

In a nutshell

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JACOBI MEDICAL CENTER IN THE SPOTLIGHT

Article by Deborah V. York

During 2008, we hope to spotlight PECARN HEDAs and describe the institution, the ED and how each institution conducts PECARN research. For this issue of the PECARN Newsletter, we are spotlighting Jacobi Medical Center, part of PEDNET.

Jacobi Medical Center, in the Morris Park section of the Bronx, NY, was founded in 1955 and serves as the teaching hospital for Albert Einstein College of Medicine, which is directly across the street.

Jacobi provides health care for some 1.2 million Bronx and New York area residents. One of 11 municipal hospitals that comprise the New York City Health and Hospitals Corporation (Bellevue Hospital Center is another NYC Health and Hospitals Corporation facility), Jacobi is also a regional center for burns, snake bites and hyperbaric medicine, boasting the only multi-person hyperbaric oxygen chamber in the New York City area. Jacobi's Pediatric Emergency Department (ED) is the only Level I pediatric trauma center in the Bronx or southern Westchester County. The pediatric ED is located in a brand new facility, which includes 15 exam rooms and 2 state-of-the art trauma bays with direct access to the ED radiology suite. In addition, there is a special child abuse interview room. There is a 16 patient asthma treatment area staffed by respiratory therapists, 24 hours a day.



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Approximately, 40,000 children under the age of 18 years receive care each year in the pediatric ED. Ninety percent of the patient population is either African American or Hispanic. The Pediatric Emergency Medicine (PEM) division consists of 8 PEM trained attendings and 7 PEM fellows. Dr. Ellen Crain serves as the Division Director, as well as the PECARN site PI for Jacobi.



As a pediatric ED located in an inner-city academic medical center with consistent research output, Jacobi's pediatric ED is a prime spot for conducting PECARN research. In addition to the PECARN studies, Jacobi has 5 emergency medicine related studies currently underway in the pediatric ED at Jacobi. Dr. Crain is a renowned, established clinical researcher, particularly as a national leader in the area of pediatric asthma research in the ED. As principal investigator for the National Cooperative Inner-City Study and the Inner-City Asthma Study, sponsored by NIAID, Dr. Crain had overall administrative responsibility for the implementation of the studies at the Albert Einstein College of Medicine.

Jardiris Collado, the HEDA Research Assistant for Jacobi, describes the Jacobi staff as being very cooperative with study enrollment, in part resulting from the long-standing, strong academic mission of the Division and consistent site PI involvement. Ms. Collado relates that the close juxtaposition of the ED to the research offices allows for quick access to the facilities she needs to conduct studies, including an ability to monitor the patients in the ED. Ms. Collado attributes her positive experience doing research in the Jacobi pediatric ED to the experienced staff of researchers, knowledgeable in conducting and publishing research; a strong academic PEM fellowship with fellows dedicated to conducting research; and a patient population that is generally eager to participate in studies. When asked to enumerate the major challenges to doing research at Jacobi, she identified the lack of computerized patient logs that could be used to track enrollment and the difficulties involved in trying to secure patient follow-up in an inner city population.

JACOBI AT A GLANCE

- * Founded 1955
- * Serves 40,000 children annually
- * Level I Pediatric Trauma Center
- * Regional center for burns, snake bites and hypobaric medicine



Good Clinical Practice Tip

Q: Do we need to provide a copy of the signed consent form to the subject's guardian?

A: According to regulation 21 CFR 50.27

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject's legally authorized representative at the time of consent. A copy shall be given to the person signing the form.

Reference: "Code of Federal Regulations, Title 21, Part 50: Protection of Human Subjects. April 2006. Clinical Research Resources, LLC.



Federal Corner

The EMSC National Resource Center Welcomes Two New Program Managers

Jim Morehead, MEd, BS, NREMT-P has been involved in EMS data systems development, prehospital research and managing state EMSC programs. He will be overseeing the technical assistance to state partnership grantees, and can be reached at jmorehead@emscrcn.com or (202) 476-6861.

