PECARN
Pediatric Emergency Care Appl ed Research Network

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Email your submission to *kimberlee.brown@hsc.utah.edu*

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TBI Training

Nathan Kuppermann
Chairman of the PECARN

We are excited to begin the first federally-funded investigator-initiated research study in PECARN. The PECARN Head Injury Project is called **Childhood Head Trauma: A Neuroimaging Decision Rule**. It aims to identify high- and low-risk indicators for traumatic brain injury (TBI) in children after head trauma. The ultimate goal is to reduce the number of unnecessary CT scans -and their associated drawbacks - performed on children at very low risk of brain injury.

TBI is the leading cause of death and disability in children older than 1, but occurs infrequently in children with minor head trauma. Although CT scanning is considered the "gold standard" for diagnosing TBI, and failure to diagnose the condition increases morbidity and mortality, overuse of CT scanning has serious drawbacks. The most important among them is radiation exposure, which may result in death from cancer, estimated as occurring at the rate of one radiation-induced fatality per 2,000-5,000 pediatric cranial CT scans. Minor blunt head trauma, however, is difficult to study because TBI in these children occur infrequently.

Fewer than 10 percent of CT scans performed on children after head trauma reveal TBI. Our goal in this study is to enhance the efficiency of CT use in children with head trauma. We will identify the symptoms and signs of TBI after head trauma that will guide decision-making regarding CT use. This will minimize the exposure of these children to the harmful side effects of CT scans, including ionizing radiation, the transport of children away from the direct observation of the emergency department, pharmacological sedation and additional costs.

This study will involve 25,000 children, which would not be possible without PECARN. We plan to enroll patients from May 2004 through April 2006. We look forward to your collaboration!

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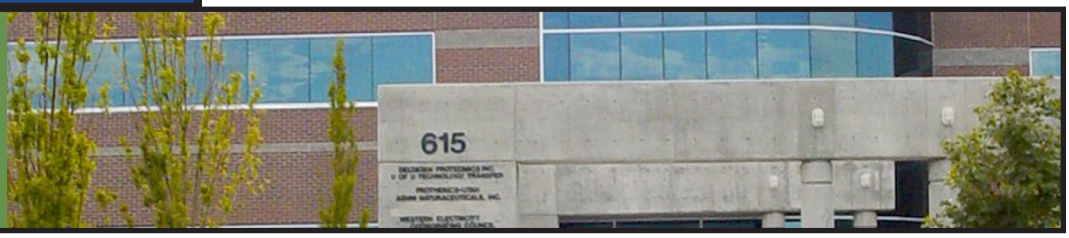

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upcomingmeetings

The PECARN Head Injury Research Project Training meeting is scheduled for **Thursday, February 5, 2004 in Salt Lake City, Utah**. This training is for the research assistants who will be participating in the Head Injury Study. Those attending the Head Injury Training Meeting should plan to arrive on the evening of **Wednesday, February 4, 2004**. More details about this training meeting will be provided in the coming weeks.

The PECARN Steering Committee Meeting is scheduled for **Friday and Saturday, February 6 and 7, 2004 in Salt Lake City, Utah**. The meeting will tentatively begin at **9:00 a.m.** with a continental breakfast starting at 8:30 a.m. It is recommended for those outside of Salt Lake City to arrive on Thursday evening.

Both the Head Injury Research Training meeting and the PECARN Steering Committee Meeting will be held at the Downtown Marriott in snowy Salt Lake City. For more information regarding the logistics for this meeting please refer to the IQ Solutions eRoom. *https://www.nedarcssl.org/eRoom/nddp/IQSolutions*

Marriott Salt Lake City Downtown
75 South West Temple
Phone: 801-531-0800

Do's and Don'ts of IRB Submission

Richard Holubkov
Chief Biostatistician

Here are a few "do's" and "don'ts" of IRB submission, from the point of view of an IRB member who is a biostatistician (so, maybe somewhere in the middle between a medical and a "citizen representative").

