



# In a nutshell

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## Preparing for a Site Visit

Regina Taylor, MA, Research Coordinator, Cincinnati Children's Hospital Medical Center



It's the day that every RA dreads, the first site visit. As soon as the date of the visit is determined, the anxiety and fear start to build. But a site visit doesn't need to be a day of dread. If you're well prepared and well organized, it can wind up being a very stress-free event. *So how can you prepare for such a day?*

Before the monitor arrives, a list of things to prepare will be sent to the site RA. The day of the visit will go quickly if all of the items on this list are ready and waiting for the monitor. I have found that the best place to start is the Essential Documents Binder (EDB). Make sure that everything is organized and easy for the monitor to find. The documents should be in order with the most cur-

rent version of each document, from the FAQs to the CVs and medical licenses of all those involved in the study. But remember, whatever goes in the binder, stays in the binder, so if there's a newer version of a document, archive the old version. There's a helpful list of what should be included in each section of the EDB on e-room.

Once you have gone over the EDB with a fine tooth comb, I like to make sure that all participant files are in order by verifying that every blank space is completed and that all necessary forms are included. On the day of the site visit, the monitor will go through each participant file and make sure that all of the data make sense and that Good Clinical Practice (GCP) was followed in collecting the information. I like to go through each file and ask myself these questions, and then confirm that all of the data to date have been entered into the database. For larger studies, such as head injury, this would be impossible, but I like to confirm that all of the files and logs are well organized and everything is accurately documented and consistent.

The more you prepare for the visit, the less anxiety and fear you will ex-

perience. A site monitoring visit is a day for PECARN to confirm that the study is running as well as they believe it is and that the protocol is being adhered to. There are ways that an RA can ensure that the data being collected are accurate and the protocol is being followed by internally checking the data.

Rather than waiting for the site monitor to point out the flaws in the data, check the participant files when the patient is enrolled to verify that all of the data gathered are logical and all deviations are identified and remedied at that time. Deviations are to be expected in any study, but it is important to work toward preventing that deviation from occurring again. In larger studies it may be easier to randomly sample participant files to make sure that procedures are being completed on time and according to the protocol. If you are following GCP, documenting everything that has occurred, and are keeping all study materials organized, the site visit will simply confirm that you are meeting PECARN's expectations. Remember, a visit isn't just one day in a study, every day that you work on a study plays a part in the monitor's findings.

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## Top 10 Questions to Ask Yourself Before the Site Monitor Shows Up:

1. Is the EDB organized with everything labeled so that the monitor can locate it without my help?
2. Is the most recent version of each document included in the EDB, and are all previous versions archived in reverse chronological order?
3. Has all staff training been documented and have all RA's and PI's signed the delegation of responsibilities list?
4. Is the IRB approval current and all communication with the IRB included in the EDB? Is there anything that the IRB needs to be notified of?
5. Are all participant and screening logs complete and consistent with all participants accounted for?
6. Are all data points complete on each patient CRF and all necessary signatures & dates complete on the Informed Consent Form?
7. Have all cross-outs been initialed and dated with an explanation of the reason for data change?
8. Are all necessary forms included with the patient file and in an organized manner so that the monitor has everything she may need in one location?
9. Have all protocol deviations been documented including a plan for preventing those deviations from being repeated?
10. Is there a space for the monitor to work and arranged meeting times with all necessary study staff? Is there HIPAA paperwork that needs to be completed?

Regina Taylor, MA, *Research Coordinator*

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### Good Clinical Practice Tip

**Q:** Can a monitor review photocopies of medical records, also called "shadow charts," instead of the originals?

**A:** As a general rule, site monitors should always review original medical records - for example, actual physician's office notes, clinic notes, and hospital medical records. A fundamental problem in relying on photocopies is that the monitor cannot be certain that the documentation is complete. That is, data may have been advertently or inadvertently deleted from pages (e.g., in the margins or on the back page of the original record). In addition, there may be data in other parts of the record, however small, that may not have been photocopied.

