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Why More Pediatric Drug Trials Are Needed

Did you know that reaching your first birthday used to be a lot tougher? In 1915, one out of ten babies died before their first birthday and another died before reaching the age of five. Today, more than 99% live to blow out the candle on their first birthday cake. The difference is lifesaving medicines. My own son has lived to reach his seventeenth birthday thanks to lifesaving medicines. He was life-flighted to Primary Children's Medical Center from an outlying hospital within 24 hours of his birth. Although he was born a month early, prematurity was not a factor in his deterioration after birth, but aspiration during the delivery. Upon arrival at the NICU, I was told he was given a 50/50 chance of surviving the night due to aspiration pneumonia. As a parent, I felt so helpless watching my tiny newborn son struggle for each and every breath. I wanted to breathe for him as I watched his little chest cave in with each inspiration. I will be ever grateful for the physicians and nurses that worked on him and also for lifesaving medicines that helped him to pull through. I'm sure his feisty spirit was a contributing factor as well. He actually pulled out his ET tube one morning and had to be reintubated. After ten days in the NICU on a ventilator, he improved and I was able to take him



JERI BURR, RNC, CCRC
Pediatric Pharmacology

home. Fortunately the medicines given to my son 17 years ago had pediatric indications; however, according to pharmacology experts, medicines such as ampicillin and gentamicin had not been adequately studied. Consider a more recent example reported in the January 2005 edition of "The New Yorker – Annals of Medicine."

"Not long ago, a three-year old boy fell off a jungle gym in Boston and lacerated his cheek. His parents rushed him to the emergency room of a nearby hospital. A nurse restrained the screaming boy while a surgeon cleaned his cheek and injected it with a small dose of bupivacaine, a local anesthetic that is widely used in adults. When the surgeon began to suture the wound, the child had a seizure and his blood pressure suddenly dropped; he was on the verge of going into shock. He was trans-

ferred to the intensive-care unit, where doctors tried to account for his symptoms. A CAT scan taken to see if the fall had caused cerebral hemorrhage showed no evidence of brain damage.

Maureen Strafford, a pediatric anesthesiologist and cardiologist, was paged to assist, and she found that the level of bupivacaine in the boy's blood was perilously high. The boy was intubated and placed on a respirator. He spent several days in intensive care before recovering from the overdose.

The package insert for bupivacaine does not provide specific dosing information for children; the ER surgeon had adjusted for the boy's weight by 'dosing down' from the amount recommended for adults. But such extrapolations cannot account for the differences in the biology of children. Even growing teen-agers who weigh as much as adults tend to absorb and metabolize medicine more quickly than adults, since organs that break down drugs, such as the liver, or excrete chemicals, such as the kidneys, take years to mature. The rate of blood flow to the skin and lungs is also higher in children, so topical or inhaled agents may be more rapidly absorbed."

Continued on page 3

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upcoming meetings

The PECARN Steering Committee Meeting is scheduled for Tuesday, May 3, and Wednesday, May 4, 2005 in Philadelphia, PA. The meeting will begin at 9:00 AM and will adjourn at 5:00 PM on both days. Breakfast will begin at 8:30 AM. It is recommended that those outside of the Philadelphia area arrive on Monday, May 2, in the afternoon or evening.

The PECARN Steering Committee Meeting will be combined with two study training sessions. On Monday, May 2 from 12:00 PM to 5:00 PM the Seizure Study training meeting will be held. Lunch will be available for those attending this meeting starting at 12:00 PM. Those outside of the Philadelphia area attending this meeting should plan to arrive on Sunday evening or Monday morning.

On Thursday, May 5 from 8:00 AM to 3:00 PM the C-Spine Injury Study training session will take place. Breakfast and lunch will be provided for the attendees of the C-Spine training meeting.

The PECARN Steering Committee Meeting and the study training session will be held at the Radisson Plaza – Warwick Hotel.

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Why More Pediatric Drug Trials are Needed continued...

Stafford stated that the surgeon's decision to improvise with bupivacaine was not unusual. Scientists, clinicians, and parents have allowed the pediatric population to be treated with unstudied medicines and therapies for years, while demanding a high level of evidence for therapies for the more stable, not growing, and less variable adult population. Although the FDA has long required that medications be screened for safety and efficacy in adults, approximately 75% of drugs approved for use in the US have never been subjected to comprehensive pediatric studies. This "off label" use is a huge problem in pediatrics. Pediatricians use medicines approved for adults, but not studied in children, all the time. A physician is allowed to use any FDA approved drug in whatever

way he/she deems beneficial and is not required to inform the parents if the drug has not been specifically tested in children. According to Stafford, regarding the three-year-old boy, "This is a perfect example of what can happen to a healthy kid."

The PECARN network is the perfect setting to institute and sponsor more drug studies for children. The infrastructure is in place to handle such multi-center clinical trials and the network has been trained on performing such studies according to Good Clinical Practice. Our children are our most valuable resource. They are the most complex, constantly evolving human beings on the planet and are waiting for us to make a difference. It is exciting to be a part of developing new medicines for children. With the knowledge gained about the use of existing

treatments and new molecular entities, our children will recover from illnesses more quickly, enjoy their childhood, and live to grow into healthy adults. I am in agreement with Diane Murphy at the FDA who states that the enormity and complexity of the new pediatric drug development program is obvious. It places an enormous responsibility on all of the parties and countries involved "to ensure trials enrolling children are designed, implemented conducted, and completed with rigor in monitoring and adherence to both good scientific and ethical principles." Seventeen years ago, I didn't know anything about Good Clinical Practices; however, thank heavens they exist! As a frightened young mother who just wanted her child to survive, I'm grateful for lifesaving medicines. Today, I love my work in clinical research and am glad to be a part of a network that is trying to make a difference.