DO fill in and check every box on the submission form, and don't forget to sign and date each line that you are supposed to. (Sometimes, not filling in a checkbox for an item such as "Will data be shared outside the Covered Entity" or "Does this study include an IND" may amplify a reviewer's concern about some part of the study.)

DO make sure that both the protocol summary and the consent form give a simple and clear picture of what is going to be happening to the subject at all times, and how long the entire study will take.

Similarly, in a randomized study, DO explain what randomization is on the consent form (and point out clearly if the subject has an unequal chance of getting one treatment or the other).

DON'T cut and paste sections from a technical "master protocol" into the protocol summary without making sure they are understandable to a moderately intelligent, nontechnical person.

DO justify the number of subjects in the study in some reasonable way. This can be done statistically with sample size/power calculations, or in more basic research settings, using practical justifications such as total number of subjects or resources available.

DON'T state something like "we are enrolling 20 subjects because we've always found significant results in the past with this many people (or mice)."

If your study is returned "Tabled" with requests for revisions or questions that seem excessively naïve or unreasonable, please DON'T express your frustration, however justifiable, in your response letter!

If the review seems to be way off on the wrong track, a brief direct meeting with the IRB chair or the Board may quickly solve the misunderstanding.

nodalnews

ACORN

- ACORN would like to welcome a new addition to our growing family. Stacey Townsend, our RA at Utah, delivered a baby boy, Brandon.
- We have three new RAs, including Emily Kim at CHOP, Leslie Fukushima at UCDMC, and Katarina Zoltan at MCW.
- We would like to thank Ryan Radecki, Jeannie Laezman, and Ben Degner for their contributions and with them the best in their future endeavors.
- We are also happy to announce that we have received word that we will be awarded the Head Trauma study by HRSA/MCHB.

CARN

- CARN has added a new HEDA! We are pleased to announce that the University of Maryland will be joining PECARN as a CARN HEDA. We welcome Rich Lichenstein to the CARN family as the site PI.
- Dr. Diana Alexander who is the site PI at Franklin Square Hospital Center will be moving to Johns Hopkins to do a cardiology fellowship. She will continue to participate in CARN and PECARN as a member of the Hopkins HEDA. Unfortunately, we will be losing Franklin Square as a HEDA site.

GREAT LAKES

- Mary Ann Gregor, Nodal Administrator, will defend her doctoral dissertation on January 30, 2004 and will be assuming the new role of a Great Lakes co-investigator. Her research study, "Short-term follow-up for acute pediatric illnesses discharged from the ED: impact on subsequent health care utilization and costs", was based on data collected from the Great Lakes Pilot Project conducted last winter.
- A search for a new Nodal Administrator is underway and it is anticipated that he/she will join the Great Lakes Node at the start of 2004. Please introduce yourself to our new NA at the PECARN meeting in Salt Lake City.
- Matt Denenberg, MD of Spectrum Health is the Site PI for the Bronchiolitis Study. Perhaps you met him at the bronchiolitis training session in San Francisco. Welcome Matt!
- Great Lakes will have a new Nodal Administrator beginning January 5. Jennilyn Suhajda is a pharmacist and will finish her Masters in Clinical Research Administration in early 2004. She has experience doing clinical research site monitoring, has managed a retail pharmacy business, and has special expertise and interest in pediatric drugs/medications.
- Dr. Johnson will be joining PECARN in replacement of Dr. Mort Brown beginning January 2004. He attended the GLMSCRN meeting on Dec. 10. His faculty profile can be viewed at: *http://www.sph.umich.edu/faculty/valenj.html*
- Dr. Ehrlich will be joining PECARN in replacement of Dr. Oliver Soldes at the beginning of the year. He attended the GLMSCRN meeting on Dec 10, as well. His CV can be viewed at: *http://www.um-pediatric-surgery.org/new_070198/new/Faculty_Members/Ehrlich/Ehrlich%20CV.htm*
- We would like to thank Dr. Mort Brown and Dr. Oliver Soldes for their hard work and participation and wish them luck in their future endeavors.

pecarnupdate

Psych (Pediatric Psychiatric Emergencies): 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 underway. Data collection is expected to begin at IRB-approved sites on December 10th. A second project is near completion: a PECARN-wide survey of Psych/Mental Health issues in the ED. Results will be presented to PECARN subcommittees in the coming months. A survey of ED physician perception of Psych/Mental Health training is next in line for development. The group will be working on that early in 2004.