Jaclynn Haymon, RN, MPA recently worked at the American Red Cross, national headquarters, as a health associate with Disaster Services. Jaclynn is an experienced hematology/oncology nurse and will oversee the technical assistance for Targeted Issue and PECARN grantees. She can be reached at jhaymon@emscnrc.com or (202) 476-6843.

Health Resources and Service Administration (HRSA) Awards Ceremony Honors EMSC's Tina Turgel

Congratulations to Tina Turgel, RN, EMSC nurse consultant, on receiving the 2007 Administrator's Citation for Outstanding Group Performance for her participation with HRSA's Health Literacy Workgroup.

Federal Interagency Committee on Emergency Medical Services (FICEMS)

FICEMS was established by Congress to address EMS issues at the Federal level, through a coordinated approach among Federal agencies. Dan Kavanaugh (EMSC) and Susan McHenry (NHTSA) are serving as co-chairs of the Data and Research Technical Working Group (TWG) which includes representatives from many federal agencies including NIH and the CDC. A two-year work plan was developed focusing on increasing the coordination of federal agencies in the fields of EMS data and research; increasing the number of federal agencies that utilize EMS research agendas to inform policy and funding priorities; and improving the availability of standardized prehospital EMS information through coordination of resources and strategies to support the National EMS Information System (NEMSIS).

Fiscal Year 2008 (FY08) Funding

In December 2007, the House of Representatives and the Senate approved HR 2764, the Consolidated Appropriations Act of 2008 which includes \$19.454 million for the EMSC Program. The House previously approved \$22.3 million, the Senate \$20 million, and a conference committee had allocated \$19.9 million for the program. However, that previous bill was vetoed by the President. Thus reductions were made across all health related bills. HR 2764, has been signed by the President, resulting in an appropriation of \$19.454 million for FY08. This is a reduction of \$346,000 for the Program from FY07 where appropriations were \$19.8 million.

EMSC Reauthorization

Over the past few months, additional members of the House and Senate have become cosponsors of S 60 and HR 2464, the

Wakefield Act, to reauthorize the EMSC Program. The House version of the bill, introduced by Congressman Jim Matheson (UT), has 68 cosponsors while the Senate version of the bill, introduced by Senator Daniel Inouye, has nine cosponsors. No further action has occurred.

EMSC Briefing

The Congressional Children's Health Care Caucus hosted a briefing on EMSC in November to educate congressional staff on the importance of pediatric emergency medical care and the EMSC Program. Joe Wright, MD, Director of the Child Health Advocacy Institute at Children's National Medical Center in Washington, DC, EMSC NRC Medical Director and Charles Macias, MD, Associate Professor of Pediatrics at Baylor College of Medicine and a Targeted Issues (TI) grantee both presented about EMSC.

NRC Completes Updates to Pediatric Toolboxes

The EMSC National Resource Center (NRC) recently updated and reorganized toolboxes on medical direction, prehospital education, pediatric disaster preparedness, and pediatric pain. Each revised toolbox features web resources, a pre-populated PubMed search, and the recently added feature "Example Practices." This new section includes a description and relevant links to model programs in the United States.

Upcoming National Meetings

12th International Conference on Emergency Medicine,
April 3-6, 2008, San Francisco, CA; [www.acep.org/
meetings/2008icem](http://www.acep.org/meetings/2008icem)

EMSC Annual Grantee Meeting: June 25-27, 2008

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PECARN Study UPDATE

C-Spine Injury in Children

Case-control analysis: We have completed abstraction on 539 cases and their associated controls. More than 4000 queries have been sent and 99% have been resolved. Several sites underwent a systematic review of the coding of substantial injuries in September. Data cleaning and the preliminary analysis is underway. Two abstracts have been submitted for presentation at the spring academic meetings.

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 at limiting immobilization to those children who are at non-negligible risk for c-spine injury. Five sites have undergone IRB review and approval. The first focus groups and focused interviews were completed in St. Louis and Milwaukee. Plans are to continue in Washington, DC area and Salt Lake City.

