



CENTRAL DATA MANAGEMENT COORDINATING CENTER

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What Mike Says...

I'd like to welcome you to the new CDMCC newsletter. It has been two years since the beginning of PECARN, and we have had remarkable progress in our network. The logical question is "Why a newsletter?" and especially, why is a digital organization resorting to paper and printing? Here are some reasons:

There are some occasions on which you really want to read something in a location that is distant from a computer.

Newsletters can convey an overview on paper that is sometimes hard to demonstrate with Web based pages and so forth. By reading this newsletter, you can get a flavor for things going on at the data center. By making it a complete, but digestible whole, we can also try to convey a little humor in what is sometimes a dreary, nerdy field.

More importantly, we believe that people like you will read this newsletter, if not for any reason than curiosity. If you can get through the eight pages, we can tell you about some important topics that you will otherwise not want to learn. Honestly, how many of you would have logged in to retrieve a Web page on patient randomization? Or proper methods of password protection? Or a biographical sketch on the new staff members



J. MICHAEL DEAN
Principal Investigator

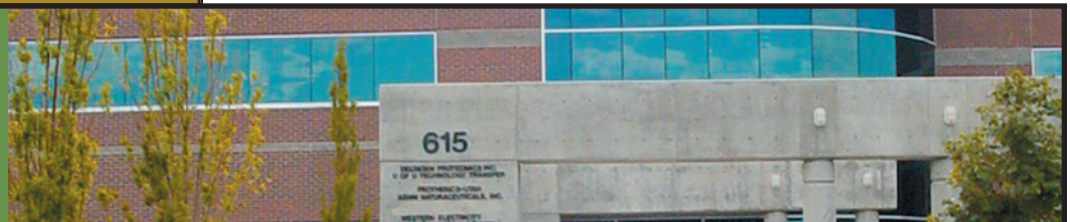
at the data center?

Don't lie (I READ the eRoom™ log files before breakfast every morning, and there are a lot of you who don't read everything available!)

PECARN is going through a lot of changes, and the CDMCC will also be changing. We are changing because of our success as a network. Nobody would have anticipated that we would have several funded projects underway as this newsletter is being written. We have built a grant writing machine, and we are now becoming a research project implementation machine. Congratulations to YOU.

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who's who

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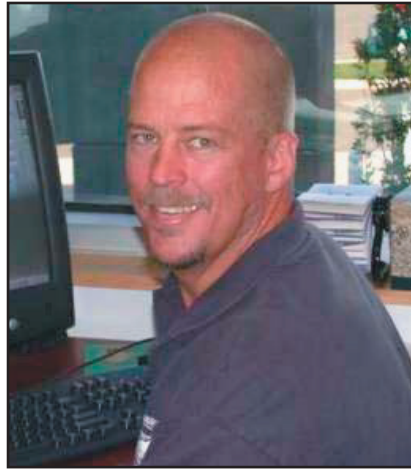
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We Want to Hear From You



CLAY MANN
Director of Research

Over the next few weeks the CDMCC will be conducting a phone interview with all HEDA Directors and Research Assistants to elicit information about your experience with the PCDP Project. We are hoping to discover what aspects of the project they thought were done well and what aspects of the research process could be improved. Since additional research projects will

soon be underway, PCDP investigators are interested in knowing how we can make the process smoother for all involved.

HEDA Directors and Research Assistants!

Please plan to receive a phone call from the CDMCC in October or November to conduct the PCDP phone interview. We expect the interview to take 30 to 45 minutes to complete. Please contact Dagan Wright if you wish to schedule a time to complete the interview (801) 587-7609. Otherwise, Dagan will contact you.

The PCDP interview is designed to elicit your response to survey questions in two ways. First, you will be asked to give your overall impression of a survey item. Next, you will be asked to provide specific details that lead you to give the overall impression that you did. Honest and complete answers will help us improve the research process associated with future PECARN projects. Please feel free to share any information that you think is important.

upcoming meetings

The **Bronchiolitis Study Training** is scheduled for **Thursday, October 16, 2003**, starting at 8:00 a.m. and will continue until approximately 5 p.m. The day will start with a Continental Breakfast at 7:30 a.m. Those attending the Bronchiolitis training meeting should plan to arrive on the evening of Wednesday, October 15th.

The **PECARN – Steering Committee Meeting** is to take place, **Friday and Saturday, October 17 and 18, 2003**. It is recommended for those outside of San Francisco to arrive on Thursday, October 16th, afternoon or evening, as the meeting begins on Friday at 9:00 a.m. A light continental breakfast will be served, starting at 8:30 a.m. on Friday.