Prehospital Working Group: Two studies are being developed further for PECARN, one on C-Spine injury and the other on Pediatric Arrest. In addition, the Working Group will be developing a HEDA survey looking at EMS systems that serve PECARN. If you would like to be a part of the prehospital working group, please contact Tasmeen Singh at *tsingh@cnmc.org*.

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) in patients with a delay sensitive condition such as appendicitis and asthma. A grant application was submitted to the NIH Oct. 1, 2003 with primary assignment to AHRQ and secondary assignment to NICHD.

Clinical Decision Rules for Identifying Children at Low and High Risk for Traumatic Brain Injuries after Mild Blunt Head Trauma: The study is actively being planned as we await receipt of funding. As soon as funding is received, we will establish subcontracts. Study PIs have been having weekly conference calls and are working on finalizing data forms, working on manual of operations, and coordinating IRB submissions. Site PI responsibility and authorship plan documents have been circulated, and Site PIs are being recruited. Project coordinators at UC Davis and the CDMCC will be hired for this study. We are coordinating a training session on Feb. 5, 2004, which will to coincide with the next PECARN meeting in Utah.

Effectiveness of oral dexamethasone in acute bronchiolitis: A multicenter randomized trial: We had a highly successful training session for this study at the October PECARN meeting. The plan is for January 2004 implementation. Eighteen PECARN centers will participate and a PECARN DMSB has been created for this study. We are getting final IRB approval at all sites. The central pharmacy will be shipping the study medication to all sites in mid-December.

Hypothermia: Please see next page.

PECARN Core Data Project (PCDP): This study will give us important epidemiological information regarding pediatric emergency department visits in the PECARN network. Data collection is now complete and the data analysis has begun. Abstracts were submitted on Dec. 8 for the Spring meeting of the Pediatric Academic Societies meeting.

Bioterrorism Surveillance: Historical data has been sent from Children's National Medical Center to Children's Hospital of Boston and real time data transfer will begin soon. Additional PECARN sites are getting IRB approval or are in the early planning phases.

Great Lakes Node Pilot Project: Predictors of Follow-up in Acutely Ill Children: This was a prospective, observational study conducted in 3 EDs. A publication plan has been submitted to GWAPs, a manuscript has been drafted and will be submitted for publication during the first quarter of 2004.

Use of Lorazepam for Pediatric Status Epilepticus: A Double-blinded Randomized Diazepam Contolled Clinical Trial: In response to an NIH RFA, Children's National Medical Center (CARN-RNC) submitted a grant application to conduct a randomized clinical trial of Lorazepam versus Diazepam for the treatment of pediatric status epilepticus. If funded, the study will be the first in PECARN to utilize an FDA exemption from informed consent. Five PECARN sites are participating, one site from each node and a 5th site to be determined. These include, Children's Hospital of Philadelphia, Children's Hospital of Buffalo, Children's Hospital of Michigan (aka Prashant's hospital), Children's National Medical Center and one site TBD.
Since this is a contract mechanism, the NIH informed CARN in November that they were in competitive range for the grant and they are currently in negotiations with them. A site visit to the applicant institution in scheduled in mid-December.
The original grant was submitted at approximately $2.94M. The NIH funded a data coordinating center akin to the CDMCC for this series of RFA's and therefore asked us to remove some costs in the negotiations. The current budget is $2.7M.
The grant application and associated documents can be found in the steering committee voting eRoom archive at *https://www.nedarcssl.org/eRoom/nddp/SteeringCommitteeVotingeRoom/0_3ea3*