Diagnostic Grouping System

The investigative group has worked with the CDMCC to make the Diagnosis Grouping System available to researchers and others interested in grouping diagnosis codes. Both an Excel and a SAS program have been created that will report 4 different groupings for ICD-9 codes entered into the programs. Three groupings are related to the DGS and one is related to the Severity Classification System. These groupings are also available in the cubes of the PCDP. The Excel and SAS programs have been tested for clarity and ease of use and will be available soon on the PECARN website. The DGS manuscript is being reviewed by authors

and will be submitted to Annals of Emergency Medicine.

Bronchiolitis Study

Drs. Corneli, Zorc, Holubkov, and Kuppermann are leading a secondary analysis of the bronchiolitis data (the whole study group will be acknowledged as part of the working group in any resulting publication). This analysis is focused on identifying those infants with prolonged lengths of stay, and development of a prediction rule to identify these infants with needed hospitalization. Sites are in the process of obtaining IRB approval to abstract and verify actual hospital discharge dates which will be needed for this analysis. Once complete we will begin data analysis and manuscript preparation.

Traumatic Brain Injury

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 has been ongoing throughout 2007, and is in its final phases. The study PIs continue to travel frequently to the PECARN Central Data Management and Coordinating Center (CDMCC) for data cleaning and analysis. Two abstracts were presented at the PAS and SAEM meetings in 2007- one abstract on the epidemiology of TBI in PECARN and another on the inter-rater reliability of variables for the decision rule. We have completed data analysis for the decision rule, and the manuscript describing these findings is in preparation. In addition, the manuscript regarding inter-rater reliability of clinical findings is almost ready for submission. We hope to submit

both manuscripts for publication by early 2008. We anticipate continuing to work on sub analyses throughout 2008, and submitted 5 abstracts regarding different TBI sub-studies to the PAS and SAEM meetings in 2008.

Prehospital Working Group

The data is undergoing cleaning and an abstract is being generated for the fall AAP meeting.

Intra-abdominal Injury

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. Patient enrollment began in May 2007. We have currently enrolled 3807 patients with a capture rate of 75%. Site monitors have now been trained and site monitoring visits will begin in February. The study will have another training session in April associated with the PECARN meeting in San Francisco. Patient enrollment is expected to continue through August 2009.

PECARN Core Data Project

All sites now have final 2006 data, and the cubes have been updated. The deadline for submission of 2007 data will be April 1, 2008. We will be happy to help in any way possible to streamline the submission process to the CDMCC. The PCDP working group is also developing the "Registry" project that will link PCDP to electronic medical record data as endorsed by the steering committee in September. For preliminary analysis of PCDP data, you can either use the cubes or complete a data request form. The cubes can be accessed at

PECARN Study UPDATE

<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

EMS Populations

Thanks to all the hard work of the PECARN investigators and research coordinators, the EMS study is well underway. Nearly all sites have IRB approval. Each agency has received a letter of explanation and an individualized request for their electronic data. We are tracking each agency's progress towards data submission and have set up eRoom accounts for agencies that are nearing submission. One EMS agency has successfully uploaded their electronic data to the secure eRoom and several others are close to submission. We continue to work with sites and agencies to work out existing obstacles to data submission. The CDMCC will work to clean these data and report back to agencies and sites as necessary.

Patient Safety

Data analysis is underway for the climate of safety survey, the PI survey on ED characteristics, and the association between ED characteristics and the perception of staff's climate of safety. Sites are transmitting their de-identified incident reports to the CDMCC. We have received 5 months worth of incident reporting data that will help us to determine ways to increase error reporting and reduce medical errors.

Therapeutic Hypothermia After Pediatric Cardiac Arrest (THAPCA)

The NHLBI has agreed to accept

our application for the (THAPCA) trials. Nearly 30 sites from PECARN, CPCCRN and a few other large children's hospitals will conduct two separate clinical trials that will study the efficacy of therapeutic hypothermia in both the out of hospital and in hospital settings.

Seizure

Four of the current ten participating sites have completed the community consultation phase and received formal approval from their IRB's to begin the RCT phase of this study. All site initiation visits have been completed for these sites. Initial enrollment for approved sites is expected to begin as early as January 2008. Community consultation is ongoing at all remaining sites.