CICELY AUGUSTINE, MPH
CARN Research Assistant

Consenting Immigrant Populations by Saajan Patel and Cicely Augustine

English, but even then, the question arises as to how much is understood. After all, one can easily recall a lecture or book, which though written in their native language remained confusing. Similarly, even translated information may not be fully comprehended due to the complexity of the material².

How then can one ensure that consent given is in fact informed, and is based on a feeling of true autonomy? Karen M. T. Muskavitch, a professor of bioethics at Boston College, offered a series of suggestions during a symposium series held at Indiana University³. The first suggestion is to evaluate body language when giving information, which is possible in both short-term and long-term studies. When the translator speaks to the potential enrollee, does the person seem to be considering the information to make their choice, or do they act as though receiving a set of instructions on what will happen regardless of their

decision? Long-term studies enable the researcher to begin a dialogue with the enrollee, educating them while assuring that information about the study continues to be understood as well as the ability to withdraw. Ultimately, Dr. Muskavitch makes the point that a greater initiative needs to be taken with regards to consent involving education of communities as to the principles of research and the rights of the research subject, an endeavor that goes beyond the mere signing of a form.

Emergency care settings pose unique challenges to researchers trying to obtain informed consent. In these settings, language barriers compound the challenges of patient recruitment. Daily, PECARN investigators and research assistants encounter patients that speak an array of languages. When consenting patients that are not fluent in English remember to: 1) Read the body language of the parent and the patient; 2) Seek the assistance of a trained medi-

cal translator when needed; and 3) Consider cultural beliefs about clinical research. Researchers who utilize the services of trained medical translators, and augment verbal explanations with written materials, may increase the patients' knowledge and understanding of the study, enabling them to make an informed decision about participating⁴.

1 Perkins, Jane. Overcoming Language Barriers to Health Care. *Popular Government*, vol. 65, no. 1, Fall 1999, 38-44.

2 Betancourt, Joseph R. Green, Alexander R. Carrillo, J. Emilio. "The Challenges of Cross-Cultural Healthcare—Diversity, Ethics, and the Medical Encounter" *Bioethics Forum* 16(3): 27-32.

3 Muskavitch, Karen M. T. APPE "Research Ethics: Cases and Commentaries, Vol 5."

4 Dawson, A, and S. A. Spencer. "Informing Children and Parents about Research." *Archives of Disease in Childhood*, 2005; 90: 233-235.

The principle of respect for persons, as stated in the Belmont Report, confers upon the researcher the responsibility of presenting information to a potential enrollee in a manner that enables the person, or the person's guardian, the ability to make an informed decision as to their participation. This process becomes more challenging when there is a language barrier involved.

Part of this problem is the descriptive nature of medical terminology and symptom description in English, as terms such as "hypertension" or "allergies" do not always have equivalents in other languages¹. This creates a situation where the Institutional Review Board must approve of consent documents translated from

Students For Hire-Cheap!

The structure and function of the RA-Tech at Primary Children's Hospital

It was getting into November and the buzz around the office was shifting from Head Injury to Bronchiolitis. Being a new Study Coordinator at a hospital lacking any pre-existing RA support reserves, I was faced with the daunting task of staffing a study I knew little about (except that it may or may not be funded). I did have the good fortune of having some advise from Stacey (last year's study coordinator), so I knew some of what I was up against. So I asked myself, "Self, where would one go to find eager help for meager reimbursement?" and of course I had to answer myself "Self, there is only one true destination, the local University". Being a graduate of the Health Promotion and Education Program, I knew there existed a particular niche of people in the EMS Education department just like those of us in the PECARN network; slightly twisted in their exuberance to perfect EMS services and provide the world with tried and true methodologies to better the care of the sick and injured.

In the end, I was able to set up 6 internships with undergraduate students at the University of Utah and I gained several advantages in doing so. As a part of the internship experience, I worked with our



KAMMY JACOBSEN, EMT
PCMC Research Coordinator

hospital administration and training departments to set up a temporary Triage Technician position for the Bronchiolitis RAs. Thus, while they were waiting for Bronchiolitis patients to show up (and we did a lot of that this year), they were able to sit at the Triage desk and assist with the assessment of patients. Aside from giving the RAs a birds-eye vantage point for the screening of study patients, this also created a sort of symbiosis between the study and the ED staff. It helped to eliminate some of the resistance to us tying up rooms for 4 hours and helped strengthen "the bond" between the RA and the ED staff.

Of the six interns, 4 were EMT-Basic, 1 EMT-Intermediate, and 1 EMT-Paramedic. This opportunity gave them valuable pediatric skills to use in conjunction with their

professional certifications and the study benefited from their knowledge in many ways as well. As a part of their educational curriculum, each of them had taken basic research methodology and had some experience in reading and writing research papers and were able to be quickly oriented to study procedures. Because of their certifications and past experience in EMS, they were able to quickly orient to hospital procedures as well.

At the request of the Internship supervisor at the University of Utah, the interns have planned to have an informational banner put in the hospital break room to inform emergency department staff of the PECARN network and the importance of EMSC. There will be accompanying brochures for those wanting more in-depth information. This will serve as a final project to meet the Health Education requirements and I believe, it will serve to improve communications between ED staff and the network and will increase enthusiasm for future projects (including another year of Bronchiolitis). All-in-all I believe I stumbled upon a "perfect fit" in my quest for cheap help. I look forward to doing it all again for another season next year.

