

# Spring 2010

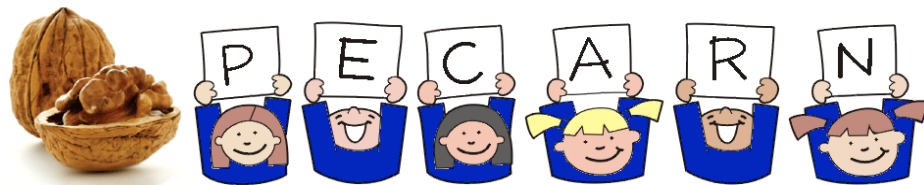
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## In a nutshell

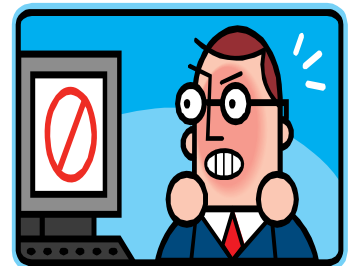
### Queries, Queries, Queries... Why Won't You Just Go Away?!

Submitted by Alecia Peterson, BS - *Clinical Data Associate (CDMCC)*

Despite popular belief, Clinical Data Managers (CDM) do not query sites to make the Research Coordinator's life miserable or to create job security. The truth is that CDMs dislike queries as much as you. However, the rules written against study data are an extremely important part of arriving at the study results. A 'rule' is defined as a check between one or more data elements for data discrepancies. The rules are written to ensure that the study data are logical, consistent, and complete. Without our data validation review, quality study analysis would be impossible and our research to improve quality of care meaningless.

So what can you do at your site to receive fewer queries? First of all, keep in mind that the more subjects you enroll, the more queries you will have – this is the nature of the beast. BUT, you can reduce your number of queries if you...1) Read the Manual of Operations. The study MOO always contains a section describing

data entry guidelines. By following these guidelines, you will proactively avoid queries. 2) Contact your study's Clinical Data Manager for help. There are no trivial questions. If you are unsure about anything, please do not hesitate to call or email with questions. 3) Read the Study Protocol. Within the protocol, the data elements are listed (not always in a nice list but they are always in there). Understanding the protocol will give you insight into what data are important and therefore items that you will be queried on if the data recorded in the database are not logical, consistent, or complete. 4) Review the Study Workflow. Workflows contain important information about data collection, such as where or how to collect the required data. In addition, Workflows will often contain the definitions of data elements that are being captured. 5) Pay attention to the type and frequencies of queries. Often, a large percentage of a site's queries are generated by one



or two data elements. If you address one problem you may see a large reduction of query volume.

And finally, following this one simple rule can dramatically reduce the number of queries your site receives... **COMPLETE YOUR FORMS!** If you enroll a subject complete all of the forms required for that visit in a timely manner (we usually give you 3 days) or you will be queried. The flip-side of this is if you leave a form pending for more than three days, you will be queried. Incomplete forms is the number one type of query across all studies, even all networks at the CDMCC. Don't let this be your nemesis.

## PECARN Research Coordinator Meeting: Progress and Update

Submitted By: Emily Kim, MPH - *Nodal Administrator*  
Sally Jo Zuspan, RN, MSN - *Program Manager*

At the January PECARN meeting, the Research Coordinators participated in an all-day training meeting. Thirty Research Coordinators from 22 HEDAs attended. The agenda for the meeting covered the following topics, which were identified as areas of interest by the Research Coordinators: site monitoring, the PECARN research agenda, clinical topics in PEM, the impact of PECARN research, and an overview of EMSC. We also organized a structured brainstorming session to gather Research Coordinator input on improving implementation of studies in the network.