Reference: Good Clinical Practice: A Question and Answer Reference Guide. May 2006. Edited by Mark P. Mathieu.

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# Federal Corner

## IOM Reports on Emergency Care Released June 2006

On June 14, 2006, three reports were released for the IOM study titled, "The Future of Emergency Care in the United States Health System." The study's scope includes the full range of emergency care services, including 9-1-1 and medical dispatch, prehospital EMS (including ground and air medical services), and hospital-based emergency and trauma care for adults and children, and the need for research in EMSC. The reports addressed three key focus areas: prehospital, hospital-based, and pediatric emergency and trauma care, as well as provide an integrated overview of the emergency care system in the United States. The news release addresses the following items: (<http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=06142006>)

- **Emergency Medical Services: At the Crossroads**
- **Emergency Care for Children: Growing Pains**
- **Hospital-Based Emergency Care: At the Breaking Point**

Committee chairpersons presented their findings and recommendations during a webcast from the Annual EMSC Grantee Meeting on Tuesday, June 20, 2006. To view this webcast, go to [www.mchcom.com](http://www.mchcom.com) and select "2006 Annual EMSC Grantee Meeting" on the lower right, then select the "Tuesday Webcast" and scroll down to the end and click on "The Institute of Medicine Study on the Future of Emergency Care in the U.S. Health System"

A workshop series for report dissemination has been developed. The first workshop will take place Friday, Sept. 7<sup>th</sup> in Salt Lake City, Utah. Additional workshops are scheduled for Chicago, New Orleans, and Washington, D.C. Complete information on these workshops and how to register for them can be found at: <http://www.iom.edu/CMS/3809/34454.aspx>

## Series on EMSC Published in CPJEM Journal

The June 2006 issue of *Clinical Pediatric Emergency Medicine (CPEM)* features several articles written by EMSC colleagues, including staff at Children's National Medical Center, in Washington, DC. A few of the articles appearing in this, the second half of a two-part issue focusing exclusively on EMSC, are listed below by title and author. The first part was published in the March 2006 issue.

- **Emergency Medical Services for Children and the Institute of Medicine Revisited, 1993-2006; Wright JL**
- **Pediatric Trauma Systems in the United States: Do They Make a Difference?; Junkins, Jr. EP, O'Connell KJ, and Mann NC**
- **The 2005 Guidelines for CPR and Emergency Cardiovascular Care: Implications for Emergency Medical Services for Children; Brown K and Lightfoot C**
- **The Pediatric Emergency Care Applied Research Network: Progress and Update; Dayan P, Chamberlain J, Dean JM, Maio RF, and Kuppermann N. Publication of this issue was planned to coincide with the IOM report on the Future of Emergency Medicine in the United States Health System. To view the entire June issue of CPEM, go to <http://www.journals.elsevierhealth.com/periodicals/ycpem/current>.**

## Emergency Pediatric Services and Equipment Supplement (EPSES) Update

An article based on the EPSES 2002-2003 survey data, Factors associated with ability to treat pediatric emergencies in US hospitals, by Catharine W. Burt, Ed.D., and Kimberly R. Middleton, B.S.N., M.P.H., was submitted in May to the *Journal of Pediatric Emergency Medicine*. Ms. Middleton and Ms. Linda McCaig are currently working on a report of pediatric visits to EDs in 2003 to 2004, which will either be an Advanced Data Report or Series report. Data collection has begun for the 2006 EPSES, including extra children's hospitals.