PECARN Policy by Mike Shults, MA

We have a mandate and obligation from the National Data Demonstration Project (NDDP) grant guidance to create PECARN policies governing how we do our research. These policies begin with the Steering Committee (S.C.) Bylaws that govern how we go about creating and approving these policies. By majority vote we have approved Policy and Procedures that outline the roles and responsibilities of the S.C. and its subcommittees, an Intake Procedure for reviewing and approving new research proposals, an Implementation and Oversight Workflow covering how we conduct research, rules for publishing findings, as well as Standard Operating Procedures (SOP) that

address specific important topics. We currently have SOPs on Site Monitoring and Adverse Event Reporting, but plan to complete further SOPs on such topics as Protocol, CRF, MOO development as well as site, nodal, and CDMCC research performance. Our policy needs to be flexible enough to encompass a broad range of research environments and types of studies with PECARN. Appropriate policies provide working agreements that facilitate our research within this context and provide a consensus-based playing field. Towards that end it is constantly being revised and updated to facilitate and help us improve our efforts.

nodalnews

CDMCC

- Congratulations to Christy Hansen, CDMCC Executive Secretary, who welcomed a beautiful baby girl on April 5th. She was 5 lb, 11 oz, 19" long and was named Serena Hansen.

ACORN

- Duke Wagner has been promoted to the Research Coordinator position for the Di-

vision of Peds Emerg Med at MCW. Duke has a very interesting and unique background/skillset as a Chiropractor, running his own private practice for 12 years. We are lucky to have Duke and congratulate him on his new position in the ACORN node.

GREAT LAKES

- The Great Lakes node welcomes the

new nodal administrative team, Sherry Goldfarb, nodal administrator and Valerie Stevenson nodal project coordinator.

- We also welcome the following new research assistants: Elizabeth Duffy, Children's Hospital of Michigan; Betsy Wilson and Jeff Trytko at DeVos Children's Hospital/Spectrum Health System; and Nan Spawr-Seaton at Marquette General Hospital.

PCDP Abstracts

Abstract	Objective	Conclusions	Presentation
1. Epidemiology of Pediatric Emergency Department Recurrent Visits Author: Elizabeth Alpern	To describe the epidemiology of pediatric patients with recurrent ED visits.	A large number of pediatric ED visits are accounted for by a minority of patients with recurrent ED visits. Young children, those with public insurance, and some minority populations who visit the ED are at an increased risk for recurrent visits. Future evaluation of how these factors influence high ED utilization may improve patient care.	Pediatric Academic Society Annual Meeting Presentation Time: Mon., May 16, 5:15 PM - 6:45 PM. Poster Session III ~ Exhibit Hall (WCC) Society for Academic Emergency Medicine Presentation Time: Tues., May 24, 9:00 AM. Poster Session
2. Use of Geographic Information Systems (GIS) to Locate High Risk Areas for Injury Prevention Author: Jim Chamberlain	To determine whether there are high-risk census tracts for injuries requiring ED visits.	GIS mapping of readily available electronic data from hospital computer systems can be used to identify high-risk census tracts for community injury prevention efforts.	Pediatric Academic Society Annual Meeting Presentation Time: Monday, May 16, 12:00 PM. Platform Session ~ Room 150B (WCC)
3. Disagreement in Pediatric Emergency Visit Diagnosis Information From Administrative and Clinical Data Sources Author: Marc Gorelick	To determine the agreement on final diagnoses between two sources, electronic administrative sources and manually abstracted medical records, for ED visits in the nationwide Pediatric Emergency Care Applied Research Network (PECARN).	ED diagnoses retrieved from electronic administrative sources and manual chart review frequently disagree, even if similar diagnosis codes are grouped together. Agreement varies by institution and by diagnosis. Further work is needed to improve the accuracy of diagnosis coding; development of an EMSC-specific grouping system may be beneficial.	Pediatric Academic Society Annual Meeting Presentation Time: Tuesday, May 17, 8:00 AM. Platform Session Room 147 (WCC)
4. Descriptive Analysis of Psychiatric Related Illnesses in PECARN Author: Prashant Mahajan	To describe emergency department visits for psychiatric related illness (PRI) in PECARN.	The PECARN data is consistent with national data indicating that PRI visits account for a significant proportion of ED visits and adversely impact resource utilization.	Pediatric Academic Society Annual Meeting Presentation Time: Tuesday, May 17, 12:00 PM - 1:30 PM. Poster Session IV ~ Exhibit Hall (WCC)
5. Variations in Diagnostic Testing in the ED for Pediatric Non-urgent Illnesses Author: Rachel Stanley	To demonstrate variations in diagnostic testing in ED patients with non-urgent diagnoses.	Institutional practices may be more important than provider training, staffing models or hospital characteristics in determining diagnostic testing rates in children with non-urgent illnesses. Potential areas for future research include benchmarking diagnostic testing in well-defined risk groups and adherence to accepted testing guidelines.	Pediatric Academic Society Annual Meeting Presentation Time: Tuesday, May 17, 12:00 PM - 1:30 PM. Poster Session IV ~ Exhibit Hall (WCC)
6. The Epidemiology of Children With and Without Health Insurance Seeking Emergency Care in the Pediatric Emergency Care Applied Research Network Author: James Tsung	To describe and compare the subset of patients identified as lacking health insurance to insured children in the PCDP.	Uninsured children were more likely to use the ED for non-urgent problems and to have ED diagnoses related to lack of access to non-ED care. Children with chronic diseases presenting to EDs were more likely to be insured. Further study of uninsured children seeking care in EDs may provide additional information and insight into this vulnerable population of children.	Pediatric Academic Society Annual Meeting Presentation Time: Tuesday, May 17, 12:00 PM - 1:30 PM. Poster Session IV ~ Exhibit Hall (WCC)

pecarnupdate

Psych Working Group: Data collection for the PWG Pilot Project, "Referral Patterns and Resource Utilization for Pediatric Emergency Department Patients Presenting with a Psychiatric or Mental Health Problem: The PECARN Psych/Mental Health Working Group Pilot Study" is ongoing while investigators and Site Coordinators work to answer data queries. The group has been working on cleaning data and obtaining missing data elements from all five sites.