newfaces

Sally Jo Zuspan

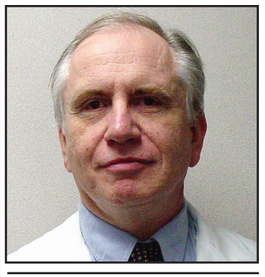
I am excited to be a part of the PECARN network as the new Program Manager. My educational background includes a master's degree in Burn Trauma Nursing. I have worked as a pediatric emergency nurse, pediatric clinical specialist and trauma coordinator at large children's hospitals in Ohio and Texas. I also served as a lobbyist for the American College of Surgeons Committee on Trauma advocating for trauma systems. My research interests include trauma systems, pediatric emergency care, and injury prevention. My family and I were stationed with the military for the past three years in Stuttgart, Germany where we had great fun and adventure traveling throughout Europe.

Rene Enriquez

I'm excited to be part of the PECARN network as the CDMCC's Data Resource Manager. Prior to joining the CDMCC I was working for the University of Utah's Clinical Research Center and was responsible for coordinating and implementing the data management portions of NIH and multi-center clinical research studies. While at the CRC I initiated the development of CRIS (Clinical Research Integrated System), a system that streamlines the development and implementation of research databases. I graduated from the University of Arizona with a BS in Management Information Systems. I'm currently finishing a MS in Medical Informatics at the University of Utah. My research interests are focused on data management of research data, metadata reuse, and research system frameworks. I am married, have two daughters, ranging in age from 9 weeks to 3 years. A personal goal of mine is to some day learn how to fly and obtain my pilot's license.

Rich Lichenstein

Dr. Richard Lichenstein is joining PECARN as the site PI for the newest HEDA site, the University of Maryland. Dr. Lichenstein is Associate Professor of Pediatrics, Director of Pediatric Emergency Medicine and Associate Director of the Combined Pediatrics Emergency Medicine Residency Program at the University of Maryland. There are 91 inpatient beds at University Hospital for Children accounting for 4,500 admissions annually, including 1,000 admissions to the PICU/IMC. The Pediatric Emergency Department as of November 2002 is in a state of the art facility with 17,000 encounters per year and growing. Dr. Lichenstein's research interests include pediatric therapeutics, telemedicine & psychiatric emergencies.



Frank Moler
Principal Investigator

An In-Depth Look at the Hypothermia Study

Cardiopulmonary arrest (CA) in childhood is a tragic event that very often results in either death or poor quality long-term neurologic outcome. Recent clinical trials in adult populations have reported both improved neurologic outcome and survival in highly select patients receiving short-term mild hypothermia (32-34° C) following out of hospital arrests. The efficacy of mild hypothermia in children following cardiac arrest in the modern era is not known. In uncontrolled reports two decades ago, moderate hypothermia (30-32° C) in contrast to mild (32-34° C) hypothermia was associated with trends towards worse outcomes. In this clinical trial planning grant application, 15 children's hospitals with large intensive care units will obtain pilot data, from the medical records of patients who have sustained a CA in either the outpatient or inpatient setting. Characterization of this population will include arrest specific details, etiology, patient characteristics, hospital course, interventions received, hospital survival, and neurologic outcome. Approximately 500-1000 patients are anticipated to meet study criteria and their charts will be retrospectively reviewed over the 12-month period of this pilot study. The data from this study will be used to create inclusion and exclusion criteria, to calculate sample size requirements, and prepare documents needed for a futurerandomized controlled trial (RCT) of hypothermia following pediatric cardiac arrest. Duration of time to successfully enroll patients from this cohort of 15 children's hospitals for a future RCT will be estimated. The PECARN support of this study with its existing clinical trials research infrastructure that includes a steering committee, five clinical trials supporting subcommittees, and a central data management coordinating center (CDMCC). The CDMCC will make operational all data and analysis related tasks of this application, and assure all study sites are compliant with regulations concerning data security and confidentiality.

