

## Next Network Trial Involves Corticosteroids

On March 12, the Network's Prioritization Committee held a conference call to select the next study to be implemented in the Network. The new study will be a randomized, double-blind placebo-controlled trial to see if administering antenatal corticosteroids to women expected to deliver imminently at 34 to 36



week 3 days will decrease the need for respiratory support for the infant. Dr. Cynthia Gyamfi from Columbia University is the lead investigator for the protocol. There will be 2100 women in each arm.

Prior to the call, the Network PIs, in consultation with their center staff, ranked and submitted to NICHD the top three studies from a list of nine Network-approved protocols. The ranking was based on scientific merit and importance, potential impact, and cost effectiveness and feasibility within the Network. The other two protocols receiving top priority were the *STAN trial: a randomized clinical trial of fetal ECG ST Segment and T wave analysis as an adjunct to electronic fetal heart rate monitoring*, proposed by Drs. Belfort, Varner, Saade and Hankins, and the *17-alpha Hydroxyprogesterone caproate as Adjunct Therapy for Preterm Labor*, proposed by Drs. Ruddock, Wen and Saade.

The Committee acknowledged the fact that there would be a large positive contribution to public health if the results of this new corticosteroid trial show benefit. The MFMU Network will vote on the final details of the protocol at its April meeting. Dr. Spong has suggested that investigators consider requesting permission to withdraw protocols that have been in the Network's queue for some time if there is no interest in continuing to pursue them in the MFMU. Approval by the MFMU Steering Committee would need to be obtained for withdrawal to occur.

## NICHD Renamed the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

On December 21, 2007, Congress passed a public law renaming NICHD to the Eunice Kennedy Shriver National Institute of Child Health and Human Development. On March 3, 2008, Mrs. Shriver, family members, friends and guests attended a special event on the NIH campus to acknowledge the renaming. Mrs. Shriver was instrumental in the creation of the Institute in 1964, having persuaded her brother, President John F. Kennedy, to support her efforts to establish ongoing research in child and human development. She has devoted her life to improve the lives of children with intellectual and developmental disabilities, including the founding of the Special Olympics.

The NICHD also renamed its Mental Retardation and Developmental Disabilities Research Centers Program to the Eunice Kennedy Shriver



Intellectual and Developmental Disabilities Research Centers Program. The renaming honors Mrs. Shriver who was a member of the Institute's first advisory council and who guided the establishment of the 14 university-based facilities in the program which seek to "advance the diagnosis, prevention, treatment, and amelioration of intellectual and developmental disabilities."

## Logo Design Contest Announced

The time has come, and the decision made, that the MFMU Network should have a new logo! Perusing the NICHD web site, one sees that a number of extramural clinical research networks, in addition to health communication campaigns and programs, have a unique design or symbol representing the focus of their work. The current MFMU Network logo is actually an adaptation of one of the early NICHD logos. There now are numerous NICHD logos, the newest one appears in the above article about the renaming of the Institute.

Therefore, let the contest begin! Please submit your design to our Program Scientist, Dr. Spong, who has agreed to be the judge. The deadline for submission, or a note indicating that you are working on a design, is April 30.

## Last CAPPS Patient Randomized on February 29

The MFMU Network's largest study to date, the CAPPS trial, finished randomizing patients on Leap Year Day, four and a half years after it began. Over 10,100 nulliparous, low risk pregnant women were randomized to receive either



vitamins C and E or placebo to see if antioxidants can prevent the occurrence of preeclampsia. More than 2,400 of these women were also enrolled in the Prediction Study which will be analyzing their blood, urine and biophysical data for markers that may identify those women who are at risk for developing preeclampsia.

Results are expected to be reported in late 2008 or early 2009 since the last patient will not deliver until October 2008. The medical charts of patients who are designated as having preeclampsia or pregnancy-related hypertension are being reviewed centrally to determine whether the diagnostic criteria for the primary outcome are met. As of this month, over 2,000 charts already have been reviewed, with another 700 or 800 anticipated before the outcome of the study can be determined.

## Results of Two Network Trials Reported at SMFM

The MFMU Network's BEAM (Beneficial Effects of Antenatal Magnesium) trial, presented by the protocol subcommittee chair, Dr. Dwight Rouse, was the lead presentation in the first plenary session at the Society for Maternal-Fetal Medicine's 28<sup>th</sup> annual meeting in Dallas, and received the award for best plenary presentation. The BEAM trial showed that magnesium sulfate treatment during pregnancy reduced the rate of cerebral palsy in children of women with a high risk of preterm birth. Moderate to severe cerebral palsy occurred in 1.9% of the children of women treated with magnesium sulfate versus 3.5% in the placebo group (RR 0.55; 95% CI 0.32 to 0.95). However, the primary outcome, which was the composite of moderate or severe cerebral palsy, stillbirth, or infant death, was not different between the active and placebo groups.