Head Injury Study: As a network, we have now enrolled more than 13,000 patients, putting us more than 1/2 way home! Our overall self-reported capture rate is ~ 80 percent. We expect to pick up enrollment numbers when summer starts again, when head injury rates unfortunately rise. Because we are slightly behind on the number of patients with a GCS 14-15 and with patients who have the outcome "TBI in need of acute intervention," we plan to continue enrollment through the originally projected date of March 2006. We are currently performing another round of site monitoring visits for all sites. Additionally, there has been some internal site monitoring in the form of PI self-audits implemented into the study. This monitoring has been critical to the success of the study, as it has helped insure and maintain data quality. It has become clear that in order to produce a very high-quality study that will greatly impact how we care for patients, we are asking the Site PIs to increase their oversight responsibilities. Site PIs are now performing intermittent audit checks on their site's eligible patient screening success. They have also started reviewing all CRF4s for patients with positive CTs and CRF 6s for patients who were hospitalized for 2 or more nights for data entry accuracy. Research assistants and coordinators have started the Patient Chart/CQI/Trauma Registry/Morgue checks for patients who left the ED and were unable to be contacted for follow

up. A great and hearty thank you to all participating PECARN members for all of your hard work. The Childhood Head Injury Study is going to be a great success!

Bronchiolitis Study: Despite a mild, low volume bronchiolitis season, participating sites did extremely well in enrolling eligible patients. The study is now on target enroll at least 600 total patients. A strong season next year could get us closer to the optimal number of 800 patients. Enrollment as of the end of April 2005 equals 209 patients for the season and over 400 total for both seasons. Some sites exceeded their enrollment of last year despite the mild nature of the disease across the country. Three sites screened and enrolled patients through March 31st and eight sites continued through April 20th. The three remaining sites have chosen to continue actively screening patients past April 20th due to the number of eligible patients that they are seeing and their enrollment rates through the month of April. Funding support from EMSC was received mid-study and was helpful in supplementing staff support. RA support was superlative. Reporting of adverse events and protocol deviations was thorough, and site monitoring visits were completed on schedule. The CDMCC will begin to clean the data once each enrolled patient has completed follow-up and all the data is entered into the database. Each site will receive an end of season site monitoring visit before the next Steering Committee Meeting in September.

Hypothermia Study: As of April 14th, there are 455 records in the Hypothermia database. Although the study ended December 31st, obtaining records has been challenging for some sites. We have extended the data submission deadline to Friday, May 20, 2005. Once all the records have been submitted, we will begin the process of sending queries and cleaning data. Thanks to all Investigators and

Abstractors for their hard work!

PECARN Core Data Project: The ongoing annual collection (2003-2007) of PCDP electronic data is now in progress. Sites should have already submitted IRB renewals or addendums in this regard. The deadline for the initial submission of 2003 electronic data to the CDMCC was March 15, 2005. To date, 11 sites have submitted 2003 data. The deadline for the submission of 2004 electronic data to the CDMCC is July 1, 2005. Please direct any questions regarding this process to Libby Alpern at alpern@email.chop.edu. Two manuscripts based on the original PCDP data have been submitted to journals for review. The titles of these two manuscripts are; "Epidemiology of a Pediatric Emergency Medicine Research Network: The Pediatric Emergency Care Applied Research Core Data Project" and "Availability of Pediatric Emergency Visit Data From Existing Data Sources". Two additional manuscripts are currently in preparation. In addition, six abstracts will be presented at the Pediatric Academic Society Annual Meeting (2 oral presentations and 4 poster presentations) and one at the SAEM Annual Meeting.

Use of Lorazepam for Pediatric Status Epilepticus: The Lorazepam Seizure Study is in full swing. Two patients have been enrolled by UC-Davis! Eight sites have IRB approval, 4 sites have been received site initiation visits, and several patients have been screened. Additional sites will be initiated in May. Since this is the first study that falls under FDA oversight for PECARN, we are learning a lot about regulatory documents, site monitoring and enrolling patients within minutes of ED arrival. We are also starting to plan for study 2, a randomized controlled efficacy trial of Lorazepam and Diazepam. Since the funding for study 2 is contingent on enrollments from study 1, all sites are working hard to get started and get (en)rolling.



