PECARN
Pediatric Emergency Care Applied Research Network

PECARN In a nutshell

Issue 2.1 Winter 2007

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

# Organizing a Research Study From the Start

by Erin Rockney, Project Coordinator, Children's National Medical Center

In my previous job, I was hired to coordinate a research study that had enrolled patients for three years, without a steady study coordinator. The overworked PI was trying to run the longitudinal observational study all on her own while still keeping up with her full-time clinical practice. She was an incredibly bright and ambitious physician, but couldn't realistically keep up with the growing study by herself.

What I found during my first few weeks of work was not pretty. There were lost consent forms, patients charged for research visits, and patient study visits that had been completely missed. I spent the first three to four months of my job going through old files just trying to develop an organizational system to fix the numerous glitches, I was also working with the IRB to be completely transparent about our study's past mistakes. It was an ugly time for the study, but after sorting through past documents to patch together what had and hadn't been done, I helped the PI create an infrastructure that was much easier to maintain and helped organize the study so it ran much more smoothly and even more independently than before.

This past summer, when I was hired at Children's National Medical Center to coordinate a brand new study, I was excited by the idea of starting and organizing a study from scratch. It was a daunting process. I had seen the consequences of having a poorly organized study. I didn't want to find myself in a position where I would have to devote weeks or even months to reorganize a mess for which I would be responsible. During my first few weeks in the position, I took a lot of time to be proactive about creating a good system. I found that there were a few simple things a study coordinator could do to prepare a research site to ensure a theoretical study plan would run smoothly in practice throughout the entire course of a study.

I discovered the most important way to prepare is to create a realistic infrastructure within which to work throughout the project.

In the case of multi-center studies, you will usually be provided with a general plan to follow, which often includes databases, a manual of operations, and an essential document binder. These are generally inflexible and should be completed exactly as specified. For many other parts of the study, you can create or adapt materials to cater to your site. The more convenient and easy you make the study procedures, the more likely they will be completed accurately in every case. Here is a list of a few easy steps you can take to get your study off to a good start:

1. Set up a useful enrollment log. In many cases, you will be provided with one, but you can usually add information if you would like. For example, if you are conducting a medical record review, set up the log so you record the date you requested each medical record, the date you received it, and the date you returned it. Or if you are enrolling patients in the ED and need to contact them again within a certain time frame, record the date the next phone call is due. When you do make contact, record the date the contact was made. Make the log so it's not only a record of the study participants, but also a record of the stage you're at with each case.

2. Create kits. Put together all of the materials you will need for each case into packets that can be used by whoever is conducting the enrollment or data collection. Depending on your study, this could include an informed consent document, data collection forms, and sample collection materials. Also be sure to include a checklist in the kit along with detailed instructions on how to conduct the data collection so you can be sure that the person conducting the enrollment is completing all of the necessary steps.

3. Document everything. Make a note of anything that you feel might be of use in understanding the data. You may think you will remember the specific

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circumstances surrounding a particular case, but if you are anything like me, you won't.

4. Organize individual case folders identically. Include a checklist in each folder and make sure the forms on the checklist are stacked in the same order as the checklist. This makes the site monitor's job much easier.

5. Find and organize a storage area. This includes both physical space such as filing cabinets as well as electronic space. Create folders, both in your computer and in your filing cabinets that can accommodate the documents you create throughout the study. This can include everything from budget information to shipping forms to extra source document forms.

In most cases, it's easier to devote time to creating an infrastructure before a study actually begins than having to go back and try to fit already completed study materials into a new system of organization. Try to run through the entire study in your mind to figure out how to streamline the process before you actually start.