Both the **Bronchiolitis training meeting** and the **PECARN Steering Committee Meeting** will be held at the **Renaissance Parc 55 Hotel** in the heart of **San Francisco**. For more information regarding the logistics for this meeting please refer to the IQ solutions eRoom.

<https://www.nedarcssl.org/eRoom/nddp/IQsolutions>

nodalnews

ACORN

- We have a wonderful addition to our Node. Libby Alpern is the proud mother of Ava Sarah. We wish her all the best!
- Nate is back from Europe and we have two new ACORN proposals, Diagnosis Categorization and C-Spine Immobilization, for submission.
- The proposal PIs, Evaline A. Alessandrini, MD, MSCE, and Julie Leonard, MD, are both new to PECARN.

CARN

- CARN welcomes Kraig Melville's (Calvert Memorial

Hospital) new baby girl.

- Allen Walker's (Johns Hopkins) daughter got married this summer. Congratulations to both the fathers.
- CARN has a new website at www.dcchildrens.com/cpp

PED-NET

- Dr. Steve Miller of the Children's Hospital of New York-Presbyterian (Columbia

WARNING
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FE-13 EXTINGUISHING
SYSTEM. DO NOT ENTER WITHOUT
AUTHORIZATION DURING OR
AFTER DISCHARGE

University) will be permanently assuming the position of PEDNET Principal Investigator as of August 1, 2003.

- Each of the investigators wishes to thank Dr. Nadine Levick for her important contributions to the initial development of the PEDNET node as the founding Principal Investigator.

Checklist of Essential Documents

The PECARN Core Data Project's active research phase is winding down. It is important for all HEDA PIs to ensure that their "essential documents" are organized and stored in the Investigator Study Binder. This binder was sent to each HEDA site in May, 2003 by the CDMCC.

The following list represents the essential documents required for the PCDP Binder:

PCDP Protocol with Waiver of Consent

- Record of all protocol versions filed (alternate location(s) if not filed in binder)

Manual of Operations

- Alternate location(s) if not filed in binder
- Other supplemental information provided by PCDP Working Group or CDMCC
- Data Collections Forms (blank sample)

*IRB Correspondence

- IRB membership roster
- IRB application and PCDP summary
- IRB approval letters (include all approved amendments)
- Record of submission and approval dates
- Annual progress reports and renewal documentation
- Copies of other IRB correspondence

*Site Correspondence

- Correspondence between investigator and PCDP/CDMCC
- Correspondence between Research Assistant or other study staff and PCDP/CDMCC
- CDMCC correspondence (concerning site visits, regulatory, data extraction and submission)

*Other Correspondence / Notes to File

- Documentation of unusual events or communications
- GCP irregularities or non-compliance

Telephone Communications Log

- Alternate location(s) if not in binder
- Signature and delegated responsibilities (completed)

Clinic Staff

Regulatory Documents

- FWA # (Available through your IRB Office)
- Curriculum Vitae (PI and Co-Investigator, if applicable)
- Medical License (s) of investigators
- Confidentiality Agreement with CDMCC
- Current lab certificates
- Lab normal ranges
- Sign in log for visitors and representatives

**Location of email file(s) if not hard copy*

pecarnupdate

Bioterrorism Surveillance:

Historical data has been sent to Children's Hospital of Boston and real time data transfer has begun. Children's National Medical Center has submitted historical data to Ken Mandl and is ready for streaming of data. Additional sites are in the IRB approval process or early planning phases.

Clinical Decision Rules For Identifying Children At Low and High Risk for Traumatic Brain Injuries After Mild Blunt Head Trauma:

This is a prospective study of children with minor blunt head trauma to identify high-risk and low-risk indicators of brain injury. The goal is to derive the evidence on which to base appropriate use of head computerized tomography (CT) in children with acute head injury, which will hopefully reduce the number of unnecessary CT scans for children at very low risk for brain trauma. This will minimize the exposure of these children to the significant drawbacks related to this procedure (ionizing radiation, transport of children away from the direct observation of the emergency department, pharmacological sedation, and additional health care costs) The study received PECARN approval and was submitted as an R01 grant application to NICHD on February 1st, and to MCHB on March 1st of 2003. NICHD score it at 174 (20.9 percentile) and MCHB Research Program 103.79 out of 100. They are awaiting news on funding.

Disparities Study:

The purpose of this study is to measure racial and ethnic disparities in access to medical care (prior to ED arrival as well as in the ED) using a delay sensitive condition such as appendicitis and asthma. A response to PCRADS has been submitted and a grant application to the NIH will be submitted OCT. 1,2003.