web sites

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

Consort Agreement

Richard Holubkov
Chief Biostatistician

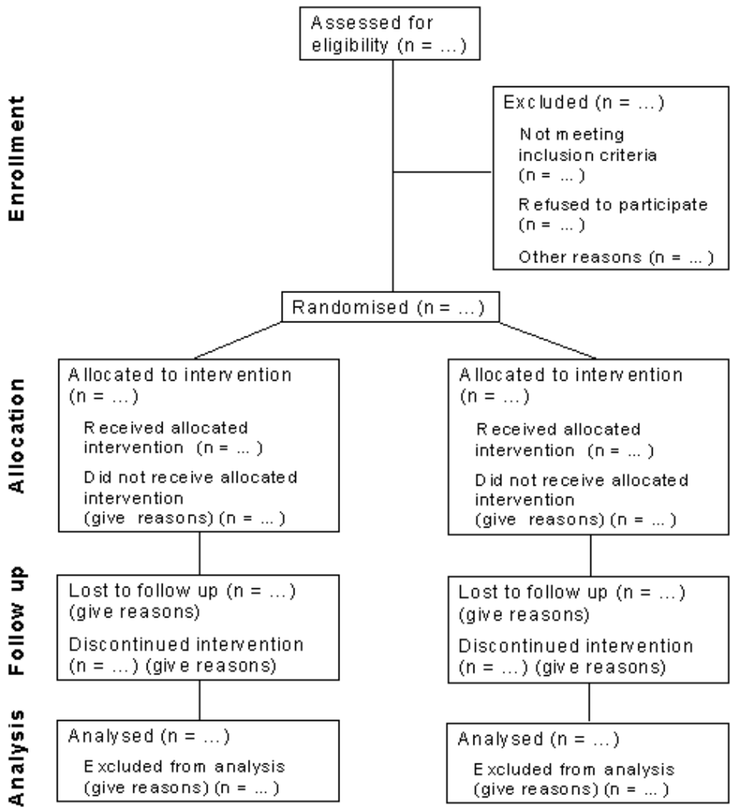
Those of you involved in the bronchiolitis study planning may have been exposed to something called "the CONSORT statement". CONSORT, which stands for CONsolidated Standards Of Reporting Trials, is a checklist of 22 items that need to be reported when the results of a randomized trial are submitted for publication. So, CONSORT can be thought of as a roadmap for what needs to be kept track of when a trial is being designed and carried out.

It's not completely surprising that two different clinical trials comparing the same treatments can give differing results; this can certainly happen by chance alone. But certainly, one study can be "stronger" than another in different ways. A double-blind study is less likely to have bias than an open-label study. Results from a study where 90% of eligible patients were randomized may be less biased, and more generalizable, then findings from a study where 75% of eligibles refused to participate, and similarly a long-term study is stronger if subject retention during follow-up is high. If the proportion of randomized subjects who don't receive the assigned treatment is large, an intention-to-treat analysis can be misleading. And so on. The CONSORT checklist (you can find the article, effectively in the public domain, at *http://www.consort-statement.org/revisedstatement.htm* lists characteristics of the trial that the growing number of health care and biomedical journals that have adopted CONSORT will be looking for in the write-up. Having this information will allow physicians as well as more statistical types such as meta-analysts with information to evaluate the quality, rigor, and potential generalizability of the results of a given trial, on its own and in comparison to other similar studies.

In the planning of the bronchiolitis study, we have been particularly concerned about what is expected in terms of documenting patient flow. The CONSORT patient flow diagram, reproduced below, indicates that some sort of accounting system is expected starting with all subjects who are assessed for eligibility as potential trial subjects. Any assessed or approached potential subject who drops out **at any point in the trial process** has to be accounted for with a reason for dropping out!