eRoom

PECARN Core Data Project: <https://www.nedarcssl.org/eRoom/nddp/PECARNCoreDataProject>
 Hypothermia: <https://www.nedarcssl.org/eRoom/nddp/Study-HypothermiaPlanningGrant>
 Bioterrorism Surveillance: <https://www.nedarcssl.org/eRoom/nddp/Biosurveillance>
 Effectiveness of Oral Dexamethasone in Acute Bronchiolitis: A Multicenter Randomized Controlled Trial
 Clinical Decision Rules for Identifying Children at Low and High Risk for Traumatic Brain Injury
 Cervical Spine Injury Study: <https://www.nedarcssl.org/eRoom/NDDP/Study-CSpine>

newfaces

Sherry Goldfarb, Nodal Administrator



I am delighted to be the new nodal administrator for the Great Lakes Region. My educational background includes a Bachelor of Science Degree from Michigan State University and a Master of Public Health from University of Michigan. I began my career as a personnel management specialist at the Veterans Administration Medical Center in Ann Arbor. Later I served as the Staff Assistant for Consumer Affairs for the Regional Director of VA Great Lakes Region and as the Administrative Officer for Surgery Service at the VAMC in Ann Arbor. I left the VA system to become the Section Administrator for Plastic Surgery at the University of Michigan. I took some time off when I first had my children and then went back to work part time as a Research Associate in Plastic Surgery at the University of Michigan. My family includes my husband, Mike, two children, Alex 13 and Megan 10, and a little dog named Biscuit. I volunteer both in our school and the community and I enjoy many activities including traveling, skiing, horseback riding, reading, taking pictures and scrap booking when time allows.

Valerie Stevensen, Nodal Administrator

I started with the University of Michigan Health System as a respiratory therapist in 1987. During my time there I served as a supervisor, then as the Clinical Specialist in the Trauma-Burn Center. In 2002 I joined the Center for the Advancement of Clinical Research (CACR) as a clinical monitor/ project manager for NIH funded, multi-center trials for the University of Michigan Medical School. I have been married six years and have a 4 year old son named Miles. I enjoy snowmobiling and stained glass work.

Emmanuel Pena, Project Coordinator



I am the new Project Coordinator for the Lorazepam study at the Morgan Stanley Children's Hospital of New York-Presbyterian. For the past seven years, I have dedicated my time to the study of Biology. After obtaining my graduate degree with a focus on Cancer Biology last year, I decided to embark on a new journey in clinical research. I ultimately want to pursue a career in Immunology focusing on allergies in children. I am originally from NYC, but for my undergraduate and graduate studies I had the opportunity to live in New York's Hudson Valley. Living there sparked my interest for the outdoors. As a result of that, I have added running and hiking to my list of hobbies, which already included playing baseball and going to the movies.

Nan Spawr-Seaton, RN, MSN, CCRN, TNCC

I have been in nursing for the past 27 years in a variety of arenas. I am currently the Critical Care Clinical Nurse Educator for the Heart Institute at Marquette General Health System. I am active on a variety of committees, varying from Product Standardization to the Trauma Committee. I am responsible for the orientation and on-going education for our ICU and CCU. Additionally, I interview, manage, educate and mentor our Critical Care Internship program. In this program, we select from four to nine graduate nurses three times a year for a prolonged orientation. I have been married for the past 26 years. I have two children, ages 10 and 14. I also have two cats, ages 1 and 10 years. My hobbies include beaded jewelry and quilting.

Good Clinical Practice Tip

Q) "What is the purpose of monitoring?"

- A) The purposes of trial monitoring are to verify that:
- The rights and well-being of human subjects are protected.
 - The reported trial data are accurate, complete, and verifiable from source documents.
 - The conduct of the trial is in compliance with the currently approved protocol and amendments, with GCP, and with applicable regulatory requirements.

Reference: Good Clinical Practice: A Question and Answer Reference Guide. June 2003. Douglas Mackintosh, Dr.PH, MBA, MS Hyg, GCPA, Inc. Vernetta J. Molloy, MBA, RN, GCPA, Inc. and Mark P. Mathieu.

ct

lled Trial: <https://www.nedarcssl.org/eRoom/nddp/BronchiolitisRCTProject>

es after Mild Blunt Head Trauma: <https://www.nedarcssl.org/eRoom/nddp/HeadTraumaStudy>

Establishing a Research Assistant Program at your Hospital



PETER DAYAN, MD
PEDNET NODAL PI

Over the past few years, Dr. Dayan and I have been asked about how we run our volunteer research assistant (RA) program here at the Morgan Stanley Children's Hospital of New York-Presbyterian (MSCHONY) and how we have been so successful recruiting volunteers. As you all know, having help makes all of the difference, and without it the PECARN work load can become unbearable. Therefore, we would like to take some time to provide you all with some information on how to create and develop a successful volunteer research assistant program at your respective hospitals. However, if your department is only doing one or two research studies at any one time and is not thinking about the possibility of adding more studies, then establishing a full RA program is not worth it.

The first thing that you will need to do is to identify and select a dedicated attending physician and coordinator from your department to supervise the volunteer program. Having two supervisors is necessary because the workload is too much for any one physician to handle on his or her own. The coordinator can be anybody that you would like it to be (an existing RA, a department administrator, an administrative assistant, etc), but it should be somebody that is full-time at your hospital that is easily accessible. It will be their responsibility to make sure that the RAs have all taken and passed GCP and HIPAA exams for your institution, answer any and all questions that the

RAs might have, write medical school recommendation letters when necessary, and handle any other issues that may arise.

Identifying areas where you can recruit potential RAs can sometimes be difficult. We have found that some of the best places to recruit RAs are from local colleges and universities, especially through a Pre-Health or Pre-Professional Office. These offices can easily reach more students than you can through posting flyers around any campus. Now depending on the resources available at your hospital, you will have three options for establishing your program. You can either establish your program for pay, college credit, or purely volunteer. At MSCHONY, our RA program is the purely volunteer type. If you go the volunteer route like us, then play up that being part of your program looks good for medical school applications. Also, because you have established a good relationship with the Pre-Health or Pre-Professional Office or Academic Dean's Office, these offices will reinforce the benefits of being a part of a program like yours.