After you have created this organization system and have everything in what you believe is the most convenient place, the next step is to train the other researchers on the team so they have a complete understanding of the process. One of the most important things is to make sure each researcher is comfortable about how to gain informed consent for the study. I have found it helpful to write a script and give it to the other researchers to read through. Do not encourage them to read word for word from the script during the actual consenting process, but rather suggest they read through it to get a sense of the major points of the study and also to get an idea of a good way to organize a conversation with the patient or his parents. Scripts may need to be submitted to the IRB for approval ; check with your IRB to be sure. Next, give each person the opportunity to run through a mock consent process with you as many times as they feel they need to become completely comfortable with it. If a research assistant is uncomfortable with the informed consent, the patient and his or her family will be uncomfortable with it as well and are unlikely to agree to participate. During the mock consent process, make sure everyone is confident in their knowledge of the study by asking what you anticipate to be commonly asked questions.

Even though you may spend lots of time perfectly planning your study, it is inevitable that you will discover some glitches when you actually put the study into practice. That's ok! Be willing to adapt your study to make it as easy as possible for both the patients and the researchers so you collect high quality data while also providing the patients with a good clinical research experience. These tips should help you get off on the right foot toward conducting a well run PECARN research study.

## Good Clinical Practice Tip

**Q: What IRB approval documentation do you need to have in your Essential Documents Binder (EDB) prior to the clinical phase of a trail commencing?**

**A: Your EDB should include dated, documented approval/favorable opinion of IRB/IEC of the following:**

**Protocol and any amendments; CRF (if applicable); Informed consent form(s); Any other written information to be provided to the subject(s); Advertisement for subject recruitment (if used); Subject compensation (if any); Any other documents given approval/favorable opinion.**

**The purpose of this information is to document that the trial has been subject to IRB/IEC review and given approval/favorable opinion. This information also documents the version number and date of each document.**

**Reference: Guidance for Industry: Good Clinical Practice: Consolidated Guidance (ICH-E6)**

## Whos Who


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# Federal Corner

**New EMSC Program Website**

The EMSC Program is pleased to launch its new website: http://mchb.hrsa.gov/emsc

Special features include:

- Toolbox highlighting specific pediatric topics (e.g., pain management, disaster preparedness, prehospital education)
- Current *EMSC News* items
- Navigation bar with quick links to helpful information (e.g., state activities, funding opportunities, and EMSC products and resources)

Visit the new website for information to support grantees, health professionals and families regarding pediatric emergency care issues. (The old EMSC website (www.ems-c.org) no longer exists; it automatically re-directs to the new site.)

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

The Institute of Medicine reports on *The Future of Emergency Care in the United States Health System* released on June 14, 2006 have over 100 references to NHAMCS data and citations to our reports and publications that use NHAMCS data.

> McCaig LF, Nawar E. *National Hospital Ambulatory Medical Care Survey: 2004 Emergency Department Summary*. Adv Data. 2006 June 23;(372):1-32. http://www.cdc.gov/nchs/data/ad/ad372.pdf

An upcoming pediatric report is *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., which was submitted to Pediatric Emergency Care journal and is currently being revised based on suggestions from the journal. Ms. Middleton and Dr. McCaig are currently working on a report of pediatric visits to EDs to include 3 years of data which will either be an ADR or Series report.

Data collection for the 2006 EPSES, including the extra 25 children's hospitals, is expected to be completed by January, and data should be available by Fall 2007.

**Federal Interagency Committee on EMS**

Proposed by the Bush Administration and established by Congress through the Department of Transportation's (DOT) reauthorization legislation, FICEMS is charged with coordinating Federal Emergency Medical Services (EMS) efforts. The demands on our Nation's EMS systems are extremely diverse. Patients might include car crash victims or heart attack sufferers, and range in age from children to seniors. EMS workers respond to day-to-day emergencies and to major natural and man-made disasters – and in every type of situation and setting imaginable. The several Federal agencies that currently support EMS reflect this diversity of incidents, patients, and providers. FICEMS presents a tremendous opportunity to demonstrate and expand high-level collaboration and to focus increased Federal attention on Emergency Medical Services. FICEMS has been restructured and enhanced to include high-level administrators from DOT, Department of Health and Human Services (DHHS), and the Department of Homeland Security (DHS).

Peter Van Dyck, MD, PhD, Associate Administrator, Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), has been appointed by DHHS Secretary Michael Leavitt to represent HRSA on the newly structured FICEMS.

