In a nutshell

Defining Quality Performance Measures for Pediatric Emergency Care
Evaline Alessandrini MD, MSCE, Principal Investigator

The recent Institute of Medicine Report on “The Future of Emergency Care in the U.S. Health System,” and the associated “Emergency Care for Children: Growing Pains” report, have highlighted shortcomings related to pediatric emergency care (PEC). A significant recommendation to emerge from these reports calls for the development of standards for emergency care performance measurement. Progress in health care quality improvement has not widely crossed into PEC, current efforts do not address pediatric disease frequency and severity, and these efforts do not focus on outcomes.

The Defining Quality Performance Measures for Pediatric Emergency Care project was undertaken to address this need. Funded by an EMSC Targeted Issues grant from the Health Resource Services Administration, the project is slated to run between 2007 and 2010. Four overall study aims have been delineated: 1. To identify performance measures that comprehensively reflect pediatric emergency care across IOM quality domains, Donabedian’s quality framework and pediatric emergency care disease frequency and severity; 2. To assess the current and future status of data availability for performance measures; 3. To confirm the validity and credibility of chosen performance measures; and 4. To integrate the first three aims into a PEC quality report card, a list of data requirements needed to capture performance measures and a roadmap for future research which prioritizes performance measures in need of further validation. We are currently approaching the end of the first year and have made significant progress towards these aims.

A 28 person expert panel comprised of physicians, nurses, improvement methodologists and patient advocates from across the country was assembled and convened for the first time in April of this year. There are four working groups within the panel, organized by the IOM quality domains of: 1) Effectiveness, 2) Safety, 3) Timeliness and Efficiency, and 4) Equity and Patient Centeredness. Accomplishments to date include the creation of a comprehensive EMSC performance measure library, and a consensus session of each work group that yielded over 300 individual EMSC performance measures. The hard work of paring this initial list down has begun this summer, using electronic Delphi surveys of all expert panel members. During our study meeting in Dallas on September 9th, we expect that we will be left with approximately 100 performance measures overall. The coming months will then see this remaining list of measures reduced further after evaluation by national stakeholder groups. Ultimately, we will craft operational definitions for each measure as well.

Mark your calendars for the Winter PECARN Steering Committee Meeting to be held in Washington DC. It will be December 9th, 10th, and 11th.
When I left the oncology biochemistry laboratory to begin working with PECARN, I was immediately taken aback by differences between bench and clinical research. I suppose what struck me the most were the nitty-gritty details that bench researchers are fortunate to be able to ignore. Sign/date, single line through and other good clinical practices advocated in PECARN seemed like very efficient ways to waste time. It took me awhile not to curse a bit under my breath when I wrote the wrong date, but I did slowly come to realize the importance of GCP. While there are big differences between bench and clinical research, I am happy to report that many of my skills transferred over.

In bench research, an uncontrolled experiment is worthless and an experiment without notes on every detail of the process will get you nowhere. This practice can work for and against you in the world of clinical research. In a lab, all variables are at your fingertips: age of specimen, what specimen ate this morning, temperature of room, how much oxygen specimen is breathing, etc. Because of the lack of boundaries and the vast amount of technology, bench research can be controlled in a way unfathomable to clinical researchers. Getting used to the lack of control when working with human subjects has been difficult. However, the passion for precision and documentation I learned in bench research has taught me to try my best to control the variables I can and to record everything else.

The second lesson learned in bench research, and perhaps most important for maintaining sanity, is patience. Research is not a job of instant gratification. We researchers take what rewards we can, when we can; but rewards are generally few. This is something anyone who has worked in a lab has come to accept; often it is months before you have a successful experiment. Similarly in clinical research, studies often span years before producing results—patience is key here.

Finally, most bench researchers have three or four experiments running at one time. This prepared me well for PECARN, where I often need to switch between studies throughout the day. Because of my previous lab experience, I am able to prioritize projects and deadlines quite efficiently.

Overall, it has been interesting to participate in such different research avenues. Seeing human clinical trials evolve from bench research helped me to understand the importance of all research, and also taught me precision, documentation, patience and multi-tasking. I know many of you out there look for previous clinical research experience in hiring new research assistants/coordinators. I’d like to offer this up as evidence that many of the skills learned in bench research are in fact transferable.
EMSC Reauthorization Update
Previously this year, the House of Representatives approved HR 2464, the Wakefield Act, by a vote of 390-1. The Senate has yet to consider S60, the Senate’s version of the bill; however, there are currently 12 co-sponsors and it is believed that the Wakefield Act will be reviewed later this year.
You may recall that in order for a reauthorization bill, such as HR 2464, to become law, both the House and the Senate must vote on, and pass, their respective versions of the bill.