During the brainstorming session, participants were asked to provide feedback in response to four leading questions as summarized in the feedback (in abbreviated form) below:

The biggest obstacle to doing my job is...	What I wish I knew more about is...	What would help me the most in my job is...	The smartest thing I've done to make my job easier is...
<ul style="list-style-type: none"> <li>• Institutional variation makes it difficult to follow one standard protocol without making interpretations.</li> <li>• Lack of 24-hour coverage for patient enrollment</li> <li>• Lack of administrative support</li> </ul>	<ul style="list-style-type: none"> <li>• Timelines of PECARN Studies</li> <li>• Progress of PECARN Studies</li> <li>• Grants</li> <li>• Budgets</li> <li>• Good Clinical Practice</li> <li>• ER clinical practice</li> </ul>	<ul style="list-style-type: none"> <li>• Better initial training and follow-up on training</li> <li>• More opportunity to provide input before and during studies</li> <li>• Better communication and support, including               <ul style="list-style-type: none"> <li>- Information about upcoming studies</li> <li>- Timely resolution of questions</li> <li>- More communication between network RCs and site PI</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Train clinical staff</li> <li>• Train research staff</li> <li>• Communicate with clinical staff</li> <li>• Maintain excellent organization of research documents</li> </ul>

The Nodal Administrators collated the feedback received during the brainstorming session and scheduled time every couple of weeks to review a portion of it and develop action plans. We have not addressed all feedback to date, but continue to work on it. Nodal Administrators report back to the PECARN Research Coordinators, relaying proposed action plans and soliciting input. The feedback and action plans are also sent to the PECARN executive committee, the PECARN program officer, and the EMSC NRC for review. The important changes which have been initiated as a result of this process are as follows:

- Whenever possible, we will hold study trainings separate from PECARN meetings so that we allow for more time/more comprehensive training.
- We will ask Research Coordinators to play a more central role in planning study training sessions.
- We will involve a small group of senior Research Coordinators in testing study implementation practices (piloting).
- We will hold bi-nodal or network-wide conference calls to review major changes to any ongoing study.
- Senior Research Coordinators will be identified at training sessions and asked to help field study-specific questions from junior Research Coordinators.
- We will explore the possibility of forming a Research Coordinator advisory group.
- We will provide Grand Rounds slides at the start of all new studies and encourage site PIs to present these slides at their HEDAs. When budget and time allow, we will encourage study PIs to travel to participating HEDAs to present Grand Rounds slides and motivate staff.

The PECARN Research Coordinators are a dynamic group, and full of valuable ideas for network improvement. We are happy to have taken initial steps toward better incorporating their voices in the setup of PECARN and PECARN research. We look forward to putting some of these ideas into action during the start-up of future studies.

### Next PECARN meetings:

#### September, 2010 at the Gaylord hotel outside of Washington, DC

September 14: Pre-meetings (TBD - likely RC meeting)

September 15-16: Steering Committee meeting

#### January, 2011 at the Conrad hotel in Miami

January 19: Pre-meeting

January 20-21: Steering Committee meeting

January 22: Post-meeting



Mark your calendars

## EMSC Releases Targeted Issues Grant Guidance

The grant guidance for Targeted Issues was released early March with funding for up to five new grants for fiscal year 2010. Applications should address specific needs in the field of pediatric emergency care that transcend state boundaries. In addition projects should address at least one of the following priorities:

- Improvements in pediatric care provided by emergency medical services (EMS)
- Improve services for acutely ill or injured children in rural settings
- Evaluating or creating an evidence base for existing State Partnership performance measures
- Pediatric patient safety in the prehospital or emergency department setting
- Utilize NEMSIS data to evaluate a testable or descriptive pediatric research question.

Objectives must meet a demonstrable need, and methodologies and strategies for achieving the objectives must be realistic, appropriate, and scientifically sound. Each application must contain an evaluation plan that contains measurable outcomes and clearly defined time frames for conducting the evaluation.

The funding level for each new Targeted Issue grant will be \$300,000 a year for three years with a project start date of September 1, 2010. Application guidance is available at [www.grants.gov](http://www.grants.gov), and the application deadline is April 23rd, 2010. Applicants should carefully review the project focus areas on pages 1 - 2 of the application guidance.

## State Partnership Performance Measure Development Project

In an effort to continue its focus on accountability and performance, the HRSA/MCHB has tasked the National Resource Center to evaluate and refine performance measures for the EMSC State Partnership grantees. The performance measure development team, which includes 5 special consultants and representatives from HRSA, the EMSC National Resource Center, and NEDARC have had monthly conference calls to develop the generation of performance measures for 2012.