**National EMS Information System (NEMSIS)**

State data is being submitted to the National Center for Statistical Analysis at NHTSA.

Future announcements will be made when the data is publicly accessible For more information, go to www.nemsis.org.

**Interagency Committee on EMSC Research (ICER) Meeting**

Dan Kavanaugh, MSW, LCSW-C hosted the most recent ICER meeting, which included a presentation on the IOM Report *Emergency Care for Children: Growing Pains (June 2006).* For contact information on agency participants, or for the synopsis of their reports to the Committee, see the ICER meeting minutes from September 2006 posted in the PECARN eRoom at https://www.nedarcssl.org/eRoom/NDDP/NDDPSteeringComittee/0_cc92 (under Steering Committee/ICER folder/ICER Materials 2006).

**Peer-Reviewed Journal Articles of Interest**

**Preparedness of Selected Pediatric Offices to Respond to Critical Emergencies in Children.** - Santillanes G, Gausche-Hill M, Sosa B. *Pediatr Emerg Care* 2006; 22 (11): 694-698.

**Pediatric mental health emergencies in the emergency medical services system**. Dolan MA, Mace SE. *Ann Emerg Med* 2006; 48(4): 484-6.

**Evaluation of a Web-based education program on reducing medication dosing error: a multicenter, randomized controlled trial.** - Frush K, Hohenhaus S, Luo X, Gerardi M, Wiebe RA. *Pediatr Emerg Care*. 2006 Jan;22(1):62-70.

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| **JANUARY** | | | |
| 1/9/2007 | 1/13/2007 | NAEMSP Annual Meeting/Pediatric Research Workshop | Naples, FL |
| **FEBRUARY** | | | |
| 2/7/2007 | 2/8/2007 | EMS Research Ethics Conference: Development of Guidance for the Application of the Exception from Informed Consent for Emergency Research | Washington, D.C. |
| 2/9/2007 | 2/10/2007 | AAP Committee on Pediatric Emergency Medicine | Santa Fe, NM |
| 2/13/2007 | 2/13/2007 | ICER Meeting - EMSC NRC | Silver Spring, MD |
| 2/12/2007 | 2/14/2007 | NAEMSE National EMS Education Standards Meeting | Dallas, TX |
| 2/22/2007 | 2/25/2007 | ENA Leadership Challenge | Boston, MA |
| **MARCH** | | | |
| 3/3/2007 | 3/7/2007 | AMCHP Annual Conference | Arlington, VA |
| 3/15/2007 | 3/17/2007 | ACS Committee on Trauma | Denver, CO |
| 3/16/2007 | 3/17/2007 | AAP PIC Steering Committee Meeting | Hermosa Beach, CA |
| 3/24/2007 | 3/25/2007 | STN Annual Conference | Las Vegas, NV |

# PECARN Study UPDATE

### Bioterrorism Surveillance:

We've decided to remove the Biosurveillance study from the immediate PECARN queue. While we continue to recognize the importance of the study topic, we have been unable to identify a promising funding source for a PECARN project. Ken Mandl will continue to gather biosurveillance data, and continue the search for a funding opportunity. In the meantime, if sites are interested in establishing data transfer with Children's Hospital Boston independent of PECARN, they should contact Ken Mandl at Kenneth.Mandl@childrens.harvard.edu

### C-Spine Injury in Children:

We have identified 318 of the 550 needed cases. Within the current sample, more than fifty cases are age < 8 years and ten cases are age < 2 years allowing us to overcome weaknesses of prior cohorts which contain only a handful of children in these age groups. The target deadline for completion of data abstraction is February 28, 2007 with query completion in March and data cleaning in April. Please confer with your site C-spine team to develop a strategy for completion. During the January pre-meeting, Darcy Scharff, a focus-group methodologist, will facilitate a plenary to design the sampling strategy for the EMS focus groups. This meeting is open to PECARN members with interest or expertise in conducting prehospital research.