Emergency Medical Services for Children National Resource Center (EMSC-NRC) Awarded to Children’s National Medical Center, Washington, D.C.
The EMSC Program announces that Children’s National Medical Center is the successful applicant in the recent competition for the EMSC National Resource Center (NRC) operations. Children’s National has served as home for the NRC since 1991. The NRC provides technical assistance to grantees, develops resources for the layperson and professional as it relates to improving pediatric emergency care, provides electronic communications for the Federal Program, serves as the clearinghouse for EMS products and resources, conducts legislative analysis, works with national organizations, and supports the EMSC Program officers Dan Kavanaugh and Tina Turgel.
Please visit the website at www.childrensnational.org/EMSC

Funding for the Federal EMSC Program
On June 19th, the Subcommittee on Labor, Health and Human Services and Education of the House Committee on Appropriations approved the Fiscal Year (FY) 2009 Labor, Health and Human Services and Education Appropriations Bill. While the subcommittee has yet to publicly release the funding levels for individual programs, it is speculated that the bill includes an appropriation for the EMSC Program. You may recall that following the subcommittee mark-up, the appropriations bill will move to the House Committee on Appropriations for consideration.
On June 24th, the Senate Subcommittee on Labor, Health and Human Services and Education approved its version of the FY 2009 Labor, Health and Human Services and Education Appropriation Bill. On June 26th, the Senate Committee on Appropriations approved the bill, which includes a recommended appropriation of $20 million for the EMSC Program. Next, the appropriations bill will move to the full Senate for consideration.
As you may recall, in order for an appropriations bill to become a law both the House and Senate must agree on a final version.

EMSC Stakeholders Meet in Washington, DC
The EMSC Partnership for Children Stakeholder Group met in Washington, DC from July 14-15, 2008. The group is a collaborative of diverse national organizations, federal agencies, and EMSC Program grantees convened to improve the emergency medical care of children through the exchange of knowledge, development of partnerships, and provision of input and counsel to the EMSC Program. At the July meeting, the group gave input on the implementation of State Partnership grantee performance measures and also discussed an upcoming external evaluation of PECARN. Volunteers from the stakeholder group will work as advisors to the NRC as it conducts an external evaluation over the upcoming year.

National EMSC Data Analysis Resource Center (NEDARC) awarded to University of Utah, Salt Lake City, UT
NEDARC is a national resource center designed to help state and territory EMSC Managers and EMS officers develop capabilities to collect, analyze, and utilize EMS data. The University of Utah has served as the home of NEDARC since 1995. In addition, NEDARC hosts a variety of workshops including ones focused on scientific grant writing.
Please visit the website at www.nedarc.org
**Febrile Illness & Biosignatures**

We have completed year one enrollment. Each site collected 1-3 samples in year one for a total of 53 samples across all sites. All samples were shipped and received by the Bioinformatics Core Lab and analysis for RNA quality is underway. The sites are completing data entry and resolving queries. Remote monitoring is in progress and site monitoring visits will be conducted at each site prior to the start of year two enrollment. A training session will be held on Tuesday, December 9th in Washington DC prior to the Steering Committee Meeting. Enrollment for years 2 and 3 will begin immediately following the training session.

**Bronchiolitis**

In a secondary analysis of the Bronchiolitis study, we created a prediction rule to identify which infants with bronchiolitis are hospitalized and which require prolonged hospitalization. The data for this secondary analysis was gathered, analyzed and presented at both the PAS and SAEM meetings in May 2008, and a manuscript is currently being prepared.

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

Case-control analysis: We have completed abstraction and eligibility verification for 540 cases and 2,776 controls. Preliminary analysis resulted in four abstracts that were presented at the spring academic meetings: two at PAS and two at SAEM. Additional data cleaning and the comparative analysis to identify pediatric specific risk factors to CSI are underway. The focus this fall will be completion of the comparative analysis, launch of secondary analysis and preparation of abstracts for the spring academic meetings.

This aspect of the CSI study aims to use focused interview and focus group methodology to identify the barriers and facilitators to EMS participation in research aimed at limiting immobilization to those children who are at non-negligible risk for C-spine injury. Nine sites have undergone IRB review and approval. The focus groups and focused interviews were completed in St. Louis, Milwaukee, Salt Lake City, Buffalo, Rochester, DC and Baltimore. Throughout the fall, we will continue to conduct focused interviews with all echelons of EMS leadership, preliminary analysis and report development.