## NRC Posts First Two Videos in iPEMS Podcast Series

The EMSC National Resource Center (NRC), in collaboration with the Alliance for Pediatric Emergency Medication Safety, has produced a series of podcasts called iPEMS. These multimedia podcasts target medical students, residents, and fellowship trainees, focusing on three objectives: (1) educating trainees about pediatric medication safety issues in the emergency setting, (2) describing potential solutions to improve medication safety, and (3) equipping trainees with the tools to implement a quality improvement initiative in their training programs.

Developed by the NRC's Dr. Tiffani Johnson, the first two podcasts - "Introduction of Patient Safety" and "Human Factors in Medication Safety" - are now available online. For access, visit:

<http://www.childrensnational.org/EMSC/EducationTraining/VideoAudioPodcasts.aspx>

## EMSC TI Grantees Publish Project on Pediatric ED Family Presence



Funded by an EMSC Targeted Issues (TI) grant, Children's National Medical Center primary investigator Karen O'Connell and her team have published "Family Presence during Trauma Activations and Medical Resuscitations in a Pediatric Emergency Department: An Evidence-Based Practice Project." Appearing in the March 2010 issue of the *Journal of Emergency Nursing* (Vol. 36, Issue 2, Pgs. 115-121), this project documents the feasibility of implementing a family presence intervention in a pediatric emergency department (ED) while ensuring uninterrupted patient care.

## Legislative Update

**EMSC Appropriations:** On Monday, February 1, the President released the Administration's fiscal year (FY) 2011 budget request, which recommends that the EMSC Program receive \$21.5 million for the upcoming fiscal year (October 1, 2010 to September 30, 2011). This is the same amount the Program is funded at for the current fiscal year, FY 2010.

As you may know, the release of the Administration's budget is one of several steps in the annual Federal budget and appropriations process. The Administration's budget is a non-binding proposal containing detailed funding recommendations for Federal agencies and programs for the fiscal year. Although the President submits the budget to Congress for its consideration, the budget is not a bill and does not become law. In forming the congressional budget resolution, which contains Congress' budget priorities and sets general spending limits on federal activities for a particular fiscal year, Congress may alter the Administration's budget.

In spring, Congress begins the appropriations process, providing funding for federal agencies and programs for the fiscal year. Both the House of Representatives and the Senate pass their own respective versions of each appropriations bill, including the bill funding the Departments of Labor, Health and Human Services, and Education, which contains funding for the EMSC Program. If the House and Senate have passed different versions of the bill, each chamber appoints members to a conference committee. The conference committee works out the differences between the two versions of the bill, and the House of Representatives and the Senate vote on the compromise bill. The final version of the bill is sent to the President for his signature.

**EMSC Reauthorization:** On December 24, 2009, the Senate passed H.R. 3590, the Patient Protection and Affordable Care Act, by a vote of 60-39. The House of Representatives approved the measure on March 21, 2010 by a vote of 219-212 and the President signed the bill into law on March 23, 2010. H.R. 3590 includes a provision to reauthorize the EMSC Program for five years, from fiscal year 2010 through fiscal year 2014, and authorizes an appropriation of \$25 million for the Program in fiscal year 2010, increasing to about \$30 million in fiscal year 2014. Recall, however, that funding is provided through the appropriations process. Authorization is simply a suggestion of how much funding Congress thinks a Program should receive in any given year. The only change to the Program is to the grant cycle, increasing it from 3 years with an optional 4<sup>th</sup> year to 4 years with an optional 5<sup>th</sup> year.



### Biosignatures Study

The third year of sample collection is underway and over 170 samples have been collected since January 1, 2010. The study principal investigators are currently reviewing all of the positive cultures and positive viral studies to identify those with proven bacterial infections and proven viral infections. Once identified, a portion of the samples will be analyzed on the gene chips to define the initial diagnostic bacterial Biosignatures.

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

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,774 controls. Three secondary analyses will be presented at the 2010 PAS meeting: Presentation for Outcomes of CSI in children transported directly to trauma center vs. those transported after stabilization at outlying hospitals; and posters for Cervical Spine Injuries (CSI) in Children Sustained during Sports and Recreational Activities (SRA); and Factors Associated with Cervical Spine Injuries (CSI) in Children Participating in Sports and Recreational Activities (SRA). The main manuscript which presents the results of the case-control analysis is currently under review. Manuscripts are being written for three secondary analyses: Description of CSI Patterns in Children, AARS, and Utility of Plain Films in the Diagnosis of CSI in Children. Additionally we are preparing an abstract for AAP and a manuscript which addresses SCIWORA.