Categories of dropping out can include: patient not eligible, eligible but refusing consent, consenting but not treated, treated but dropping out during follow-up, or completing the study but not included in the final published analysis. Reasons for dropping out can be many and varied.

Good study planning involves meeting the letter of the CONSORT statement without excessively burdening the study in terms of resources needed to track exclusions and dropouts. The careful review of patient flow, and other study details, needed to conform to CONSORT can make a proposed trial stronger and more efficient in many aspects (in addition to keeping statistical-type people happy and employed).



spotlights

Stacey Townsend, RA (ACORN)

Hello everybody. I am the Bronchiolitis Study Coordinator/ Lead RA at Primary Children's Medical Center in Salt Lake City, Utah. I graduated from medical school here last spring and took the year off before starting a residency in pediatrics to have a baby. My son, Brandon, is eight weeks old now and is the joy of my life. I also have a wonderful husband of five years, Scott. In our spare time, we enjoy water skiing, camping, hiking, and now more than ever, sleeping. I hope to get to know all of you better over the next year.

Amy Drongowski, RA (Great Lakes)

I have recently completed my Master's in Medical Sociology at Eastern Michigan University. I was born in Ann Arbor and have worked at the University of Michigan for the past 11 years in Pediatric Surgery/Pediatric Trauma - certainly feels like half of my lifetime! My graduate thesis, "Consumers lack basic knowledge about their child's health insurance coverage", was based on data collected in the Pediatric Surgery clinic. I joined the Great Lakes Node in mid-September, 2003.

Tasmeen Singh, Nodal Admin. (CARN)

PECARN would call me a BIRCLA (**B**orn in **I**ndia, **R**aised in **C**anada, **L**iving in **A**merica) **eh**. In addition to working as a CARN nodal administrator, I am also the EMSC coordinator for DC and manage the Center for Prehospital Pediatrics at CNMC. I go to school part-time working towards a Doctor of Public Health degree in Health Policy. I am also a paramedic and teach PALS and PEPP and have an MPH in epidemiology. If you think I should have my head examined, don't worry, I am married to a psychiatrist.

Steve Miller, Nodal PI (PED-NET)

A native New Yorker, Steve did his undergraduate work at Columbia University in English, and later completed medical school at CU's College of Physicians and Surgeons. He completed his Pediatrics residency at Montefiore Medical Center, and was chief resident at Bronx Lebanon Hospital Center/Albert Einstein College of Medicine. Steve later served as co-Coordinator of Resident Education, as well as Director of Education and Pediatric Emergency Service at Bronx Lebanon Hospital.

In 1993, Steve came to Columbia University Babies and Children's Hospital-New York Presbyterian Hospital where he served as the founding Director of Pediatric Emergency Medicine. Today, it has nine PEM board-certified attending physicians, an accredited fellowship program and a new 8000 foot state of the art home, featuring a level I 2-bay trauma area, 16 examination bays, a reverse isolation room and a child-friendly waiting area.

Steve is also the Director of Medical Student Education in Pediatrics, and the Arnold P. Gold Associate Professor of Clinical Pediatrics. Dr. Miller's academic work has been in the area of medical education. He has disseminated his work through a series of invited professorships and national workshops, and he has published in the area of humanism in medicine.

Steve is married to Dr. Dodi Meyer, a native of Argentina and Assistant Clinical Professor of Pediatrics and Director of the Dyson Initiative at the Children's Hospital of New York-Presbyterian. They have three bilingual children Jesse (as in Jesse James) age 11, Maya age 10 and Nico age 6. Steve plays guitar and has a famous relative in the entertainment industry. Steve has a burning desire to play Hamlet at the Delacorte Theatre in Central Park.

