



# The MFMU Networker

Volume XII Issue 4

December 2002

## CAPPS Trial Nearing Implementation

Dr. Jim Roberts has concluded, after conducting a study at Magee-Womens using a vitamin capsule combining vitamins C and E, that ascorbic levels rose appropriately using this particular antioxidant supplement. Thus the manufacturer, J.R. Carlson Laboratories, was selected to provide the vitamins for the RCT part of the Combined Antioxidant and Preeclampsia Prediction Studies. The product, called E Gems with C, is a soft gel capsule containing 200 IU of Vitamin E and 500 mg of C and is affectionately referred to as "Black Beauty" since it is pure black. The matching placebo contains mineral oil. Eminent Services will label and package the capsules in blister packs for distribution. Eminent will also conduct stability tests on the vitamins to determine any components of degradation and then will do sample tests every three months to check for potency loss over time.

During the last subcommittee meeting, the protocol was modified to include a week-long placebo compliance run-in for consenting patients and to clarify other details. It was sent to the principal investigators to review and to respond by December 13 with their approval and/or comments. It also has been reviewed by the GWU IRB and the DSMC. After some minor revisions, the final protocol will be distributed to Network members. The FDA should notify NICHD by January 3 about whether an IDE will be required for this trial. The nurses training will be held February 19, the day prior to the next Steering Committee meeting.

The protocol for the Prediction section of the study is still being worked on and will likely be implemented soon after the start of the trial.

## C-Sections Hot Topic in the News

The front page of the December 16 issue of the *Washington Post* featured an article on the rise in cesarean births, stating that the number of American women giving birth by cesarean section has reached an all-time high, with nearly one-quarter of babies now being delivered by this surgical procedure. The cesarean rate jumped 7 percent in 2001, reaching 24.4 percent of all live births, the highest rate since the government started collecting the statistics in 1989.

Many of these C-sections are completely voluntary and are requested by patients who do not want to encounter vaginal deliveries for a variety of reasons. Obstetricians began reducing the number of repeat cesareans in the 1980s and 1990s, when they began to encounter medical problems, according to the article. By last year, the percentage of women having a vaginal delivery after a previous C-section dropped 20 percent, to an all time low of 16.5 percent, according to preliminary data from the National Center for Health Statistics.

The MFMU Network's current C-section study should shed some interesting light on these statistics. Four analyses on the first two years of C-section data will be presented at SMFM in February.

December 31 is the last day of delivery for patients to be registered into the Cesarean Registry study. All data forms for C-section patients must be entered by March 31. Edits and audits on all data forms will continue until the database is cleaned up.



*CAPPS Subcommittee meeting at the BCC, November 19. Clockwise from left, Les Myatt, Elizabeth Thom, Jim Roberts, Heather Juliussen-Stevenson, Peg Cotroneo, Rebecca Gersnoviez. Not pictured: Ken Leveno, Vicki Pemberton, Menachem Miodovnik, Cathy Spong, Susan Pagliaro and Lucy Leuchtenburg.*



## Project Updates

**BEAM:** Steve Weiner claims that if centers keep up the current recruitment rate, this trial will be finished one year from now!! Meanwhile, quality assurance is ongoing, with training for the follow-up examiners taking place at the Kennedy Krieger Institute in Baltimore, February 3-4. The annual videos from the pediatric examiners for the neurological exam are due by the end of February. Please send them to Bruce Shapiro, MD, Kennedy Krieger Institute, 707 N. Broadway, Baltimore, MD 21205.

**FOX:** The BCC has begun issuing recruitment reports every two weeks to PIs, Coordinators and NICHD. Though more than 550 patients have been recruited, the rate needs to double if the study is to finish in three years as planned. The reports will help identify centers that need assistance in patient recruitment and management. Sensor contact registration continues to improve, with a median of 78% vs. the 67% reported in the Garite study. The first annual progress report for the IDE has been submitted to the FDA. Work on the meconium aspiration syndrome ancillary protocol continues, along with the development of a new data form. This form will be completed on all babies with meconium stained amniotic fluid at delivery, an estimated 15-20% of all infants.