Effectiveness of oral dexamethasone in acute bronchiolitis: A multicenter randomized controlled trial:

The study hypothesizes that dexamethasone will be more effective than placebo in preventing hospital admission of infants with bronchiolitis. There will be 14 HEDA sites participating. These sites are in the IRB approval process. There will be a Bronchiolitis Training on Oct. 16, 2003 in San Francisco.

Focus on Prehospital Use of Benzodiazepines for Pediatric Seizures:

An application to the Pediatric Epilepsy Foundation was denied. However, pilot data collection will continue at Children's National Medical Center (CARN).

Great Lakes Node Pilot Project

This study evaluated the factors associated with and the barriers to, follow-up of children with an acute illness after discharge from the ED.

This was a prospective, observational study conducted in 3 hospital EDs in the Great Lakes node: 1) a large, urban children's hospital; 2) an urban, inner city community hospital; and 3) a suburban University-affiliated hospital. The parent/guardian of children aged 2 months to 17 years were recruited from October, 2002 – April, 2003. After obtaining informed consent, an initial survey was conducted with the parent of a child with either: 1) an asthma exacerbation, 2) gastroenteritis, or 3) bronchiolitis and who were being discharged from the ED with recommended medical follow up within 5 days. The child's parent/guardian was surveyed by phone 2 weeks following the ED visit to assess follow-up. The medical record was also reviewed. A total of 572 parents were eligible, 16 refused to participate (2.8%), and 556 were recruited. A total of 531 participants (95.5%) completed telephone interviews. 308 parents (58.0%) completed follow-up as instructed. Data analysis is currently taking place.

Hypothermia:

The PECARN supported Hypothermia for pediatric cardiac arrest planning grant application has been funded by the NICHD (See eRoom /Study -Hypothermia, for list of sites). This feasibility study is in preparation for a future randomized controlled trial. At this time, clinical centers are in the process of obtaining IRB approval for this investigation and the study data collection forms are being finalized. Pilot data collection is scheduled to begin January 2004.

NIH Grant for a Randomized Controlled Trial of Lorazepam versus Diazepam

A grant application was submitted to NICHD on July 14, 2003. This was reviewed on September 9, 2003. Scores are expected in late October, 2003, for funding to begin December or January, 2004.

projectwebsites

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

PECARN Core Data Project (PCDP):

This study will give us important epidemiological information regarding pediatric emergency department visits in the PECARN network. All phases of data collection are nearing completion.

At printing, the following data has been collected:

Phase I: 23/25 (7 resending)
IIA electronic data: 20/25 (2 resending)
Phase IIB/C chart review data" 23/25
Site PI QA: 11/25
RA QA: 14/25

Currently, the PI and RA Quality Assurance data is being completed and submitted to the CDMCC. Qualitative phone interviews will be conducted as each node completes their QA data. The phone interview will be conducted by Dagan Wright, PhD from the University of Utah. CDMCC will be scheduling interviews with the PI and RA at each PCDP site. All PCDP information, including **site updates and overdue items** can be found in the PCDP eRoom

Pediatric Psychiatric Emergencies:

The Burden subgroup of the Psychiatric Working Group recently submitted the protocol "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" to the PECARN subcommittees for final review on August 25, 2003. An earlier version of this proposal was reviewed and approved by PCRADS at the October 2002 PECARN Steering Committee meeting. The primary goal of this pilot project is to identify typical sources of referral of pediatric psychiatric patients to the five participating hospitals and to describe the organization of care and utilization of resources at each hospital. The objectives of this project are to: 1) Identify the patterns for referral to the PED for patients with psychiatric complaints, and 2) Identify utilization and organization of resources, and level of training of providers available for PPPDs at hospital Pediatric Emer-

newfaces

TJ Craig, Computer Systems Administrator



Mr. Craig has 10 years experience with computers systems working in various areas of information technology, most recently specializing in storage area networks and infrastructure for large databases.

Drew DeMarco, Computer System Analyst



Mr. DeMarco provides IT systems support to end users at the CDMCC. His technical skills include x86 hardware maintenance, troubleshooting and upgrades, most standard workstation operating systems and software packages, domain user account management, LAN support and maintenance, end user support for database applications, VPN troubleshooting, support for mobile productivity equipment and systems, tape backup systems, and support for common systems administration tasks.

Amy E. Donaldson, MS, Biostatistician



Ms. Donaldson specializes in public health applications of statistical analysis. She has experience in the planning and evaluation of randomized controlled trials and research related to injury and emergency medicine. She received her MS degree from the University of Michigan in Biostatistics and will be an integral member of CDMCC's statistical team.