## National EMS Information System (NEMSIS)

This joint initiative between HRSA/MCHB and NHTSA now has 48 states and 2 territories who have signed memoranda of understanding. In this calendar year, there will be 8-10 states submitting data. The central data repository is at NHTSA, with technical assistance provided by the University of Utah. Website is [www.nemsis.org](http://www.nemsis.org)

## Past Meetings

### **MAY 2006:**

**Interagency Committee on EMSC Research (ICER) Meeting** *Rockville, MD*  
Hosted by the EMSC Program

Dan Kavanaugh, MSW, LCSW-C hosted the ICER meeting, which included a presentation on Developing the Evidence-base for Residential Injury Control by a NICHD/CDC grantee, Kieran J. Phelan, MD, MSc from Children's Hospital Medical Center in Cincinnati, OH. In addition to this guest speaker and EMSC federal staff, Committee participants included federal representatives from the National Highway Traffic Safety Administration, the CDC/National Center for Health Statistics and CDC/National Center for Injury Prevention and Control, U.S. Army/Walter Reed Army Institute of Research, the Federal Drug Administration, The National Institute of General Medical Sciences, National Institute for Child Health and Human Development, National Heart, Lung and Blood Institute, and the Institute of Medicine liaison to The Future of Emergency Care in the U.S. Health System study. The next ICER meeting will be held in late September.

For contact information on these participants, or for the synopsis of their reports to the Committee, see the ICER meeting minutes from May 2006 posted in the PECARN eRoom at [https://www.nedarcssl.org/eRoom/NDDP/NDDPSteeringCommittee/O\\_cc92\(under Steering Committee/ICER folder/ICER Materials 2006\)](https://www.nedarcssl.org/eRoom/NDDP/NDDPSteeringCommittee/O_cc92(under%20Steering%20Committee/ICER%20folder/ICER%20Materials%202006)).

### **JUNE 2006:**

**Annual EMSC Grantee Meeting, Silver Spring, MD**

For the first time, the EMSC Program provided a Research/Targeted Issues track separate from a State Partnerships track at the Annual EMSC Grantee Meeting, which was very well-received by the grantees. During the meeting both PECARN and TI grantees presented their work, and a special panel of IOM subcommittee chairs provided information on the new IOM report on emergency care. The EMSC Research Hero's award was presented to Dr. John "Mick" Tilford, a health economist and former EMSC grantee from the University of Arkansas. The EMSC 2006 Annual Grantee meeting webcasts and presentations can be accessed at <http://www.mchcom.com/>.

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## TRANSLATING RESEARCH INTO PRACTICE (TRIP): *LOST IN TRANSLATION?*



By Emily Kim, MPH, ACORN Nodal Administrator  
UC Davis Medical Center

### What is it?

The aim of TRIP is to improve the outcomes, quality and effectiveness of healthcare by identifying and implementing strategies to encourage physicians to adopt proven practices. Currently, it takes as long as 1-2 decades for research to be adopted into clinical practice<sup>1</sup>.

### Why is it important?

The delays and failure to translate research into practice remains a major barrier to improving health care quality. One review of studies showed that only 3-5 percent of patients with chronic medical conditions in the U.S. received recommended care<sup>2</sup>.

### Who cares about it?

The Agency for Healthcare Research and Quality (AHRQ) has identified translation research as a major priority, and has funded many TRIP projects in the past years with the goal of identifying best strategies for translating research findings into clinical practice.

Who else cares about it? **PECARN does!**

### How do you do it?

There is a lot we don't know about how to translate research into practice and get healthcare providers to adopt proven practices. Here's what we do know (or think we know):

1. Successful translation of research findings into practice may depend not only on physician *awareness* of a new practice, but also on *acceptance* and *adoption* of that practice<sup>3</sup>.
2. Accomplishing *acceptance* and *adoption* requires that we focus on behavior-oriented strategies in addition to knowledge-oriented strategies<sup>4</sup>.
3. Different contexts, care settings, clinicians, patients and organizations require different approaches to encourage acceptance and adoption<sup>1</sup>.

### How can this be applied to PECARN?

PECARN is in the process of developing several clinical prediction rules (for traumatic brain injury, identification of cervical spine injury and for identifying intra-abdominal injuries in children with blunt abdominal trauma). Once these rules are developed and validated, we will have an excellent opportunity to make a first attempt at multicenter TRIP research in Pediatric Emergency Medicine.