### EMS Focus Group

This aspect of the study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed to limit immobilization to children who are at non-negligible risk for C-spine Injury. Focus groups and focused interviews with all echelons of EMS leadership were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, D.C., and Baltimore. All transcripts were reviewed and comments were categorized into topics

such as qualities, beliefs, barriers, motivators and suggestions. We are currently reviewing these categorizations and writing the manuscript.

### IAF Appendix Study

The aims of Intra-abdominal fat (IAF) - appendix study are to examine whether IAF plays a role in visualization of a normal appendix and whether we can predict which patients will have adequate IAF. Currently, all sites have completed the main data collection, and those sites assessing the inter-observer reliability of radiographs are in the final phase of radiologist abstraction. Study sample size is anticipated to be reached by the end of April, 2010 and data analysis will proceed shortly thereafter.



### IAI

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma.

Patient enrollment began on May 21, 2007 and ended on January 8, 2010! We enrolled over 12,000 patients with a capture rate of 80.9%, including over 770 with an IAI. The first abstract on inter-rater reliability will be presented at the spring research meetings. Data entry and review is on-going as follow-up is completed and the final status of patients is determined. The CDMCC continues to generate queries to ensure top data quality. Please continue to work on data entry and query resolution as we wrap up the study. Great work, everyone!

### Patient Safety and New York State Patient Safety

We have been making great progress in the NY Patient Safety study. As of April 6, 2010, 2378 eligible charts have been uploaded for review into the eRoom. Of those, 1661 have been reviewed by the study nurses. The overall goal is 3285 charts over 12 months. This breaks down to 1095 charts per site. We are 72.4% of the way to our ED chart upload goal and 50.6% of the way done with the review of the ED charts. We are 100% complete on incident report reviews for 6 sites in the network. The investigators are continuing to review the incident reporting data for the first year of the Patient Safety study, while incident reports are continuing to be sent to the CDMCC from all participating sites.

### PECARN Core Data Project

Please recall that 2009 PCDP data should not be submitted to the CDMCC. Discussion continues about future submissions.

PCDP Data for 2002 – 2008 are still available in the cubes. For preliminary analysis of PCDP data, you can use the cubes or complete a data request form (found in the PCDP eRoom). The cubes can be accessed at <https://www.utahdcc.org/reportportal>. Contact [andrew.demarco@hsc.utah.edu](mailto:andrew.demarco@hsc.utah.edu) to obtain or reset your cube login and password. For any questions, please contact Libby Alpern at [alpern@email.chop.edu](mailto:alpern@email.chop.edu).

### Performance Measures

San Antonio marks the last expert panel meeting for this project. Results from a recent stakeholder survey, with physicians, nurses and parents providing critical input and an ongoing data availability survey will be provided to the panel. A preliminary group of top measures will be created at the meeting, drawing us closer to completion of a primary project aim



*Conducting High Priority,  
High-Quality Research in  
Pediatric Emergency Care*

### Pre-hospital Infrastructure

This study collected data for 521,239 runs from fourteen EMS agencies for the years of 2004-2006 through HEDA partnerships with the agencies. These fourteen submitted data sets consist of varying size, amount of missing data, and format. Twenty-two EMS agencies ultimately participated in the study, with eight unable to submit data. Data collection is complete. Much progress has been made and work continues toward preparing the data for analysis.

### Seizure

The Pediatric Seizure study (officially titled the Use of Lorazepam for Pediatric Status Epilepticus: A Randomized, Double-Blinded Trial of Lorazepam and Diazepam) is currently ongoing with 11 participating sites actively enrolling; including newly recruited Children's Hospital Denver who is approved to enroll only preconsented patients at this time. Three new additional sites are currently at different stages of coming aboard to help increase patient enrollment - Baylor College of Medicine (Houston) has recently completed their community consultation and is presenting results to their IRB, and 2 Canadian sites - Alberta Children's Hospital (Calgary), Children's Hospital of Eastern Ontario (Ottawa) are working on their EFIC submissions to their REBs (IRB equivalent). With a total of 166 patients enrolled, we have now met 70% of our projected enrollment numbers.