Quality Performance Measures

This project, funded by an EMSC Targeted Issues Grant, began in September 2007. The first aim of the project, to identify clinically meaningful performance measures of quality that comprehensively reflect pediatric emergency care, is underway and has been approved by IRB's. Members of the project's four working groups have been finalized, PECARN Nodal Champions have been identified (ACORN: Alessandrini; CARN: Chamberlain; PEDNET: Tunik; GLMSCRN: Stanley) and an advisory panel is being formed. A library of EMSC quality indicators is being developed. First work group meetings will occur at the Steering Committee meeting on April 8th, 2008.

Biosignatures

The IRB submission materials were released to the study sites on November 20, 2007. The CDMCC conducted a thorough review of each

site's informed consent document prior to IRB submission to ensure that all required elements of consent were included. Twenty PECARN sites will be participating in this study as well as University of Texas Southwestern. Six sites, including the CDMCC, have received IRB approval. The study training session will take place on January 29, 2008 in New Orleans, prior to the PECARN Steering Committee Meeting.

Psychiatric Emergency Pilot Project

The study investigators are revising the manuscript after feedback from the Grant Writing and Publication Subcommittee. We hope to submit the manuscript for publication shortly.

Pediatric Sedation Pilot Study

Congratulations and a big thank you to the sites that have completed the sedation safety pilot study! 17 sites have completed 5 weeks of patient enrollment and data collection. Patients are continuing to be enrolled at 3 sites and one additional site is awaiting IRB approval. Dr. Roback and his team at the University of Minnesota are in the process of summarizing patient accrual numbers and capture rates. The pilot study data will be used to revise our NIH grant proposal. The data from this project will be used to refine the design and methods of a proposed multi-center ED safety study designed to enroll over 20,000 children receiving procedural sedation. This pilot will demonstrate feasibility of the methodology of the larger study, clarify the patient population of the multi-center sites, and produce data needed to make power calculations and test proposed statistical analyses.

Study Highlight

Jacobi's Secret to IAI Success

Written by Jardiris Collado and Dr. Stephen Blumberg

Anxious about screening patients?

Struggling with enrollment numbers?

Can't sleep at night worried about missed eligibles?



Fear not, PECARN! Jacobi's about to let out its best kept secrets on its Intra Abdominal Injury study success.

PREPARE:

Preceding the start of the Abdominal Trauma study, it was absolutely crucial that we enabled and empowered ourselves with the knowledge and resources necessary to accomplish the stated objectives. We identified as many potential barriers as possible, and then set up a staff training session. The purpose of the training session was to communicate the objectives clearly and effectively as well as the barriers that we had identified.

MAINTAIN:

So you've given your staff the ammo necessary to successfully become a lean, mean, enrolling machine. What now? Even the best machines get a little rusty at times so it is important to take preventive actions. Here we have weekly Fellows conference meetings where we address any questions and concerns, reiterate inclusion/exclusion criteria, provide updates if necessary all in an environment fostering continuous improvement.



MOTIVATE & UPDATE:

It's very important to keep the team motivated and positive about the study as well as current on its progress. Whether via weekly/monthly emails sent by either the PI or RA or face to face interactions, let your team know that they are working towards an attainable and important goal. Additionally, we let them know where we place compared to the other hospitals in the network to encourage them to continue their hard work.



REWARD & RECOGNIZE:

Let's face it, everybody likes to feel important and appreciated for their efforts so why not reward and recognize them? Give your staff public credit and acknowledgement for their contributions. Healthy competition is a good thing. It tends to bring out the best in everyone, so we have set up a rewards system based on enrollment numbers. For every patient enrolled or screened, the physician receives a star on the enrollment chart. At the end of the month, the physician with the most stars receives a small gift, a certificate certifying them as the "Enrollment Champ of the Month," and the satisfaction of seeing their name on the enrollment chart and certificate displayed in the ED staff area.

Congratulations!