Second, and probably the most important thing, is to make the program interesting to all of the volunteers. The more interesting you can make it for your volunteers the better the experience is for them. This can be accomplished by frequent meetings where you are teaching them something either about a new study that is about to be implemented in the department, or giving them frequent updates on the status of the studies that they are assisting with. The latter option is helpful because this way the RAs can all see what they are contributing to even if they are not recruiting too many of the study patients while they themselves are in the Pediatric Emergency Department (PED). Another reason for holding a meeting may be to gain feedback from the volunteers as to how the program is going and what areas can be improved upon. Without the pulse checks, the program will not be as successful as it can be and not have a



CARL BROWN, MPH
RESEARCH COORDINATOR

high retention rate of volunteers from year to year. Providing the RAs with food and refreshments at these meetings, it is a good idea.

Third, and this point is very closely related to the previous point, you have to give the RAs a specific role while they are in the PED. Because the PED can sometimes be quite chaotic, many of the RAs can become intimidated while they are in there, and too scared to approach any of the staff members. However, if they have a clearly stated role, then it helps break the ice for them and the PED staff. Another important icebreaker is for either the supervising physician or coordinator to frequently show up in the PED and help smooth out any issues that RAs may have. The RAs will appreciate it more than you will know.

Now, all of this may seem like a lot of work, but the rewards gained by having the volunteers is well worth the effort. If you do set up a research assistant at your hospital, the more successful you will be at doing research out of your PED, and the better the data will be as well. Furthermore the more help that you have and the better the data that you gather, the more research you are able to do at your hospital. This last point has definitely happened here at MSCHONY. As the volunteer RA program has grown, so has the amount of research projects that we are able to do here to our delight. We hope that this has been helpful to you, and that you are able to create a successful program of your own.

Bronchiolitis Site Monitoring by Rita Gerard, BS, CCRP

Many of you have asked what to expect when I come to visit your site to monitor the Bronchiolitis study. I have outlined an example of a monitoring day below:

Please Note: This is not an exhaustive list of the items reviewed. This list is meant to give an idea of the level of detail at the monitoring visit.

0900-0930: Arrive at the site

- Inventory the documents provided, ask for documents that are missing
- If medical records are not provided, ask RA where they are located
- Ask RA if we have an appointment with the pharmacy(if applicable)
- Ask RA "Is there anything you would like me to know before I get started?"
- Ask RA to check back with me in a few hours

0930-1030: Review the Essential Document binder and MOO

- Confirm that approved version numbers are most recent (Protocol, CRF, etc)
- Note consent form versions/dates approved for reference during participant record review
- Review certificates for expiration dates(e.g. Medical licenses, CAP/CLIA)
- Review Delegation of Responsibility, noting individuals that have been given consent privileges, to compare to participant consent forms
- Review for current season documents (e.g. emergency unblinding, DSMB letter)
- Note any SAEs and protocol deviations for participant chart review comparison

1030-1230: Study participant document review

- ICF review:
 - ~Check each page for blanks,
 - ~Confirm that the signed consent was the correct/approved version at the time of consent
 - ~Confirm consentor is authorized to give consent,
 - ~Confirm that signatures are dated by signer,
 - ~Confirm that a consent note file was completed
 - ~Review consent form note to file and note time of consent
- Source Verification-compare CRF data points to source document file
 - ~Check each CRF page for blanks
 - ~Note inconsistencies between source document and CRF for RA review and correction if appropriate
 - ~Confirm day of follow up is within 10 days of drug administration
 - ~Compare time of consent, time of randomization and time of drug administration to make sure they happened in that order
 - ~Confirm times of vital signs are within protocol specifications
 - ~Note any protocol deviations not yet documented by RA

1230-1330: Medical Record Review

- If medical records are at a separate location, go to location and review charts
- Review for eligibility and adverse events

1330-1415: LUNCH

1415-1445: Meet with RA regarding regulatory document review

1445-1515: Inventory study drug

- Confirm inventory based on shipped minus administered
- Confirm vial numbers match inventory sheet
- Is drug adequately secured?
- If there is a research pharmacist: ask how things are going, any problems?

1515-1545: Review screening logs (usually in the ED, so I have a mini tour of the ED)

1545-1615: Meet with PI to go over findings

1615-1700: Work with RA

- Review findings in detail with RA,
- Make corrections if possible,
- Collect missing documents if available
- Teaching points: For instance, I may spend 20 minutes on the importance of and reasons for documenting informed consent
- Interview RA regarding specific CDMCC concerns (i.e. consenting process)

1700: Thank you for all your hard work, see you again soon...

Federal Corner

This edition highlights recent meetings of interest to the EMSC research community and announces that the new EMSC Research Program Announcement PA-05-081 was published in the NIH Guide to Grants and Contracts. This joint research funding initiative involves MCH Research, AHRQ, CDC/NIOSH and 5 NIH agencies committed to support EMSC research (topic must coincide with their agency's mission). For more information on the PA, agency priorities, or proposal submission, go to <http://grants.nih.gov/grants/guide/pa-files/PA-05-081.html>

February 11th, the Interagency Committee on EMSC Research (ICER) met in Rockville, MD, where Mike Dean presented an update on PECARN. Also at the meeting:

1. The CDC/NCIPC presented their new research agenda. They had decided the agenda needed to focus more on acute injury care, especially:

- Interventions in acute care settings (i.e., teachable moment)
- Measuring of costs & benefits
- Clinical information systems – pre-hospital and hospital communication
- After a public comment period on the draft, the final research agenda will be presented in May 2005 at the CDC/NCIPC Annual meeting in Colorado.
- They are considering whether new or existing (e.g., PECARN) networks should be used for acute injury care research.
- Translating research findings from evidence-based guidelines into practice is a major challenge.

