academic Emergency Medicine*, in press.

Epidemiology of a Pediatric Emergency Medicine Research Network: The Pediatric Emergency Care Applied Research Network Core Data Project. *Ped Emerg Care*, 2006; 22: 689-99.

Availability of Pediatric Emergency Visit Data from Existing Data Sources. *Academic Emergency Medicine*, 2005;12: 1195-1200.

# PECARN Study UPDATE

## Seizure Study

Study I: We have now enrolled 61 patients and are in our data analysis phase.

Study II: The second part of the study, which will be a randomized controlled, double-blinded trial of lorazepam versus diazepam, will encompass two phases. The first phase of the study is community consultation (CC) and public disclosure. Each of 11 participating PECARN sites has developed and submitted to their IRBs a plan for conducting community consultation consistent with requirements put forth in 21 CFR 50.24 on the use of the Exception from Informed Consent (EFIC) in emergency care research. Six of these eleven have received formal verbal approval from their IRBs to begin community consultation. Sites will begin to implement their plans once they receive IRB approval—the first sites are expected to conduct community meetings pursuant to their CC plans by early May.

The second phase will be the RCT phase. Patient enrollment will begin once each site's local IRB has determined that adequate community consultation and public disclosure has been conducted.

PECARN is the first to implement EFIC in a pediatric research trial and are very excited to meet the requirements of the FDA regulations.

## EMS

The Prehospital Infrastructure Project is making great progress. We have been receiving the agency surveys and the project investigators will meet at the CDMCC in late May to identify the final list of variables for the data transfer from our partner EMS agencies. This continues to be an exciting project and we look forward to being able to use the data to develop future more in-depth EMS research.

## Prehospital Working Group Survey

The data has been analyzed and Kathy Lillis, MD will be reporting the results at this upcoming PECARN meeting.

## Patient Safety

The Patient Safety Study which aims to reduce medical errors in pediatric emergency departments is well underway. Site PIs should be submitting their completed surveys by April 13, 2007. Surveys of the emergency department staff will be starting shortly. Although we will not be using identifiers, it is important to calculate the response rate for the staff surveys. Therefore, please be sure to count how many staff you send the surveys to. IRB approvals for the second part of the study to collect incident reports from sites are pending.

## Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA)

Frank Moler came to the CDMCC in March to identify data elements for the THAPCA protocol. The Manual of Operations is in development and the protocol is being finalized. The Pilot study to identify eligible patients in real time is ongoing. Many sites have IRB approval or prep to research approval. The CDMCC will collate this data and it will be used in the grant submission.

## Bio Signatures

This project, which was approved by the Steering Committee in January 2007, is being prepared for a submission for an EMSC Targeted Issues Grant on April 16, 2007. The principal objective of this proposal is to introduce rapid turnaround microarray technology for diagnosis of serious bacterial infections in young febrile infants in PECARN. In this phase of the study, the goal is to demonstrate the ability of PECARN to consistently and reliably collect high-quality small volume blood samples for RNA analysis, to send the samples to the Bio Informatics center in Dallas, to demonstrate the stability of the RNA and to establish diagnostic bacterial and non-bacterial biosignatures in febrile infants in the context of a multi-center ED setting.

## Levetiracetam

Levetiracetam to Prevent Post-Traumatic Epilepsy (PTE) (The Keppra Study) This project received concept approval from the Steering Committee in January 2007. The full protocol, which addresses comments made by the committee in January, will be reviewed by PRADS and presented by Dr. Klein at the April meeting. This protocol is scheduled to be reviewed and voted on by the full Steering Committee in September. Klein plans to submit for RO1 funding for the October 1 review cycle.

The principal objective of this study is to determine whether Levetiracetam administered for six months to subjects with head injury with a high risk for developing post-traumatic epilepsy is effective in preventing epilepsy following head injury.

## Quality Performance Measures

This project is being prepared for submission for an EMSC Targeted Issues grant on April 16, 2007. This proposal builds upon the investigative team's strong track record of EMSC clinical and collaborative research and employs the infrastructure and expertise of the Pediatric Emergency Care Applied Research Network (PECARN). In our prior work funded by the EMSC program, we developed a clinically sensible Diagnosis Grouping System (DGS) and Severity Classification System (SCS) that comprehensively describes PEC disease frequency and severity. We will use these tools and other accepted methods of quality assessment in this proposal to assure that performance measurement in PEC is comprehensive. We outline our efforts to measure the quality of pediatric emergency care in a meaningful fashion.

## EXCEPTIONAL NEWS:

## UPDATE ON EXCEPTION TO INFORMED CONSENT FOR EMERGENCY RESEARCH



by Ron Maio, Principal Investigator Emeritus GLEMSCRN

Over the last 6 months or so, several noteworthy things have happened in the area of Exception to informed consent for Emergency Research (EICER).