1 Agency for Healthcare Research and Quality (AHRQ). Translating Research Into Practice (TRIP)-II. AHRQ Pub. No. 01-P017; March, 2001.

2 Schuster MA, McGlynn EA, Brook RH. How good is the quality of health care in the United States? *Milbank Q* 1998;76:517-63, 509.

3 Davis DA, Taylor-Vaisey A. Translating guidelines into practice. A systematic review of theoretic concepts, practical experience, and research evidence in the adoption of clinical practice guidelines. *CMAJ* 1997;157:408-16.

4 Wyszewski L, Green LA. Strategies for Changing Clinicians' Practice Patterns. A New Perspective. *J Family Practice* 2000;49:461-464.



# PECARN Study UPDATE

## Bioterrorism Surveillance:

Children's Hospital Boston continues to gather 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. Technical discussions are about to begin with Howard County Hospital. A pre-proposal is under review at the Agency for Health Care Research and Quality. Ken is also in discussions about the proposal with appropriate personnel at the Centers for Disease Control and Prevention. 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. We have 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. Optimally, the full demonstration of this capability should be ready by fall 2006, to coincide with other major national demonstration projects for the Office of the National Coordinator of Health Information Technology. The Biosurveillance group continues to hold monthly conference calls.

## C-Spine Injury in Children:

All nineteen C-Spine sites are actively collecting data. Enrollment volume has steadily increased and we anticipate accumulating the largest case series of cervical spine injured children ever reported. A plenary meeting for the EMS focus group phase of our project will be held in association with the Fall PECARN meeting.

## Bronchiolitis Study:

Due to the rapid response and resolution of queries at the Bronchiolitis study sites the query and data cleaning process is complete. Data analysis is currently underway at the CDMCC.

### Diagnostic Grouping System:

As of June 2006, the DGS was revised and now includes 21 Major Groups and 77 Subgroups. The major change was the division of the Infectious ENT Subgroup, which represented almost 15% of all diagnoses in the PCDP. The following four new Subgroups have replaced Infectious ENT: Infectious Ear Disorders (4.9%), Infectious Dental Disorders (0.4%), Infectious Mouth & Throat Disorders (3.1%), and Infectious Nose & Sinus Disorders, including URI (5.9%). Currently study investigators are concluding the correlation analyses between severity ratings in the DGS and other measures of resource use from EM datasets, and plan to present the results at the September 2006 steering committee meeting in Chicago.

## Traumatic Brain Injury:

Participant enrollment for the derivation phase of TBI reached 34,000 by the end of April 2006. The decision rule will be derived based on these data. Sites continued to enroll approximately 10,000 participants through September 2006, and data collected during this period will be used to validate the decision rule. Data cleaning and querying began in June in preparation for data analyses. Overall, sites have maintained a steady 78% capture rate. Thanks to everyone for the hard work and dedication to this project – we expect it to be a smashing success!

## Psychiatric Emergency Pilot Project:

Data abstraction and queries have been completed on schedule. Data analysis is nearly complete and manuscript writing is in progress.

## Prehospital Working Group:

All sites have completed the EMS survey. Data analysis is in progress.

## Hypothermia:

The R21 ended March 2006. Data has been cleaned and analysis is beginning.

The R34 was funded July 1 2006 to June 30, 2007. A two day meeting was held in Washington DC on August 16 and 17th with representatives from the NIH, PECARN, CPCCRN, AHA, and a Canadian Trials group to begin discussions on the protocol for a future RCT of hypothermia for pediatric cardiac arrest.

## PECARN Core Data Project:

The 2002-2005 data have been processed for all sites, and a final dataset will soon be available for all years to date. For preliminary analysis of PCDP data for study design development, you can access the cubes from the PCDP eRoom at: [https://www.Nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0\\_5935](https://www.Nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_5935), or complete a data request form. The request form can be found at: [https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0\\_a670](https://www.nedarcssl.org/eRoom/NDDP/PECARNCoreDataProject/0_a670) Submission of 2006 data will be due April 15, 2007. Be sure to complete the annual renewal of your IRB submission. Please contact Libby Alpern at: [Alpern@email.chop.edu](mailto:Alpern@email.chop.edu) with any questions.