Brian Gadoury BS, Software Developer



Mr. Gadoury has 6 years of experience in web application design/development, a B.S. in Computer Science from Northeastern University, and a habit of intentionally skiing off cliffs at Alta & Snowbird.

Janna Talbot, Student Assistant



Ms. Talbot is a part-time employee at the CDMCC working as an administrative assistant. She is attending school at the University of Utah and will begin the Elementary Education Program in the Fall of 2003.

What is Good Clinical Practice (GCP)?

GCP is a minimum standard for the performance of research involving human participants. It ensures the validity of trial data and provides a uniform standard for the design, conduct, recording, and reporting of clinical trials. Most importantly, it ensures that the rights, welfare, and safety of subjects are maintained and consistent with the World Medical Association Declaration of Helsinki, titled "Ethical Principles for Medical Research Involving Human Subjects."

The Good Clinical Practice Guideline (CPMP/ICH/135/95) was developed in 1995 by the International Conference on Harmonization (ICH) and is applicable in Europe, the United States and Japan. It is also accepted by the regulatory authorities in Australia, Canada, the Nordic countries and the World Health Organization, which was instrumental in its development.

Good Clinical Practice was approved as a guideline in July, 1996 and implemented in January, 1997. The guideline should be followed when generating clinical data that will be submitted to regulatory authorities, investigations that involve therapeutic intervention or observation of human subjects.



SUZANNE PLUMB
Project Manager

In the past the emphasis on coordinator and monitor GCP training has been based on the prevalent assumption that training coordinators is a substitute for training investigators. This is no longer acceptable to the FDA, Institutional Review Boards and Federal funders. A clear message is being sent to the research community that properly trained investigators and staff is the standard. Because investigators are clinically, ethically and legally responsible for the conduct of the trial, they must be knowledgeable in all aspects of the research process.

The basis for conducting a clinical trial or any trial involving human subjects is that there must be some likely benefit derived from the research and that any potential risks associated with the trial are outweighed by the potential benefits. An awareness of GCP, and an ability to enforce it, is paramount when considering the rights, well-being, and safety of the trial participants. The advancement of science is secondary to these considerations, but nevertheless, this same awareness is critical to the quality and integrity of the research findings.

An important CDMCC responsibility is to ensure ethical, regulatory and protocol compliance by everyone involved in research conducted by PECARN. The CDMCC is urging all HEDA Principal Investigators, Nodal Administrators, Research Assistants and other research staff to take the 1.5 to 2 hour training on the following website: www.ees-learning.net. This training offers an opportunity to learn and understand Good Clinical Practice Guidelines. It is offered through the Veteran's Administration and covers some particular VA regulations, but overall it is an updated, thorough presentation. And it is free for our use.

spotlight



Fu-Chih Cheng

Fu-Chih Cheng holds a Ph.D. in statistics from North Dakota State University. Prior to starting his statistical practice at the Central Data Management Coordinating Center, he was a statistical consultant at the Information Technology Services of North Dakota State University for 5 years.

Fu-Chih has worked on a wide range of biological, environmental, and pharmaceutical projects involving statistical analysis. These projects include forecasting of disease incidence, toxicology studies for dosage levels,

prevalence of smoking studies, survival analyses, and sample survey designs for various projects.

He has a wide range of professional interests, such as data mining, discrete choice models, multilevel modeling, microarray data analysis, multivariate statistical methods, and period analyses. It is his aim that statistics should be used in the decision-making processes of business, government and the community. In line with his belief that statisticians must do more to interpret their work.

Random Selection - Why & How?

Coordinators participating in the PCDP at the larger hospitals, who had more than 60 ER admissions for a selected abstraction day, encountered the Coordinating Center's "randomization module", where you told us how many admits you had that day, and we printed out a list of which 60 to abstract. Certainly, statisticians like to select subjects and to assign study treatments in a random fashion, but is this always necessary?

The archetypal (and true in some context somewhere) story statisticians like to tell is of the researcher who wanted to test a new agent on rats. He had a crate of 10 rats infected with some disease. Taking great care not to look into the crate, he pulled out 5 rats that were assigned to the old drug, while the 5 others got the new agent. He found that the rats on the new drug did substantially better, surviving longer than those treated with the old drug. Yet, the new drug that looked promising in this small study was found not to have any effect in later randomized trials. What was going on? Well, the rats that the researcher was able to pull out of the crate were sicker than the other rats (which, being healthier, were able to run away



RICHARD HOLUBKOV
Chief Biostatistician

and elude his grasp). This unexpected and unintentional imbalance biased the study findings.