Not the least of these is the IRB submission phase of the Pediatric Seizure Study (Use Of Lorazepam For The Treatment Of Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) that is headed by Jim Chamberlain. This is the first US Pediatric study to ever use EICER since the rules for its application were promulgated in 1996: Jim and the rest of PECARN are truly blazing a trail in regard to Pediatric Emergency Care research. Many of you are probably already aware of this, however, I'd like to bring you up to speed on a few other important things:

#### Update of the 2000 Guidance

In July of this year, the FDA updated its guidance on EICER, last given in 2000. FDA asked for written comments regarding it and also offered an opportunity to deliver testimony in October of 2007. PECARN's comments were superbly crafted by Jim Chamberlain, Tasmeen Singh (CARN Nodal Administrator Emeritus), and Jill Baren. Because of my distinguished appearance and presence (bald head, gray beard, nasal and sonorous voice) I was tapped to deliver the testimony. I think PECARN was able to address important issues pertaining to pediatric patients that no other discussants touched upon. This testimony, along with selected others, was recently published in *Academic Emergency Medicine*<sup>1</sup>. If you're interested in the Guidance and reading all the comments and testimony submitted to the FDA on this issue, you can go to:

2006 Guidance -<http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gdl0001.pdf>

Docket -<http://www.fda.gov/ohrms/DOCKETS/dockets/06d0331/06d0331.htm>

#### EMS Research Ethics Consensus Conference

In February of this year, an EMS Research Ethics Consensus Conference was held in Washington DC. The conference was funded by the National Association of EMS Physicians (NAEMSP), the National Highway Traffic Safety Administration (NHTSA) and the Agency for Health Care Research and Quality (AHCRO). This undertaking was led by the National EMS Research Agenda team, with Mike Sayre as the PI. The purpose of the meeting was to produce a guidance document which will be widely disseminated to clinical researchers, study sponsors and members of IRBs. It is anticipated that this document will provide valuable support for interpretation and application of the current federal regulations regarding emergency research conducted under the exception from informed consent. In addition to Emergency Medicine researchers who made up the majority of attendees, there were researchers from other disciplines as well as IRB staff, research coordinators, prehospital care providers and representatives from federal agencies. Although a substantial portion of the discussion addressed the use of EICER in the prehospital setting, discussion also included its use in the ED.

First several presentations were delivered to review various issues.

Then participants rotated among a number of discussion groups including:

Community Consultation

Local IRB and Investigator roles in EICER studies

When does the IRB need an IND or IDE?

Multiple IRB Review- Need for a National Review Body?

EMS Agency need for Federal Wide Assurance

Opting out of EICER Studies/Objecting to use of the data

Is informed consent really possible in emergency research?

Are ethical principles and emergency research compatible?

Discussion leaders then presented summaries of their group's discussions. General discussion along with a panel discussion followed. Jim Chamberlain, Tasmeen Singh, Rachel McDuffie (Great Lakes Nodal Project Manger) and I were all in attendance and we made sure pediatric issues were considered during the discussions. There was consensus that indeed, ethical principles and emergency research are compatible. There also seemed to be support for a National IRB to review EICER studies, although the logistic challenges are formidable. These and other issues will be discussed in detail in the consensus statement document. A draft document consensus statement has been prepared and will initially be reviewed by a working group that was formed prior to the meeting. It will then be put on line and open for general comments. I suggest that sometime in May you go to: [www.researchAgenda.org](http://www.researchAgenda.org) to take a look at it.

#### Change of EICER policy at University of Michigan

Although of primary concern to us Wolverines, this next item is still noteworthy. In 1997 the UM Medical School's IRB (IRBMED) went on record stating they would not even consider for review any EICER studies. Over the last several years I and others have worked to change that policy. Recently, the Medical School Executive Committee voted to change that policy. Rachel Stanley has recently submitted the initial application for the Lorazepam trial, which is the first EICER study to ever be reviewed by IRBMED. IRBMED board members and staff think this is very important research and are incredibly supportive. Furthermore, they are excited about getting involved in innovative and cutting edge research regulatory activities.

These are very exciting and challenging times for Pediatric Emergency Care research. I think we are all in store for a wild wonderful ride—and PECARN is at the wheel. So drop the top baby and let's go!

<sup>1</sup>Chamberlain, James M., Singh, Tasmeen, Baren, Jill M., Maio, Ronald F. **Food and Drug Administration Public Hearing on the Conduct of Emergency Clinical Research: Testimony of Pediatric Emergency Care Applied Research Network**

Acad Emerg Med 2007 0: j.aem.2006.11.024

<http://www.aemj.org/cgi/content/full/j.aem.2006.11.024v1>

## Spotlight



**Prashant Mahajan, MD, MPH, MBA**

I work at Children's Hospital of Michigan (which for some reason is called Prashant's Hospital in the PECARN corridors and has been indelibly etched in everyone's memory). I have been with PECARN and Great Lakes node since its very inception and the transformation of this network has been a pleasure to watch. PECARN has grown from a silo-type nodal centric organization to a full research centric network. I come from an institution that is clinically extremely busy (93,000 visits for 2006 and ~ 45% rise since 1996) which traditionally has not been very academically productive. By participating in PECARN studies, I have been able to steer the thinking at my ED towards the importance of participating in research and possibly getting more colleagues to conduct more rigorous research in pediatric emergency medicine (PEM). PECARN offers an immense opportunity to learn from the most

experienced leaders in PEM and a chance to be mentored in spite of geographical distances.