Electronic Data Entry: What it is and why you want it

Brian Gadoury
Software Developer

The Electronic Web Entry project, driven by the Hypothermia and Bronchiolitis studies, is very cool. Study sites will be able to submit their patient study data to the CDMCC using a Web browser to fill out a form on our secure website. There are no obtuse VPN clients to install, firewall ports to open, etc. All patient data is automatically encrypted using SSL, the same technology that protects your credit card number when you buy something online.

It all starts with you pointing your web browser to our Web Entry website. Once there, you'll login using your Web Entry username and password. You'll be presented with a list of all the forms in the study. Click on the name of the form you want to complete. Now enter all your data into the form and click the submit button. Here is where it gets good. When you click submit, the Web Entry system scans the entire form for problems such as invalid dates (February 30th), impossible values (a temp of 130 degrees) and missing data (forgot the patient number.) If there are any problems with the data, an error message is displayed, explaining exactly what's wrong and how to fix it. Once all the data looks good, it is recorded in the CDMCC database. This helps ensure the data is accurate and complete before it gets to the database.

In summary, the Electronic Web Entry project will make it easier for more sites to provide cleaner and more accurate data. With this framework in place, the CDMCC will be able to support more concurrent studies while ensuring a very high level of data quality. This, I think you'll agree, is very cool.

Bronchiolitis: Frequently Asked Questions

The Bronchiolitis Study will be beginning to enroll patients in January, 2004. After a productive meeting in San Francisco in October, several issues were clarified, updated or changed. To keep everyone up to date with the specifics of the study, a long list of Bronchiolitis FAQs has been developed. Here is a brief sample of some of the questions that are pertinent to the study process. They represent some of the most common issues that have surfaced. Additional questions and answers can be found in the Manual of Operations, or on eRoom.

What classifies "Mild" disease as an exclusion criteria?

If the patient's symptoms are "mild," by definition they are not eligible for the study. Mild means they have been given an RDAI (Respiratory Distress Assessment Instrument) score of less than 6 by a study-trained clinician ***and*** they have *"adequate"* oxygen saturation, ***and*** the patient is breathing comfortably. Sites at typical altitudes will define adequate saturations for this study as greater than 92%. If the patient meets all the criteria for "Mild" disease at the time of initial evaluation by the participating clinician, then check the appropriate box and discontinue screening. The patient is not eligible to continue the study. Be sure to finish filling out the screening log.

What do we do if a patient has been randomized, but has not received the medication yet and deteriorates (i.e. is intubated or transferred to the ICU, or leaves the hospital for any other reason)?

All randomized patients need to be analyzed for statistical purposes. This will be uncommon, but in this event we should record all available data, especially that which would allow possible follow-up.

What happens if a patient vomits the drug after some time period, for example 1 hour? Do we continue to observe the patient? What about follow-up?

If the patient vomits within 20 minutes, this should be recorded on the data form C2, #4. No further drug will be administered, however, because as you will recall, the vial was randomized and we do not know if the patient received drug or placebo. If the patient vomits after 20 minutes, it is not even necessary to record it. In any case, observation and follow-up should continue as it would otherwise.

How close in time do the RDAI, vital signs and oxygen saturation need to be done?

All measurements for all three study exams should be done within 20 minutes of each other. When the nurse/technician is recording the examination information, remind them to do it while the patient is awake, upright, and calm. If your site routinely performs nasal suctioning, the examination should be performed *after* the patient has received suctioning and is given time to calm down.

How long does a patient need to be off oxygen for their oxygen saturation to be considered a room air saturation?

The patient should be off oxygen for at least one minute for the oxygen saturation to be considered a room air saturation. If, however, the patient's oxygen saturation falls to less than 80% in less than a minute, it is not necessary to wait the full minute before putting them back on oxygen. In this case, document the oxygen saturation as 79% and allow the nurse to put the oxygen back on the child.

How soon after the patient has been discharged do I need to enter the data from the CRF to the web?

The data entry to the website should be completed within 3-5 days of the ED visit. In addition, the Follow-up CRF should be entered onto the web within 3-5 days of its completion.