### TBI

The TBI project continues to reap the benefits of the great work by many. All four abstracts submitted for the 2010 PAS/SAEM meetings were accepted. One will be presented at the PAS Presidential Plenary session, and a different one was selected for a potential award at the SAEM meeting. This brings the total to 17 completed and presented abstracts (none have been turned away!), on top of 3 published manuscripts. As you know, the main Prediction Rule manuscript was published in *The Lancet*, and we continue to receive positive feedback from around the country. We are finalizing and submitting 4-6 substudy manuscripts in the coming months and are currently working on approximately 10 more manuscripts / TBI substudies. We hope to have all substudies submitted for publication over the next 1-2 years. Next TBI projects actively being prepared: 1) knowledge translation of the prediction rule (Peter Dayan PI), and 2) progesterone for serious TBI (Rachel Stanley PI).

## Good Clinical Practice Tip:

### *What is GCP anyway?*

GCP stands for "Good Clinical Practice" and is defined in ICH E6 1.24 as:

*A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of the subjects are protected.*



Since the ICH in 1996, other regulatory bodies including the FDA have provided additional guidance and further defined GCP. As you can see, pretty much everything we do in a research study can and does relate back to GCP to some extent. Remember our goal is excellent research with credible and accurate data while protecting our subjects. GCP helps us achieve that goal.

**Submitted by Marci Fjelstad, MPH, MBA, CCRP**  
*CDMCC Clinical Research Coordinator*

### THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trials continue enrollment. The study has screened 562 total subjects; 108 were eligible, 66 were not randomized for various reasons and 42 have been randomized and enrolled into the trial. A second amendment has been completed that removed the exclusion criterion that disqualifies a subject if they have multiple arrests prior to randomization. A third amendment is currently in the works based on recommendations from the most recent DSMB meeting. Three new sites have been brought on-board – Medical College of Wisconsin, Columbus Children's Hospital and Phoenix Children's Hospital. Thanks to all the THAPCA sites for their hard work and commitment to this important trial!



## Research Coordinator of the Year Award

As PECARN approaches its 9th year, it seemed an appropriate time to institute a formal process for recognizing some of the most important members of PECARN - the site research coordinators (RCs). Without the hard work of the RCs, PECARN could not function. To honor their commitment to the success of our network, PECARN introduced the first annual PECARN Research Coordinator of the Year Award in January 2010.

Investigators were asked to nominate a coordinator who demonstrated the following qualities:

- An RC who contributes to the network, node or site
- An RC whom you admire and respect and who is respected and admired by their colleagues
- An RC who has overcome obstacles to help you/the network/site/node
- An RC who has had numerous accomplishments that you'd like to recognize

After many nominations, and much deliberation, this award was presented to **Jeff Trytko MS**, Research Coordinator at Helen DeVos Children's Hospital in Michigan at the January 2010 meeting in San Francisco. Jeff was nominated by Dr. John Hoyle, Principal Investigator at DeVos.

Jeff has been an RC for PECARN since 2005. He consistently demonstrates commitment to his job, demonstrates leadership and is an asset to the program. Congratulations Jeff!

A special "Thanks" to these  
5+ year veterans in  
PECARN

Bobbe Thomas  
Duke Wagner  
Elizabeth Duffy  
Haiping Qiao  
Jeff Trytko  
Kammy Jacobsen  
Marlena Kittick  
Mike Hadden  
Virginia Koors