**IAI**

The Intra-abdominal Injury (IAI) study was funded by the Centers for Disease Control (CDC) in October 2006. The study will enroll over 10,000 children with blunt torso trauma, including over 800 with IAI. The goal is to develop a clinical decision instrument to determine the indications for abdominal CT use in children with blunt torso trauma. Patient enrollment began in May 2007. As of August 15, we have enrolled 5,609 patients with a capture rate of 78.7%. This includes 358 patients with IAI. Site monitoring visits have been performed at all participating sites. In addition, the CDMCC continues to perform remote monitoring and regular queries through TrialDB to ensure top data quality. Patient enrollment is expected to continue through October 2009.

**Patient Safety**

A manuscript "Pediatric Patient Safety in 21 Emergency Departments: ED Characteristics and Climate of Safety" has been written and submitted to GAPS and then will be submitted to *Pediatrics* for review. This manuscript is derived from the surveys completed by the site PIs and those that were given to emergency department staff. The second part of the Patient Safety study: "A Quantitative Analysis of Medical Error Reporting in the Pediatric Emergency Department to Improve Patient Safety" is continuing to collect incident reports from 18 sites for further analysis.

**PECARN Core Data Project**

All sites have submitted 2007 data and almost all sites have completed the review and quality assurance for this data. Once sites are finalized, the 2007 data will be added to the cubes. Please plan for 2008 data to be submitted to the CDMCC by April 1, 2009. We will be happy to help in any way to streamline the submission process. The PCDP working group will present the “Registry” project that will link PCDP to electronic medical record data and to the Steering Committee at the September 2008 meeting.

For preliminary analysis of PCDP data, you can use the cubes or complete a data request form. Contact andrew.demarco@hsc.utah.edu to obtain or reset your cube login and password.

**Prehospital Infrastructure**

Thanks to all the hard work of the PECARN investigators and research coordinators we have partnered with 21EMS agencies. To date, eight agencies have submitted data totaling over 66,000 unique patient runs! Two additional agencies are close to data submission, eight more are completing the various approvals needed for them to submit data, and three have found they will not be able to submit data. We continue to work with sites and agencies to overcome obstacles to data submission. The CDMCC is working to clean these data and generate basic reports. Additionally, we hope to begin data collection for the qualitative portion of the study on barriers and enablers to submitting data.

**Prehospital Working Group**

The Prehospital Working Group submitted an abstract to the National Association of Emergency Medical Services Physicians national meeting in Florida in January 2009. The Prehospital Working Group has also been involved with Brooke Lerner’s study involving the development of research partnerships with EMS Agencies and also supporting Julie Leonard’s C-spine study which is currently conducting EMS focus groups.

**Psych. Working Group**

The PECARN manuscript entitled "Referral and Resource Utilization Patterns for Psychiatric Related Visits to Pediatric Emergency Departments" was accepted for publication in *Pediatric Emergency Care*. 
Study Updates continued . . .

Seizure

Nine of eleven sites have received IRB approval to begin patient enrollment. Five sites are actively enrolling and four are in the process of initiating study start-up; of these, all four have completed their site initiation visit and anticipate enrolling by early fall. The final two sites are finalizing their community consultation phase. Currently 24 total patients have been enrolled. Enrollment has gone smoothly and results are positive. A safety analysis is planned now that 10% of the total projected sample size has been met. Total opt-outs for all sites is 51 (8%) of the total approached in the context of community consultation and surveys.

THAPCA

The Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA) Trial Scientific (Moler PI) and DCC (Dean PI) applications were submitted as a cluster to NHLBI at the Feb 5, 2008 cycle. The study section was highly enthusiastic about the application and re-submission was encouraged. If funded, a total of 30 sites including two research networks (PECARN and CPCCRN) will enroll pediatric patients who have cardiac arrest to determine the efficacy of therapeutic hypothermia to improve neurobehavioral outcome in the in-hospital and out of hospital settings. This will be 2 separate RCTs.

TBI

Patient 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 continued through 2007, and is now finished (until we start working on more sub-studies!). Eight abstracts have been presented at the 2007 and 2008 PAS and SAEM meetings, as well as the 2007 ACEP meeting. Three more abstracts have been accepted at the 2008 AAP meeting, making this a highly productive study over the next 1-2 years until all 20-22 sub-studies have been submitted as abstracts (we are half-way there!). Next TBI projects: 1) knowledge translation, and 2) therapeutic intervention for serious TBI.

Remote Monitoring: Why do we do it?