## Seizure Study:

We are moving full steam ahead with the seizure study. We have enrolled 61 patients in the pharmacokinetic study over a period of approximately 16 months and are in the process of planning for the second study which will be a safety and efficacy study Lorazepam compared to Diazepam. This study will be a randomized, double blinded, placebo controlled trial conducted under an exception from informed consent. Three additional PECARN sites have been recruited to join the study team for a current total of 12 participating PECARN centers. In the Summer and Fall months, we will be completing data analysis for the pharmacokinetic study and meeting with IRB's to discuss implementation of the requirements under the exception from informed consent process for the efficacy study.

# Methodological Challenges in Multicenter Trials

By Rich Holubkov, *CDMCC Biostatistician, Associate Professor, University of Utah*

New interventions considered in studies in our network may be treatments delivered to patients like drugs/devices, or educational interventions delivered to ED or EMS staff in an effort to improve outcomes. Frequently, a new intervention is first demonstrated to be effective in a pilot setting, often a single-center study that may or may not be randomized. One of the reasons our network exists is to take the “next step” in studying the intervention in a multicenter randomized trial.

There is often concern about a “center effect” when designing PECARN studies. What if the intervention is more effective at some centers than others? What if the baseline event rate (say, admission rate for a condition) varies substantially between participating hospitals? Investigators are concerned whether differences in the “treatment effect” between centers may affect sample size, make the analysis plan more complex, or just plain make the study infeasible to carry out.

A general (and kind of simplistic) answer is that a multicenter randomized trial is feasible in the presence of “center effect”, and may not cost you much in terms of sample size, as long as you aren’t randomizing all patients or medical staff at each center to get a particular drug or intervention. Studies that randomize a whole center at once, so-called “group randomized trials”, are sometimes proposed when it’s impractical to carry out both interventions at the same hospital. Examples include educational interventions for ED or EMS staff, and very complex in-hospital intervention strategies. In group-randomized trials, differences in outcomes between centers can carry a severe penalty in terms of sample size. In addition, it’s really difficult to reliably analyze outcomes from such study designs when fewer than 20

or 30 centers are participating. It’s just plain hard to filter out the differences in outcomes attributable to treatment effect, versus differences due to “center effect”, when you don’t have many centers.

So, what about the usual study where patients are randomized separately within each hospital? The first thing I do to minimize “center effect” is to separately randomize within each center, making sure that treatments are about equally distributed within each site. This way, any substantial differences between centers will be equally allocated to the two treatment arms, keeping the overall comparison of treatments valid. Much of the time, this is all that’s necessary to control for small to moderate “center effect”.

If there is strong concern about “center effect”, there are several options that can be put into the study analysis plan. One option is to perform a stratified analysis – for example, instead of using a chi-squared test to test if event rates are different, I can effectively compare event rates within each center separately, and then look at the sum of the evidence across all the centers (epidemiology types will recognize the Mantel-Haenszel test here). This will work if there aren’t too many sites that enrolled only a few subjects, and we can even see if there’s evidence that the treatment effect differs across hospitals. I have found that in many real-life situations, a stratified analysis may not have much of a penalty in terms of number of subjects needed. Alternatively, we can actually adjust for center effect in the main analysis using so-called “random effects models”, although again this is hard to do well when the number of centers is less than 30 or so. Approaches to analyzing multicenter trials have gotten more sophisticated and easier to

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implement during my twenty years as a biostatistician. I believe that basic approaches to study design and analysis will still be appropriate in the majority of situations. We can, however, use improved computing power to simulate strong center effects (and other “bad things that might happen”) in the study plan-

ning phase, to explore if we need more subjects than we thought or should resort to more complex analysis strategies. We encourage you to consult with CDMCC biostatisticians as one of your first steps in planning a multicenter study of any kind!