### Diagnostic Grouping System:

The Diagnosis Grouping System and Severity Classification System have been completed! We are currently in the process of completing manuscripts and working with the CDMCC to make the Systems available to the EMSC community. Our plan is for NEDARC to host these tools, and for a link to be available from the EMSC website. Our PECARN colleagues will be the first to be notified when the systems are available.

### Bronchiolitis Study:

Data analysis has been completed and the first manuscript has been submitted for publication.

### 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 in progress now and all sites are responding to ongoing queries. We submitted two abstracts for the PAS meetings - one abstract on the epidemiology of TBI in PECARN and another on the inter-rater reliability of variables for the decision rule. We look forward to completion of data cleaning for the decision rule and will share final results with the group as soon as we are able. Thanks to everyone for your hard work on this study, and special thanks to those sites whose outstanding oversight of the project helped with the data cleaning.

### Psychiatric Emergency Pilot Project:

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

### Prehospital Working Group:

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

### Intra-abdominal Injury:

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. In this study, we will enroll nearly 10,000 children with blunt torso trauma. This project uses very similar methods to the PECARN traumatic brain injury study with a goal to develop a clinical decision instrument for obtaining abdominal CT scans in children with blunt abdominal trauma. Currently, IRB submissions have been prepared and submitted at each of the 17 participating sites and several sites have received IRB approval. We are now finalizing the data collection forms and manual of operations. On February 22, 2007, we will have an investigator training session in Washington D.C. for both site PIs and RAs. Patient enrollment will begin after this meeting, likely on March 1st.

### Hypothermia:

The R21 planning cohort study is nearing final data cleaning, and some analyses should be completed by the January PECARN meeting. An R34 planning grant was funded by NICHD and runs through 6/30/07. Investigators

# PECARN Study UPDATE

plan to develop a R01 RCT application by June 1, 2007.

The Collaborative Pediatric Critical Care Research Network (CPCCRN) has expressed interest in collaborating with PECARN. A meeting was held in August to develop a protocol for a collaborative multicenter trial. Major issues discussed included:authorship, a study acronym (tentatively THAPCA), and committee structure.

A neurology sub-group has also met, and will meet again in Pittsburgh to address issues related to neurology. New consultants have been recruited into the trial, and a project update has been submitted to PRADS. This study will have a large steering committee, which would include PIs, representatives from the NIH, consultants, and others.

### PECARN Core Data Project:

We now have final and locked 2002-2005 PCDP data for all but a handful of sites. 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 at

http://reports.pecarn.org/reportportal. Contact Andrew.demarco@hsc.utah.edu to obtain or reset your cube login and password. The data request form can be found at : https://www.nedarcssl.org/ eRoom/ NDDP/ PECARNCoreDataProject/0_a670.

We had two recently published manuscripts from the PCDP data: Availability of Pediatric Emergency Visit Data from Existing Data Sources. *Academic Emergency Medicine*, 2005;12: 1195-1200.

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.

Submission of 2006 data will be due April 15, 2007. For any questions, please contact Libby Alpern at Alpern@email.Chop.edu.

### 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 IRBs to discuss implementation of the requirements under the exception from informed consent process for the efficacy study.

### EMS

The Prehospital Infrastructure Project will develop an infrastructure for conducting pediatric emergency research that is inclusive of the prehospital community. We aim to demonstrate that pediatric EMS research is possible within PECARN, including the critical step of creating data sharing relationships between Hospital Emergency Department Affiliates (HEDA) and EMS agencies. This project uses methodology similar to the PECARN Core Data Project to incorporate prehospital agencies into the PECARN research network. Each HEDA will partner with a single EMS agency for this project. The only requirement for these agencies is that they maintain electronic medical record data and are willing to partner with their local HEDA. These agencies, the project investigators, and the CDMCC will then work together to develop a uniform set of basic variables that is available from all or at least most of the EMS agencies. This data will be provided to the CDMCC and a common database will be created. In the future, the National EMS Information System will make this data sharing process easier, but in the mean time this database will be used to describe the agency patient populations and to develop future prehospital research projects. So far the project is off to a great start. The final protocol has been created and approved by PECARN, and IRB applications are beginning submitted. Several IRBs have already approved the protocol. The initial study training session will be held at the January PECARN meeting. If you have any questions or would like to be involved in this project please contact E. Brooke Lerner, PhD (eblerner@mcw.edu).