2. The National Institute of General Medical Sciences (NIGMS) will fund trauma research, but not clinical trials. NIGMS could fund genomic work such as serial expression (this is already happening for adult trauma, pediatric burn, adult & pediatric sepsis), proteomic work, or any other physiological process.

- NIGMS has trauma-based training awards (T-32) which include some pediatric critical care. <http://grants1.nih.gov/training/nrsa.htm#inst>.
- The K-23 (mentored patient-oriented research career development award) is an option for EMSC researchers who are also health professionals. <http://grants1.nih.gov/training/careerdevelopmentawards.htm>

3. The CDC's National Center for Health Statistics (NCHS) data on ED visits (advanced data summary) is available in April and includes 2003 supplement data on pediatric preparedness (as well as bioterrorism and ambulance diversion).

- 2005 ED data collection has new items including an indicator that the patient was discharged from a hospital within last 7 days.
- Funding from MCHB's EMSC Program will allow NCHS to again field the Emergency Pediatric Services & Equipment Supplement (EPSES) in 2006, with an expanded sample of children's hospitals.

February 16th, the federal Interagency Subcommittee on Medical Research (ISMR) met in Bethesda, MD. ISMR is co-chaired by Dr. Michael Weinstein of the National Center for Medical Rehabilitation Research (NCMRR) and Dr. Theresa SanAgustin of the National Institute for Disability and Rehabilitation Research (NIDRR):

- T-awards are available from NICHD for pre-doctoral fellowships and training programs. (FYI, the National Institute for Neurological Disorders and Strokes (NINDS) gives a good

score for K or F award grantees who apply for R01s.)

- Social Security Administration has data linking TBI hospitalization with children's benefits program. For more information, contact Dr. Sandra Sala at ssala@ssa.gov
- This summer, NCMRR hosts a research agenda development meeting in Bethesda, MD. <http://www.nichd.nih.gov/new/conferences.htm>

March 2-4, the IOM Committee on the Future of Emergency Care in the U.S. Health System met in California. The study objectives are to: (1) examine the emergency care system in the U.S.; (2) explore its strengths, limitations, and future challenges; (3) describe a desired vision of the emergency care system; and (4) recommend strategies required to achieve that vision. <http://www.iom.edu/project.asp?id=16107>

April 10-12, the American College of Emergency Physicians (ACEP) held the "First Annual Advanced Pediatric Emergency Medicine Assembly" in Washington, D.C., which included a focus on celebrating the accomplishments of the EMSC Program over the past 20 years. <http://meetings.acep.org/meetings/PEDS05>

April 11-13, the EMSC Annual Grantee Meeting was held in Bethesda, MD. EMSC grantees and national organization partners join ACEP on the evening of Monday, April 11th as part of celebrating the EMSC Program's 20th year

By press time, the EMS Research Strategic Plan (a joint effort of MCHB/EMSC & NHTSA) will be accepted for publication in Prehospital Emergency Care. This Plan is one of eight major recommendations of the National EMS Research Agenda, encouraging concentrated efforts by EMS researchers, policy makers, and funding resources to improve clinical outcomes for EMS patients. Clinical issues targeted for additional research efforts include evaluation and treatment of patients with asthma, acute cardiac ischemia, circulatory shock, major injury, pain, acute stroke, and traumatic brain injury. The Plan calls for:

- Developing, evaluating, and validating improved measurement tools and techniques
- Research to improve the education of EMS personnel
- Research on system design and operation

Implementation of the EMS Research Strategic Plan will improve both delivery of services and care of individuals who access EMS. See www.researchagenda.org for more on the Agenda or the Plan.

To join the EMSC Research Listserv, send an email with your Name, Title, Institution and Phone number to emscresearch@emscnrc.com and you will receive weekly mailings.

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spotlights

RICH HOLUBKOV, PHD (CDMCC)



Rich Holubkov is Associate Professor in the Department of Family and Preventive Medicine at the University of Utah. He spends much of his time as Biostatistician for PECARN, and will also be very active on the new Collaborative Pediatric Clinical Care Research Network. Rich spent more than 12 years at the University of Pittsburgh, where he worked on randomized clinical trials in cardiac surgery and interventional cardiology. He finds the PECARN group much less stressful than working with surgeons! Rich earned his Ph.D. in Biostatistics from the University of Washington. Rich and his wife Dai decided to move from Pittsburgh to Salt Lake City after their daughter Josephine was born in 2001, so she could grow up in the sun surrounded by mountains. Rich enjoys hiking, traveling, and randomizing people and mice.

MARTIN PUSIC, MD (PEDNET)



Dr. Pusic obtained his Medical Degree from the University of British Columbia, a Fellowship in Pediatric Emergency Medicine at McGill and his Masters Degree in Medical Informatics from Columbia University. Dr. Pusic has only recently taken up a position with Columbia University after three years at the University of B.C. He has also worked at McGill, Dalhousie and Johns Hopkins Universities. Despite this varied geographical background, he has maintained an unwavering interest in the use of educational technology in clinical settings. He is particularly interested in the interface between education and clinical decision support. He has developed focused computer tutorials that can be delivered immediately after a trainee's interaction with a patient in an Emergency Department. He is also finishing development of an online research methods course for Clinical Fellows. Dr. Pusic has also been the site coordinator for the Pediatric Emergency Research Canada network and looks forward to helping international communication between pediatric research networks since he speaks fluent Canadian. He is happily married and has two sons, Michael and Luka.