Randomization, or random selection, is used to protect a study against biases of all sorts. Statisticians are particularly concerned about unknown, unmeasurable differences between treatment groups, or between selected and unselected subjects. If instead of picking 60 random records, we looked at the first 60 admits for that day, there could be a bias in that (say) earlier admits present with different

diagnoses than late-night admits. Or, if we sampled just the first 60 ER records that were available for review, it's possible that (sort of like the rat example) the records of the sickest patients with the most complicated records would not be available right away. While we could adjust for some of these factors statistically, randomization still protects our dataset ("on average") against unknown biases.

How are records randomly selected? Pretty much all randomization is done using a uniform number generator. This mathematical device spits out a number located "randomly between 0 and 1" (say, 0.8773, then 0.1873, then 0.3498....) as many times as is needed. If you had, say, 70 records for a particular day, we generate 70 such numbers, and pair each one with a medical record. The records corresponding to the 60 largest random numbers in this list of 70 are the ones we ask you to abstract. Hopefully, you can see that no matter how your original list of records is ordered (by triage time, by last name, or even by reason for admission), this technique will pick out a completely random sample to be abstracted.

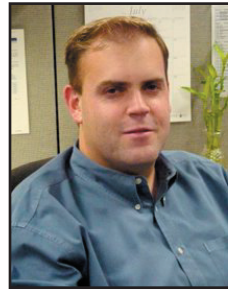


Tales from the Server Room

In light of the recent MSBLAST and SoBig virus attacks, computer security might be on a lot of your minds. Since much of the PECARN research will involve the electronic storage of personal health information, security for PECARN computers is crucial. The US Department of Home Land Security has published the following Seven Simple Computer Security Tips www.nipc.gov/publications/nipcpub/computertips.htm



**STACEY
KNIGHT**



**T.J.
CRAIG**

Let's spend some time talking about the "strong passwords." Your password is usually your first line of defense against hackers and other unlawful entry into your computer. Yet, we all have probably been guilty at one time or another of writing down our password on a sticky note on or by our computer, using dictionary (real) words, using default passwords, or using names of people or pets with a few numbers added. So why do we do this (besides plain laziness)? Perhaps it is that long complicated passwords are not easy to remember.

1. Use strong passwords.
2. Make regular backups of critical data.
3. Use virus protection software, including checking daily for new virus signature updates, and periodically scanning your computer.
4. Use a firewall as a gatekeeper between your computer and the Internet.
5. Do not keep computers online when not in use. Either shut them off or physically disconnect them from Internet connection.
6. Do not open e-mail attachments from strangers and be suspicious of any *unexpected* e-mail attachment from someone you *do* know.
7. Regularly download security patches from your software vendors.

So here are some tips for creating a long complicated password. A good rule of thumb is to always keep your password at least 7 characters in length. One way to create a password is to first, think of a phrase that you can remember, (e.g., April showers bring May flowers). Second, use a number that is familiar to you, but that cannot be traced to any of your personal information, such as using your lucky number or an old telephone number (e.g., 1303). Take the first letter of each word in your phrase and separate the letters by using your familiar numbers (e.g., a1s3b0m3f). This password would then not be a dictionary word and yet be unique to you and easy for you to remember. Another suggestion is to mix cases (e.g., A1s3b0M3f). It is also important that your password is changed at least every 60 days since, given enough time, any password can be guessed.

What Mike Says... about data forms

Data forms seem simple, but we have learned from our initial projects in PECARN that this is a complex process.

First, the data elements have to be decided by the investigators. This is a hard process, and even harder, the investigators need to go back and CUT CUT CUT the data elements down to the absolute minimum number needed to accomplish the goals of the research project. Second, the data elements need to be organized in a fashion that makes sense for someone collecting the data. Third, the paper data forms have to be designed. Fourth, the paper data forms have to be duplicated in an electronic system, usually using HTML for a Web page. Fifth, our programmer has to add validation code to the HTML so that only valid data can be added to the form. Sixth, we have to build a database in Microsoft SQL Server and hook the HTML code to the database. Seventh,

we have to take some sample charts or fake data, enter the information into the Web page, open the database, and make sure that what went in one end of the process ended up in the database, correctly. Eighth, we have to have some naive users play with the interface and tell us where we screwed up. Ninth, we have to put the Web page on our Internet Server. Tenth, we have to establish security for the Web site. Eleventh, we have to build a system for changes to be made (edits) and all changes have to be audited for regulatory purposes. Twelfth, the study manual has to have instructions for the data forms, the Web submission program, and editing methods.

When new projects come on line, the CDMCC has to place timelines on this process. You should expect 2 to 3 months will be required AFTER the data elements are frozen by the investigators.