I am presently involved in submitting an EMSC Targeted Issues Grant on the application of biosignatures (transcriptional RNA changes secondary to inciting events either infective or inflammatory) in the evaluation and management of the febrile infant. While this technology is exciting, the best part was the unbiased input that I received from many PECARN members (including the Febrile Infant Working Group, the CDMCC and members of my node). This particular grant has evolved over 2 years and I have learned quite a bit since then. It would have been impossible to pull this off without the collaboration of the members in PECARN (whether it gets funded remains to be seen). My research interest remains in the febrile infant, bronchiolitis and economic impact of ED visits/interventions on the health care system.

### Upcoming Meetings

Summer 2007—Washington, DC

September 2007- Chicago, IL

January 2007—Miami, FL

### NodalNews

#### ACORN

The ACORN node would like to congratulate Marc Gorelick, who was recently named Associate Director of the Children's Research Institute at Medical College Wisconsin. In this role, Marc will focus on developing infrastructure and strategic planning for patient-oriented clinical research on the CHW campus. We would also like to congratulate Joe Zorc at Children's Hospital Philadelphia for his recent promotion to Associate Professor of Pediatrics at the UPenn School of Medicine.

#### PEDNET

As a network we join PEDNET in welcoming Jacobi Medical Center as a new funded site.

#### GLEMSCRN

**John Hoyle, M.D.**, HEDA PI at DeVos Children's Hospital, Spectrum Health System, had a paper accepted by the by *Prehospital Emergency Care* that will be published in the July issue entitled: "Comparative Study of Airway Management Techniques with Restricted Access to Patient Airway".

**John D. Hoyle, Jr. MD**, Jeffrey S. Jones MD, Matthew Deibel MD, David Lock MD, Diann Reischman, PhD

Rachel Stanley, M.D., RNC PI has two publications in press:

**Stanley R**, Zimmerman J, Hashikawa C, Clarke SJ. Appropriateness of Children's Non-urgent Visits to Selected Michigan Emergency Departments. *Pediatric Emergency Care*. In press.

**Stanley R**, Teach SJ, Mann NC, Alpern EA, Mahajan PJ, Gerardi M, Chamberlain JM and PECARN. Variation in Ancillary Testing Among Pediatric Asthmatics seen in Emergency Departments. *Academic Emergency Medicine*. In press.

**Elizabeth Powell, M.D.**, HEDA PI at Children's Memorial Hospital in Chicago is coauthor on 2 abstracts that are to be presented at PAS in the Spring:

Steve Crotty and **Elizabeth Powell**. *Are Antibiotics Indicated in Uncomplicated Epididymo-Orchitis in Childhood?*

Frank Petruzella and **Elizabeth Powell**. *Predicting Need for Intensive Care in Children Hospitalized with RSV Bronchiolitis* (Abstract #: 750764)

Dr. Powell has also been working with the Illinois American Academy of Pediatrics to raise awareness about Firearm Legislation that may emerge from Committee during the 2007 Spring Session in Illinois.

**Steven E. Krug**, MD, Children's Memorial Hospital in Chicago, serves as Chairperson of the Committee on Pediatric Emergency Medicine. The Committee recently published *Access to Optimal Emergency Care for Children*, Committee on Pediatric Emergency Medicine in Pediatrics 2007; 119: 161-164.

## New Faces



**Bethany McCunn, MPH, EMSC**

I am the new Research Assistant for the EMSC National Resource Center. I obtained my Bachelors degree from Slippery Rock University and my Masters in Public Health from West Virginia University. Prior to joining the EMSC NRC I was with the Office of Health Services Research at WVU working with the electronic patient registry, mainly focusing on cardiovascular disease research. Outside of work I enjoy the outdoors, downhill skiing, and traveling. I am looking forward to working with everyone in PECARN.



**Nabeel Ahmed**

CARN

Nabeel Ahmed is a recent college graduate from Atlanta, GA who is enjoying life after college, where he studied Spanish, music, and science. Though constantly wondering how his interests will one day translate into something that can be called a career, for now he's liking his first full-time experience with clinical research at CARN. Knowing that most of his previous jobs have entailed working with kids, pediatric research doesn't feel too far off the path he's been treading. In an exciting way, though, it's far enough.



**Larry Cook, Statistician**

CDMCC

The CDMCC welcomes a new Statistician. Larry Cook, MStat is a PhD candidate at Utah State University and is currently working on his dissertation on Exact Methods for Clustered Data which is scheduled to be completed in the summer of 2007. Larry is the statistician for the Intra-abdominal Injury (IAI) Project.

CDMCC Site Monitoring Visits

# January-April

**C-Spine Site Visits**

Medical College of Wisconsin, WI

University of Rochester Medical Center, NY

Children's Hospital of Philadelphia, PA

Chicago Memorial Northwestern, IL