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## In the Spotlight

A Spotlight on Kym Call, BA, CCRP at the CDMCC



When we talk about longevity in the network, it is important to recognize Kym Call who has been with PECARN since its inception. Kym started working at the Intermountain Injury Control and Research Center in 2001. She was involved in the Public Access Defibrillation (PAD) Trial which was a prospective, multicenter, randomized clinical study testing whether volunteer, non-medical responders can improve survival from out-of-hospital cardiac arrest by using automated external defibrillators (AEDs). When the Central Data Management and Coordinating Center (CDMCC) was funded in 2002, Kym joined the CDMCC staff and became a part of PECARN. When Kym started with PECARN, she comprised nearly the *entire* CDMCC staff; a program coordinator was then hired in 2002 and other staff followed. Kym helped most of PECARN's initial studies get off the ground. She designed the data collection forms for the Hypothermia Planning Grant, Bronchiolitis study, Psych Working group and the Traumatic Brain Injury study and was instrumental in helping to get PCDP off the ground. She designed the initial Essential Document Binders, developed the first several Manual of Operations, and produced the initial PECARN newsletters. She was promoted to Clinical Research Coordinator in

2004 and did a superb job of coordinating the Bronchiolitis Study through its last two seasons. Since then, she has coordinated the Cervical Spine project and the Biosignatures study. She coordinated education sessions at the CDMCC for 2 years and has been involved in just about every major study in some way. She has trained new coordinators and sets the bar high for performance in every aspect of her work. She has sat through more PECARN meetings than just about anyone at the CDMCC (except for maybe Mike Dean) and has cleaned more eRooms than anyone else! Kym is respected for her work throughout the network and at the data center.

In her spare time, Kym has many hobbies including spending time with her large extended family, doing major home remodeling projects, and singing opera. She also makes a mean smoothie! Congratulations Kym on 8 great years with the CDMCC. We are lucky to have you!

## Nodal News

### ACORN:

We would also like to congratulate Lynn Cimpello, who recently received one of two KL2 awards from the CTSA at Cincinnati Children's. Lynn will be working on translational research in TBI. We congratulate Joey Mechak, the Lorazepam study RC at CHOP, on his recent admittance to medical school. He will attend the University of Maryland in Fall 2010.

Finally, we'd like to welcome Diana Rosik and Adriane Rozmarynowski, both new and bright Research Assistants who have joined the team at Medical College of Wisconsin.

### GLEMSCRN:

Congratulations to Elizabeth Duffy in her new position as the Nodal Project manager and Monitor for the Great Lakes Node. Elizabeth began working in this role on November 30<sup>th</sup>, 2009. She will spend half of her time at the nodal offices in Ann Arbor and half overseeing the research activities at Children's Hospital of Michigan.

### PEDNET:

PEDNET reluctantly says goodbye to Mollie Marr, the research coordinator at Bellevue Medical Center. She is leaving PECARN to become the Project Director of a translational research project at New York University. The project investigates the role of dendritic cells and Helper-T cells in pancreatic cancer. In addition to assisting in the development and organization of a multidisciplinary Center of Excellence for Pancreatic Cancer and Pancreatitis, Mollie will be learning how to perform bench work, including flow cytometry and various types of cell staining. Mollie is excited by the opportunity but sad to leave PECARN. We would like to express our great appreciation to Mollie Marr for her outstanding work. Please join us to say thank you to Mollie and wish her all the best in her future endeavors.



## Who's Who

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## New Faces to PECARN

### ACORN:

**Adriane Rozmarynowski** joined the staff at MCW in November, 2009. She recently earned her BA in Psychology from University of Wisconsin. Her interests include drawing, photography, cooking, bingo, and playing fetch with her new kitten, CiCi. Adriane plans to apply to grad school in clinical psychology or neurology next year.



**Diana Rosik** joined the staff at MCW in February, 2010. She has a BA in Psychology from University of Wisconsin. She is a happy newlywed who enjoys snowboarding, canoeing, traveling, reading and playing with her dog, Houdini. Diana is a humanitarian and a thrill-seeker...excellent qualities for the emergency department!

## New Jr. Faces to PECARN

Congratulations to Jeff and Glenda Trytko on the birth of their daughter **Anika Jeanne Trytko**. Born February, 22, 2010, Anika weighed 8 lbs 10oz and was 20.5 inches long. She joins big brother, Dominick (6), and sister, Makenna (5).



ACORN would like to congratulate Melanie Houchell, Research Manager at CCHMC, on the birth of her third child, **Isiah James Houchell**. Isiah was born on February 3rd, 2010 weighing 7 lbs 10oz and 19.5 inches long

**Congratulations to  
the new arrivals!**