**Steroids:** One hundred baby heel sticks have been completed, ending the blood collection on neonates delivered spontaneously less than 34 weeks gestational age. Drexel University is designing a new recruitment tool, "Helping Your Baby Mature", which is available as a brochure or on CD, including versions in Spanish. Please contact Mary Talucci, coordinator, for more information. Another gathering of investigators and study personnel from both the Canadian and MFMU Network trials of antenatal steroids will be held at SMFM on Thursday, February 6 from 6:30-8:00pm. If you plan to attend, please remember to check for the location when you arrive.

**GDM:** Eleven centers have been certified as of mid-December. Nine patients have been enrolled across the three patient groups: seven are from UAB, and one each from OSU and Columbia. Though more than 90 women have been screened, more than half were ineligible, a number have refused consent, and two-thirds were disqualified by their OGTT results. So far there have not been any major start-up problems, though the BCC has requested Quest Diagnostics to speed up their response time for the OGTT results. Research nurses have reported that the download software for the LifeScan meters has been performing well.

## NICHD Research Opportunities

Two RFAs have been issued by the NICHD that might be of interest to MFMU researchers. The first is RFA-HD-02-025, entitled "Research on the Scope and Causes of Stillbirth in the United States". The document may be accessed at <<http://grants1.nih.gov/grants/guide/rfa-files/RFA-HD-02-025.html>>. The letter of intent is due February 13, 2003, with receipt of application due March 13.

The second RFA is co-sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and is entitled "Prenatal Alcohol Exposure Among High-Risk Populations: Relationship to Sudden Infant Death Syndrome" and is available at: <<http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-03-004.html>>. The letter of intent for this is due February 17 with submission of the application due March 17.

## New Adverse Event Form Developed

A new adverse event form has been created that will be used to report all serious events deemed related to Network studies and/or unexpected in nature, severity or frequency. The form will collect specific data relating to the event. By answering these questions, the narrative can be much briefer. While generic for all Network studies, the form will be modified slightly for each protocol and will be part of the set of data forms for that protocol. In addition to being faxed to the BCC and NICHD within 48 hours of the event, the form will be keyed into the data system at the Network center. The new form was developed based on the FDA Form 3500A, which is used to report adverse events for drugs and devices, and other forms used in other major studies. The new form will be initiated with the CAPPS studies. Other studies will have access to it after the data entry software has been created.

## New Audit Format Initiated

Following the suggestion of Missy Swain, Coordinator at Wake Forest, the BCC is re-designing the format of the monthly audits. Instead of listing multiple patients per audit page, there will be only one patient per audit page. This way, audits can be kept in the corresponding patient's file. This applies to all audits except the forms audit that lists patients with overdue data forms, the type of audits that check nurse certification and initials, screening log audits if they do not refer to enrolled patients, and all C-Section data forms. Everyone hopes this will not result in an avalanche of paper, and that it even will lead to faster response time!!



**Words to Ponder:**

*You can either be honest or dishonest but you cannot be little bit honest and little bit dishonest like one can either be pregnant or not pregnant but one can't be a little bit pregnant!*

## Spong Sets Up Ad Hoc Committee

Dr. Cathy Spong is establishing an ad hoc committee of principal investigators to look into the complexities associated with Network collaborations with outside groups. Over the years, numerous organizations have approached the MFMU Network expressing interest in co-sponsoring or co-conducting research projects. The Network has also invited other institutions to share in co-sponsoring when results of the research would assist their goals.

Several of the Network studies have had, or currently have, outside funding or other means of support but no guidelines have been established. This committee will be charged with looking at various means of collaboration, the what, the who and the how, and to develop a set of guidelines.



## HIPAA Regulations Get Attention

With the April 14 deadline looming for implementing new patient privacy rules, the medical research community is researching the impact of the HIPAA regulations on its work. The Research Support Personnel Box Lunch meeting, being held February 5 at SMFM and organized by Nicki LePere, research nurse from MCP Hahnemann's Christiana site in Delaware, will feature Dr. Jerry Castellano, the IRB Chair from the same site. Dr. Castellano is very knowledgeable about this subject and serves on several national IRB and medical committees addressing these issues. He is implementing the new rules at his institution, one of the first to be fully prepared, and will share some interesting information and insights.