Nodal News

CDMCC

On September 27th, 2007, Kym Call took the Society of Clinical Research Associates (SoCRA) exam. The certification examination is made up of five major subject areas: conduct of clinical trials, institutional review boards, regulations, ethical issues, and abstracting medical records. SoCRA established the certification program for clinical research professionals in order to create an internationally accepted standard of knowledge, education, and experience by which clinical research professionals will be recognized by the medical research community. We are happy to announce that Kym passed the test with flying colors and she is now a Certified Clinical Research Professional or CCRP.

This is a reminder, please send your IRB documentation to Colleen Cummins the CDMCC Executive Secretary, or the study coordinator. Colleen is also putting together the newsletter. To reach her you can call her at 801-213-3205 or e-mail her at colleen.cummins@hsc.utah.edu

Jennie Wade placed 5th place in the Women's A league season Series for in Utah Cyclocross Race. Cyclo-cross is a crazy, insane bicycle race that consists of many laps on a short course featuring, wooded trails, grass, steep hills. The races have large natural and unnatural obstacles requiring the rider to quickly dismount, jump or run over the barrier while carrying the bike, then remount all in one motion. The obstacles could be logs, rivers snow or mud. Does this sound sane to you? The races go on regardless of weather. One recent race took place in a huge blizzard. Despite rumors suggesting that running the IAI study leaves her bruised and battered, we would like to set the record straight by saying that her bruises are indeed from being beaten up on the cycling course.



Whos Who

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New Faces

ACORN

Dr. Cheryl Vance from UC Davis Medical Center is now serving as the PECARN HEDA PI for UCD. Dr. Vance has served as the site PI for the Lorazepam study since the study beginning, but is now expanding her role in PECARN. Dr. Vance is Professor of Emergency Medicine and Pediatrics and the Chief of the Pediatric Emergency Department at UCD. We would like to extend a warm welcome to Cheryl and hope you will all take the opportunity to introduce yourselves.

CARN

I am **Jennifer Anders, MD**, a pediatric EM physician at Johns Hopkins. I am thrilled to join the CARN team. Born in Nebraska, I joined the Navy to see the world, but I only got to see Lake Michigan. After training in Chicago, my husband and I came east. When not navigating the mean streets of Baltimore or the demands of the Hopkins IRB, we hike and camp with our daughter in Maryland's beautiful parks.

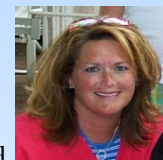


CDMCC

Please join us in welcoming **Marci Fjelstad** as a new study coordinator for the EMS study. We are excited to have her as apart of our team.

GLEMSCRN

I am **Beth A. Grundman** a Research Coordinator at Hurley Medical Center. I have been working on a pilot Pediatric Asthma Study, Pediatric Sedation Study, Intra-Abdominal Study and am looking forward to the upcoming Biosignatures study. I graduated from Eastern Michigan University. Majored in Family and Childhood Development with a minor in Early Childhood Education. Prior to working as a Research Coordinator and raising our children, I was a Director of Education in Livonia. I am enjoying being able to use my Childhood background in the pediatric emergency setting. My husband and I live in the Brighton area. We have 3 children Delanie 8, Kellie 4 and Gannon 3. When time allows I enjoy interior design, as well as playing & coaching softball.



Catriona Macardle Hi all! I am a newcomer to PECARN, but also a newcomer to America. I moved here from the UK after getting married a few months ago and I love it here. I have a BA in Anthropology and now I am in medical school. I am currently taking a couple of years off to live here, study for an MA in Medical ethics and Medical law, and learn how great research is performed!



Nodal News

ACORN

ACORN would like to congratulate Evie Alessandrini on her promotion to Director of Clinical Transformation for CHOP's new Institute to Transform and Advance Children's Healthcare. The mission of this program is to improve the health and lives of children using information to transform pediatric healthcare. Congratulations, Evie!

GLEMSCRN

PECARN/PERC Meeting : On a historical note, legendary arm-wrestler and RNC PI Rachel Stanley was defeated by Dr. Martin Osmond (Children's Hospital of Eastern Ontario Research Institute) at the Meeting this past November in Deer Valley, UT.