PECARN Begins A New Study:

## *A Clinical Decision Rule to Identify Children with Intra-abdominal Injuries*

by Jim Holmes MD, MPH

Trauma is the leading cause of death in children. Intra-abdominal Trauma is the leading cause of death in children and intra-abdominal injuries (IAI) are a frequent cause of morbidity and mortality due to trauma. Some IAIs are difficult to identify and failure to identify these injuries results in preventable morbidity and mortality. Abdominal computerized tomography (CT) is the reference standard for the diagnosis of IAI in children. CT scanning, however, has important risks, primarily the risk of development of radiation-induced malignancy. For every 1,500 children undergoing abdominal CT scanning, approximately one child will die from a malignancy induced by the associated radiation and up to three additional children will develop non-fatal malignancies from this exposure. Approximately 10% of abdominal CT scans currently performed on children with trauma demonstrate IAIs, thus CT scanning is used inefficiently.

The IAI study was funded by the Centers for Disease Control (CDC) in October 2006. The objective of this study is to develop highly sensitive, specific and generalizable decision rules for the evaluation of children seen in emergency departments (EDs) with blunt abdominal trauma. These decision rules may then serve to generate evidence-driven guidelines for the evaluation of these children.

The study methodology will be very similar to the recently completed traumatic brain injury study. However, it will be a prospective, observational study of children with blunt abdominal trauma, rather than blunt head trauma. Children with blunt abdominal trauma seen at any of the 17 participating PECARN centers will be enrolled over a two year period. We will enroll over 9,000 children with significant blunt torso trauma, including 900 children with IAI. The primary outcome for this study will be IAI in need of acute intervention (IAI resulting in death, or an IAI in need of any of the following: laparotomy, blood transfusion, angiographic embolization, or IV hydration). The patient history, physical examination findings and laboratory results at ED evaluation will be analyzed using recursive partitioning to generate a clinical decision rule(s) for the identification of children at high risk and near-zero risk of IAI in need of acute intervention. The decision rule(s) will result in more timely use of abdominal CT scanning in those children at risk for IAIs, and a decrease in use in children at near-zero risk of IAI, ultimately resulting in more efficient, safe and effective care of injured children.

Currently, IRB submissions have been prepared and submitted at each of the 17 participating sites and several sites have received IRB approval. We are now finalizing the data collection forms and manual of operations. On February 22, 2007, we will have an investigator training session in Washington D.C. for both site PIs and RAs. Once site PIs and RAs are trained, we will begin enrolling patients at the end of February and anticipate completion of patient en-

# Spotlight

## Anna Davis, MPH, BSN

I'm new to PECARN, but not to the University of Utah IICRC so I'm pleased to be back after a short two years away exploring other work environments. I couldn't resist returning to such a wonderful group of researchers, fantastic location (nestled against the mountains) and bottomless coffee and snacks in the break room! My prior experiences run the gamut; from bench work in a NIH/FDA research lab to developing public health injury surveillance systems and lots of things in between. Most recently, I was a Quality Consultant for a large hospital organization doing patient safety and quality improvement projects. I have a 6 month old girl, Ellen, and my husband and I are loving parenthood. Our golden retriever/lab mix, Willie, looks after us all and is relentless in his pursuit of quality ball fetching time and running with me on the many mountain trails around our house. Willie is a big hit with Ellen, but as she starts to eat/share food, he is developing a new appreciation for this other "being" in his house that he competes with for attention.

# Upcoming Meetings

**PECARN Steering Committee Meeting—New York, April 2007**

# NodalNews

### ACORN

The ACORN node would like to congratulate Walt Schalick on his recent appointment to the position of Associate Director of Washington University's Center for the Study of Ethics & Human Values, in charge of research. We also welcome the newest ACORN member, Walt's new daughter, born on September 3rd, 2006, 5 lbs. 12 oz and 19 inches in length. It's been a big year for the Schalick family!