The NICHD Network office is planning to have one or more presentations on the new HIPAA regulations and their impact on patient recruitment, informed consent forms and other research concerns at the February Steering Committee meeting. More information will be forthcoming after the first of the year. Official guidance on the Privacy Rule may be found at <http://www.hhs.gov/ocr/hipaa/privacy.html>



## People in the News

### Staff Additions & Changes

**Kristine Anderson** has formally accepted the position of coordinator at the University of Utah, replacing Marla Jensen who resigned to undertake a new challenge. Kris brings a wealth of knowledge to the Network, having worked in OB nursing since 1975. She opened the Antenatal Testing Center at LDS Hospital in 1986 under the direction of the head perinatologist. She worked as Nurse Administrator and Market Manager for a high risk OB home care company for seven years, covering a four-state territory, and was the OB/GYN Nurse Manager for a large HMO clinic for another four years before returning to L&D at McKay-Dee Hospital three years ago. There, she is also responsible for orienting the new Family Practice residents to the L&D unit. She is AWOHNN certified in Ultrasound to perform amniotic fluid volumes and biophysical profiles and has had advanced training in fetal heart rate monitoring. She admits to being detail oriented so research is something she really enjoys. She has two married daughters with a grandson from each. She loves to read, mainly mystery and historical novels. During the SLOC 2002 Olympics, she worked on the Doping Team (drug screening), primarily at the speed skating and curling venues.

Unfortunately, **Chris Myers**, Grants Management Specialist for the MFMU Network, has resigned his position at NICHD. We all appreciate his hard work, accessibility for answering questions and for coming to Network meetings. He has really helped to de-mystify the capitation funding process and we wish him well. No one has been named yet as his replacement.

### Personals

We are happy to announce that **Cora MacPherson** delivered her baby daughter on November 18, exactly one week after her "due date". She weighed in at 7 lbs 14 oz and is named Kate Ellen. Two and a half year old Jack is the proud big brother. We hope that Cora will continue to work from her home office on secondary analyses and other Network projects for the BCC through a service agreement arrangement.

We sorrowfully relay the news that **Jane Morrison McKeever**, BEAM follow-up coordinator for the University of Tennessee, unexpectedly passed away December 2 of an aneurysm. Jane was an outstanding follow-up coordinator for the BEAM trial, showing much sensitivity and ingenuity working with patients. She participated in the BEAM training session held at the BCC for the six new Network centers in Spring 2001, sharing strategies and ideas for patient tracking and retention. Jane went out of her way, often not related to just follow-up work, to help patients, including going to court for them and giving them clothing from church mission projects. One of our favorite stories is about a follow-up visit she coordinated that entailed flying a family back to UT. This was a new experience for the family; they had never stayed in a hotel and were nervous. So Jane spent the night with them and took the children shopping to buy bathing suits so they could swim in the hotel pool. We share the loss with Jane's co-workers and family.

# ON THE LIGHT SIDE

A familiar woe from most of us after the holiday eating, even if we aren't pregnant!



## MFMU CALENDAR

### Steering Committee Meetings

- February 20-21, 2003
- May 5-6, 2003
- July 14-15, 2003
- October 23-24, 2003

### SMFM Annual Meeting

February 3-8, 2003, San Francisco, CA

### SGI Annual Meeting

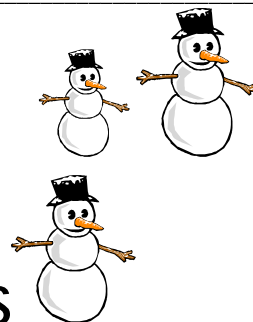
March 27-30, 2003, Washington, DC

### Important Protocol Dates

- December 31, 2002, Last patient for C/S registry
- February 19, 2003, CAPPS Training
- March 31, 2003, Final data forms entered for C/S

### ACOG Annual Meeting

April 28-30, 2003, New Orleans, LA



# HAPPY HOLIDAYS

## to all and to all

## Best Wishes for a Happy, Healthy and Safe

# NEW YEAR!