Sally Jo Zuspan RN MSN, Program Coordinator, CDMCC

In clinical research, one of the greatest challenges is maintaining a clean database. PECARN is fortunate to have experienced research coordinators with a good track record for accuracy. However, errors are bound to find their way into the database during enrollment, abstraction, and data entry. We know from previous studies that data errors must be minimized otherwise the study results can be affected and misleading. For example, in the Head Injury and Abdominal Injury studies, variables that are missing or in error more than 5% of the time may not be used in the final main analyses.

The CDMCC has many methods to catch data entry or abstraction errors. Our databases are designed with internal checking systems that can recognize data that are outside normal values. The query system is also designed to find inconsistencies in data; for example a child who is intubated is unlikely to be “alert and talkative”. Unfortunately, there are items that cannot by found by either system. This is where remote monitoring can be very helpful.

Remote monitoring is conducted when on-site monitoring is not feasible. It represents a lot of work for the sites and the CDMCC. The CDMCC designs audits with a focus on error prone variables or those of high importance to the study outcome. The sites send copies of the original source documents, and the CDMCC compares the source data to the database entry. For each audit, the CDMCC study coordinator may review hundreds of data elements. This method helps identify misinterpretations in study processes or differences in site procedures. A recent audit found different definitions for a lab test called “lactate”, and this resulted in sites reporting different values. Audits have also found cases where an intra abdominal injury (IAI) had been recorded in the database when in fact the patient did not have an IAI, as well as cases that were coded as normal that had an IAI. Discrepancies in data abstraction have been found; for example a value of “144” was entered instead of “44” for a lab test. This could not be identified with database checks because both values were inside the range. Because of remote monitoring, these errors were identified and the sites were able to correct them.

Remote monitoring is one more way PECARN produces high quality research. In recent audits, the majority of the data were correct, indicating sites are doing an excellent job. In fact some sites were error free in the last audit! However, we all want the data to be the best it can be, so look for more remote monitoring in the future.
**ACORN**
We would like to introduce two new Research Coordinators Matthew Albert, and David Johns. ACORN would like to congratulate Marlena Kittick on her upcoming wedding in October. Congratulations and best wishes from all of us!

**PED-NET**
Congratulations to Dr. George Foltin who became this year’s recipient of the EMSC Lifetime Achievement Award. Dr. Foltin’s entire career has been devoted to advocating for children and advancing pediatric emergency care throughout the nation.

PEDNET would also like to congratulate Madelyn Garcia (PI at University of Rochester for the Intra-abdominal Injury Study) on the birth of her baby boy (a future EMSC advocate).

**GLEMSCRN**
GLEMSCRN is welcoming Bema Bonsu, M.D., who will serve as the HEDA PI. Nationwide Children's Hospital is ranked as one of the nation’s ten largest freestanding children’s hospitals and pediatric research centers in the country. In 2007, the hospital was ranked 1st and 6th, respectively, on *Child* magazine's list of outstanding emergency departments and pediatric hospitals, and 12th on *U.S. News and World Report*'s list of best pediatric hospitals in the U.S.

The Great Lakes node has added Nationwide Children’s Hospital in Columbus, Ohio as the sixth Hospital Emergency Department Affiliate (HEDA). Bema Bonsu, M.D., will serve as the HEDA PI. Nationwide Children's Hospital is ranked as one of the nation’s ten largest freestanding children’s hospitals and pediatric research centers in the country. In 2007, the hospital was ranked 1st and 6th, respectively, on *Child* magazine's list of outstanding emergency departments and pediatric hospitals, and 12th on *U.S. News and World Report*'s list of best pediatric hospitals in the U.S.

The hospital, with 323 pediatric beds, is the sole pediatric tertiary care facility in Central Ohio and serves a population of 2.8 million, with one million in the pediatric and adolescent age groups. Nationwide Children’s is a level 1 Pediatric Trauma Center and the nation’s third busiest pediatric emergency department (NACHRI data). In 2006, Emergency Services (ED and Urgent Care Centers) had 144,523 visits. When restricted to the ED alone, there were 76,152 visits in 2007.

Nationwide Children’s hospital will be known as site 31 in PECARN.

**CDMCC**
Congratulations to Sally Jo who was the beginning women's 3rd place finisher in the Solitude Mountain Bike Race Series (DFL). The course was 3.7 miles of Utah’s best single track with over 1000 vertical feet of climbing topping out at 8700 ft.

CDMCC would also like to welcome the newest members Emily Bell (Statistician), Linda Herrera (Data Manager), and Angie Marchant (Statistician).

Congrats to Anna Davis who completed the Ogden Utah Marathon in 3:13. Go Anna!

**Nodal News**

**IRB Reminders**
A note from the CDMCC
While it is primarily the site’s responsibility to renew IRB approval, the CDMCC makes every attempt to send out regular IRB renewal & closeout reminders to sites.