SALLY JO ZUSPAN, RN, MSN
CDMCC PROGRAMS MANAGER

The FDA Modernization Act, enacted in 1997, mandated the creation of a database of information on clinical trials called the Clinical Trials Data Bank (CTDB). This registry creates a public resource for information on studies of drugs to treat "serious or life threatening diseases and conditions" and is maintained by the NIH in collaboration with the FDA. (www.clinicaltrials.gov). Federally funded clinical trials conducted under an investigational new drug (IND) application are required to submit information to the CTDB registry if the drug is used to treat a serious life threatening disease or condition. A federally funded researcher may also submit information on trials that exam-

Clinical Trial Registries: What are they and who needs to register?

ine non-serious conditions, but this is optional. The FDA published recommendations in 2000 that outlined submission requirements and for industry however industry submission is currently voluntary.

Just a few months ago, the Fair Access to Clinical Trials (FACT) Act was introduced with the intent of expanding the trial registration. Introduced in both the House and the Senate (HR 5252 and S 2933), the bills would require clinical trial sponsors to register all publicly and privately sponsored trials with the existing government registry. The legislation would require both federally funded and privately funded researchers to enter their clinical trials into a Federal registry and to report the results of the trials at the conclusion. It also expanded reporting to medical device trials.

Concern about selective reporting of clinical trials has recently driven medical journals to mandate registration. Because researchers often fail to report negative trial or inconclusive trial findings, the International Committee

of Medical Journal Editors (ICMJED) recently proposed registration in a public trial registry as a condition of consideration for publication. Many medical journals have followed suit. JAMA published an editorial in fall, 2004 iterating its intention to require registration before publication. Trials must be registered at or before the onset of patient enrollment and effects any clinical trial starting enrollment after July 1, 2005. For trials beginning prior to this date, ICMJED member journals will require registration by September 13, 2005. (Clinical trial registration. JAMA. 2004; 292: 1363-1364).

In PECARN, bronchiolitis is the only study that currently qualifies for registration. CDMCC has submitted a request and the trial will be registered soon.

Additional Resource Information on clinical trials can be found at <http://clinicaltrials.gov/info/resources> See the JAMA editorial at <http://jama.ama-assn.org>.

PECARN on the Road...

Month	Site	Study / Studies
January	Johns Hopkins Medical Center	Bronchiolitis
	Children's Hospital of Michigan	Bronchiolitis, Head Injury Study
	Children's National Medical Center	Bronchiolitis, Head Injury Study
	Cincinnati Children's Hospital Medical Center	Bronchiolitis, Head Injury Study
	Washington University and St. Louis Children's	Bronchiolitis, Head Injury Study
	Bellevue Hospital Center	Head Injury Study
	Children's Hospital of Buffalo	Head Injury Study
	Primary Children's Hospital	Head Injury Study
	St. Barnabas Health Care System	Head Injury Study
	University of Rochester	Head Injury Study
February	Upstate Medical University	Head Injury Study
	Bellevue Hospital	Bronchiolitis
	Children's Hospital of New York	Bronchiolitis
	Children's National Medical Center	Bronchiolitis
	Primary Children's Medical Center	Bronchiolitis
	University of Rochester	Bronchiolitis
	Upstate Medical University	Bronchiolitis
	Calvert Memorial Hospital	Head Injury Study
	Children's Hospital of Philadelphia	Head Injury Study
	Cincinnati Children's Hospital Medical Center	Head Injury Study
March	Holy Cross Hospital	Head Injury Study
	Howard County Hospital	Head Injury Study
	Medical College of Wisconsin and Children's Hospital of Wisconsin	Head Injury Study
	University of Maryland	Head Injury Study
	UC Davis Medical Center	Hypothermia
	Children's Hospital of Buffalo	Bronchiolitis
	University of Rochester	Bronchiolitis
	Upstate Medical University	Bronchiolitis
	DeVos Children's Hospital	Bronchiolitis, Head Injury Study
	Hurley Medical Center	Bronchiolitis, Head Injury Study
April	Children's Hospital of Michigan	Head Injury Study
	UC Davis Medical Center	Head Injury Study
	Calvert Memorial Hospital	Head Injury Study
	Children's National Medical Center	Head Injury Study
	Cincinnati Children's Hospital Medical Center	Head Injury Study
	Johns Hopkins Medical Center	Head Injury Study

Need Help Writing Your NIH Grant?

The National EMSC Data Analysis Resource Center is inviting PECARN investigators (faculty and fellows) to its Scientific Grant Writing Workshop August 24 - 26, 2005 at the Swissôtel Chicago. This is an excellent opportunity to have dedicated grant writing time and to receive vital feedback that could save you weeks in the writing process!

The workshop will be lead by distinguished NEDARC/PECARN faculty who will instruct and assist you as you write your NIH-funded grant. Over the course of the workshop, you will draft each section of your grant application on your laptop computer (Specific Aims, Background and Significance, Preliminary Studies, Research Design and

Methods) while receiving continual feedback from faculty.

This workshop is for experienced and inexperienced grant writers seeking to improve their skills on research-oriented grant writing. Pre-workshop preparation includes writing and submitting your hypothesis and specific aims. NEDARC/PECARN faculty will provide immediate feedback on these at the beginning of the workshop.

There is no charge to attend the workshop or for the workshop materials; printers will be available on site. Attendees are responsible for their travel and lodging.

The registration deadline is July 1, 2005. Be sure to sign up soon as space is limited. If you are interested in attending, please contact Cindy Wilmschurst at cindy.wilmschurst@hsc.utah.edu or at (801) 581-7280. We hope you will join us!