## Upcoming Meetings

### PECARN Steering Committee Meeting

Miami

January 23rd & 24th

## NodalNews

### ACORN

The Academic Centers Research Node (ACORN) would like to congratulate two of its members on their recent promotions. Nate Kuppermann was promoted to the Bo Tomas Brofeldt Chair of Emergency Medicine at UC Davis in January, 2006. Nate has already made great strides in this new role, and the department is thrilled to have such a strong leader. Evie Alessandrini was promoted to Associate Professor of Pediatrics at the University of Pennsylvania School of Medicine- a well deserved promotion. Congratulations to you both on a job well done!!

### CARN

Michelle Castro, research assistant extraordinaire at Boston also took the plunge and got married on September 2 to Jose Alberto Betances. He is a pediatrician at Boston Medical Center. Her husband surprised her with a honeymoon in Mexico after the wedding. I guess we can't fault her for missing the PECARN meeting, Congratulations Michelle!

### GLEMSCRN

Congratulations to Valerie Stevenson (Nodal Manager), who will be the Administrative Director of the University of Michigan's Neurological Emergencies Treatment (NET) Trials starting in September 2006. We will miss Valerie, but we wish her the best on her exciting new position!

### PEDNET

In the Pediatric Emergency Department North East Team (PEDNET) CHOB enrollers Osman Farooq and Zeb Memon were both admitted to the Pediatric Residency program at the Women and Children's Hospital of Buffalo (WCHOB). They will start their residency in June. We are excited for this great news! Both Osman and Zeb have done a wonderful job as research assistants for PECARN studies at CHOB. We wish them the best at their career. Margaret Boyle, RA from Upstate Medical University, will be leaving this summer to pursue a nursing degree at Pacific Lutheran University in Tacoma, WA. She will earn her Master of Science in Nursing and plans to work in the Seattle area as a Family Nurse Practitioner.

## Spotlight



**Jim Holmes, MD, MPH**

I am an Associate Professor of Emergency Medicine at UC Davis, and currently serving as a nodal champion for the TBI study.

I am originally from the southern United States, near New Orleans, LA. I did my undergraduate work at Auburn University. I then completed medical school at the University of Alabama, Birmingham before coming to UC Davis for a residency in emergency medicine (where I met Nate Kuppermann). Upon completion of my residency I took a faculty position at UC Davis and have never left. I recently completed a MPH at UC Berkeley. My research interest is the emergency department evaluation of injured patients with a particular focus on the evaluation and management of injured children.

I recently married an emergency medicine physician. We both love to travel and try to get out of the country as much as possible. I am an active birdwatcher and many of our trips are aimed at seeing rare and unusual species. I enjoy long distance triathlons but our recent traveling has significantly hampered my training time.

## New Faces

### ACORN:

Cincinnati Children's Research Team Grows! The research team at Cincinnati Children's has greatly expanded. The team has grown over the past two years from 3 coordinators to a team of 9 in response to an increase in departmental research and a strong focus on current PECARN projects. The team covers the ED 12 hours a day during the week and 16 hours on the weekends. During the fall and winter we plan to expand our coverage to 2 coordinators present during the busiest hours in order to cover data collection for both clinical systems improvement work and active research studies.

### GLRN:

The Great Lakes node welcomes new research assistants Olubunmi Fawumi at University of Michigan, and Kelsey Hines at Children's Memorial in Chicago.

### CARN:

Dr Lois Lee, TBI site PI at Children's Hospital of Boston just gave birth to Lauren Kim. Who was born on July 22 at 6 pounds 15 ounces and 18.5 inches. Both mom and baby are doing well (The ridiculously cute baby picture below, with brother).

## CDMCC Site Monitoring Visits

# June-September 2006

### Bronchiolitis Site Visits

Cincinnati Children's Hospital

Washington University /Saint Louis Children's

### C-Spine Site Visits

Boston Children's Hospital

UC Davis Medical Center (Sacramento, CA)



**Lauren Kim**