Accurate, timely documentation is **key** to efficiency at the CDMCC. Please make sure that you send all IRB renewal documents prior to the expiration date to avoid a documentation lapse. Also, please double check to be sure all the necessary information is on the approval including expiration date, name of study including version number, and name of site.

The CDMCC sincerely appreciates all of your prompt responses and willingness to help in this important responsibility.

- Heidi Niitsuma
New Faces

ACORN

At CHOP, we would like to welcome Matthew Albert. Matthew studied English at Georgetown University, but is currently in the process of applying to medical school.

At UCD, we would like to welcome David Johns. David recently completed his B.S. in Biochemistry and is also in the process of applying to medical school.

CARN

Angelique Hrycko was born in Philadelphia and is an only child. She loves being with family and friends, the beach, outdoor activities, her favorite bands are Led Zeppelin and Dave Matthews Band (that’s only obvious since she’s seen the Dave Matthews Band 26 times since the age of 12). Angelique graduated from Boston College in 2008 where she studied biology and theology. She joined PECARN because she wanted to gain clinical research experience, and learn more about research and patient care. Angelique plans to go to medical school, as well as obtain a master’s in public health.

Sandy Wong just graduated from Northeastern University where she majored in Psychology with a concentration in Biological and Chemical Sciences. Her leisure time resides in reading and playing volleyball year-round. Sandy is excited to join the PECARN research team. Her curiosity drives her to pursue a career in pediatric research. With the collaborative effort of so many sites, the PECARN network conducts intriguing studies on a daily basis and she hopes to embark on a future career in neuroscience.

Nina Badoe, B.S is joining PECARN as a Research Coordinator for the IAI Study.

Britni Barnes, B.S is joining PECARN as a Research Coordinator for the IAI, Biosignatures, and Seizure Studies.

GLEMSCRN

Phillip Villanueva: I am delighted to join PECARN as the new research coordinator for the University of Michigan. I received my Bachelor of Science degree from the University of Michigan in 2005. Prior to joining the network, I worked in nicotine addiction research and health care decision making research. My outside interests include traveling, golf, and Michigan football.

NEW FACES

Here are some of the new faces of PECARN. If you haven’t had the chance to welcome them or meet them - there’s no time like the present! So introduce yourself and say hello.

Nationwide Children’s Hospital

Daniel M. Cohen, MD, the associate Director of Emergency Medicine at Nationwide Children’s Hospital will also work with the network. Dr. Cohen is an Associate Professor of Clinical Pediatrics at The Ohio State University College of Medicine. Dr. Cohen also serves as Medical Director of the Department’s nurse practitioners. His clinical and research interests in emergency medicine include the evaluation and treatment of acute orthopedic injuries ranging from bedside evaluation to imaging and sedation. He is active in the Med 3-4 Program of The Ohio State University College of Medicine and is Chairman of the Student Review Sub-Committee.

Bema K. Bonsu, MD, is joining GLMSCRN as the HEDA PI at Nationwide Children’s Hospital in Columbus, Ohio. Dr. Bonsu is an Attending Physician in the Emergency Department at Nationwide Children’s Hospital and an Assistant Professor of Pediatrics at The Ohio State University College of Medicine. He is a member of the Society for Pediatric Research. His research interests include acute infections and inflammatory conditions, sickle cell disease and the creation of surveillance tools in the Emergency Department for monitoring emerging infections and acts of bioterrorism.

Gabriela H. Sullivan, MPH, will be starting as the new Clinical Research Coordinator in early October. She has been working in health/wellness education & prevention at the University of Vermont for the past four years. During that time she ran the peer health education program and HIV testing clinics on campus, as well as coordinated a variety of assessment & research projects. She has a Master's of Public Health with a concentration in International Health, as well as a B.S. in Microbiology. Gabriela brings both public health research and laboratory-based research experience. Gabriela is originally from Lima, Peru.
Emily Bell (CDMCC)

I have been a PECARN statistician for three months and am working on the IAI project. Working on interesting projects with researchers from all over the country has been a great learning experience that I have thoroughly enjoyed. I enjoy researching new statistical methods, and my areas of interest include ordinal regression and alternatives to kappa. I have loved math for most of my life and find statistics as the perfect way to use math to solve interesting and important problems.

I recently finished my MS degree in Statistics at Brigham Young University where I had the opportunity to work on consulting projects and as a teaching assistant. Prior to studying there, I was a high school math teacher. I am originally from Oklahoma and have now lived in Utah for about ten years. My husband and I are expecting our first baby in January.

Welcome to PECARN!