Zara (Alexandra Magdalena Winters) Schalick

### PEDNET

Lynn Cimpello and her husband Peter welcomed their new daughter Natalie Grace at 10:08am on December 19th. Natalie weighed 7lbs 4oz. Natalie joins big sibs, twins Abigail and Luke. The Cimpellos are now one player short of a hockey team!

### GLEMSCRN

Rachel McDuffie, MPH

Fall of 2006 brought many changes to the Great Lakes Node. Rachel Stanley has been appointed as the GLEMSCRN Principal Investigator. She replaces Ronald Maio who is now the Director of the Office of Human Research Compliance Review for the University of Michigan. Alexander Rogers, MD, has taken over Dr. Stanley's role as the HEDA PI for the University of Michigan. Rachel McDuffie, MPH, has replaced Valerie Stevenson as the Nodal Project Manager/Monitor. Rachel joined the node in June 2005 and she has been a Research Associate at the University of Michigan for over 4 years. Congratulations to Rachel, Alex and Rachel on their new positions!

# New Faces

**Madelyn Garcia, MD, MPH, PED-NET**

Study Principal Investigator, University of Rochester, Rochester, NY

A Senior Instructor at the University of Rochester, Madelyn completed her pediatric residency as well as her Emergency Medicine fellowship at the University of Rochester. Her research interests are in the areas of trauma and diagnostic imaging. Her previous work focused on the use of CT Scan for diagnosing appendicitis, and her future plans include conducting a larger trial to determine the optimal imaging modality for cases of appendicitis. Madelyn is married and has a one year old daughter, Sofia who keeps her busy when she's not at work.

**Alexander Rogers, MD, GLRN**

HEDA Principal Investigator, University of Michigan, Ann Arbor

I will be joining PECARN as the new HEDA Principal Investigator for the University of Michigan. Currently, I am a Clinical Instructor in the Departments of Emergency Medicine and Pediatrics. I did my residency at the University of Rochester in New York and completed a Fellowship at Emory in Atlanta. My research interests include procedural pain management as well as limited English proficiency patients. I am thrilled to have the opportunity to participate in such a high quality national research endeavor.

**Olubunmi (Bunmi) Fawumi, BA, GLRN (not pictured)**

Research Associate, University of Michigan, Ann Arbor, Michigan

I was born in Lansing, Michigan and grew up in Nigeria. I am a 2006 graduate of the University of Michigan with a BA in Economics. I plan on pursuing a career in medicine. I am excited to have joined PECARN.

**Kelsey Hines, GLRN**

Research Assistant, Children's Memorial Hospital, Chicago, Illinois

I am the new Clinical Research Assistant at Children's Memorial Hospital in Chicago. Originally from Minnesota, I earned my Bachelor of Science Degree from Northwestern University in 2004. In my free time I love to cook, and I am also a freelance Costume Technician for local theatre companies.

My Introduction to Abdominal Trauma

**Allison Jones, BA, CDMCC**

Abdominal Trauma Study Coordinator

When I heard about PECARN, I was so impressed with the amazing work you all are doing that I moved from Boston, MA to Salt Lake City, UT. To answer the first questions you may have, I do not ski (although I plan to take it up) and I am only a Red Sox fan when they're doing REALLY well. Prior to moving to UT, I was working on behavioral intervention studies with HIV+ individuals at a community health center. I grew up outside Boston, earned a BA from Smith College in Psychology and I have lived in San Francisco, CA; Washington, DC and Syracuse, NY. I look forward to working with all of you.

CDMCC Site Monitoring Visits

## September-December

**C-Spine Site Visits**

Cincinnati Children's Hospital, Cincinnati, OH

Primary Children's Medical Center, Salt Lake City, UT

Children's Hospital of Michigan, Detroit, MI

University of Michigan, Ann Arbor, MI

DeVos Children's Hospital, Grand Rapids, MI