Dr. Margaret Harper's abstract, highlighting the results of the Network's Omega-3 trial, was selected for the third presentation in the first plenary session. In this randomized, double-masked, placebo controlled trial, women who had a prior preterm delivery and were pregnant again were assigned to take either an Omega-3 supplement or matching placebo. All patients also received injections of 17-alpha Hydroxyprogesterone caproate (17P). The findings showed that Omega-3 supplementation did not reduce the rate

of preterm births in this high risk population. However, an association was reported between dietary intake of fish (a source of Omega-3) and reduced preterm birth.

## APEX Pilot Finishes, Main Study Starts

The APEX main study officially began March 1, when nurses began collecting the number of deliveries and staffing information at the twenty-five participating hospitals and recording the data on the delivery count log form. Each hospital has been provided 6 months of randomly-assigned dates (March to August 2008) on which eligible patient data will be collected. Since January, the study investigators and the Biostatistics Coordinating Center have been busy revising the data forms and updating the manual of operations based on assessments of the pilot data. These changes also required changes to the web data entry system. Therefore, while the new version of delivery count log was finalized before March 1, the remaining forms, manual, and web entry system will not be available for use until April 1.

Nurses will attend another training session on the new data forms at the April Steering Committee meeting. Over the next thirty-six months, it is anticipated that maternal and neonatal data on 120,000 patients will be abstracted and entered on the web. The results from this observational study will be used to identify process measures associated with poor outcomes as a way to evaluate the quality of obstetrical care.

## NICHD Going Green

Maggie Young, the NICHD grants officer for the Network, reminded the nurse coordinators at their last meeting that effective January 1, 2008, NIH will no longer provide paper notification of the Notice of Award (NoA) letters.

Instead, NoAs will be sent solely via e-mail to grantee organizations and will be accessible in the eRA Commons through the Status addition, NIH Financial Status be submitted using system, also located Commons. Participants who are registered on the able to view regarding currently and to submit FSRs to NIH electronically using the web-based system.



These procedures are a result of NIH's goal to have a paperless grants process. Only an individual with signatory authority in grant-related matters can register an institution; however, doing so allows faculty and staff to take advantage of the electronic submission and retrieval of grant information. More information is available at <http://era.nih.gov/commons>.

## Submission to PubMed Central Soon to be Mandatory

Beginning April 7, 2008, all publications resulting from NIH-funded research must be available to the public on PubMed Central, a new public database which will post the entire text of the article within one year of publication in a journal. In addition, as of May 25, 2008, all NIH applications, proposals and progress reports must include the PubMed Central reference number when citing an article that falls under the policy and is authored or co-authored by the investigator or arose from the investigator's NIH award.

At the time of submission to a journal, it is very important that the authors work with the publisher before any copyrights for a manuscript are transferred to ensure that all conditions of the NIH Public Access Policy can be met. Authors should submit the final, peer-reviewed manuscript and figures to the NIH manuscript Submission system (NIHMS) when it is accepted for publication in a journal.

After the NIHMS converts the author's electronic files to a standard PubMed Central format, NIHMS will email the article back the author for review and to approve its release. Some publishers have agreed to send the final published article of every NIH-funded article to PubMed

Central; the list of those journals currently doing so is viewable at <http://publicaccess.nih.gov>.

Since 2005, the NIH has asked investigators who receive NIH funding to voluntarily submit their final manuscripts within a year of publication; yet as of last September, only about five percent had done so. The NIH Public Access Policy is the result of a congressional mandate requiring that these articles be accessible to the public, ostensibly to help advance science and improve human health. Another reason is the idea is that the public, whose taxes have already paid for the research, should not have to subscribe to expensive scientific journals (average annual cost is about \$1,000) to read about the results. Investigators also may submit manuscripts to PubMed Central that will not be published in peer-reviewed journals.



## PEOPLE IN THE NEWS

- ❖ **Guy Cao** is the newest Network software programmer to join the Biostatistics Center. He recently graduated with a degree in Computer Science from the University of Maryland and has had a number of internships, including with NIH, NIST (National Institute of Standards and Technology) and the J. Craig Venter Institute, a non-profit genome research firm. He is interested in human-computer interaction, artificial intelligence, data structure and web design. Besides working on the new web data entry system, Guy will help redesign the MFMU Network's web pages. He was born in China, but has lived in the U.S. for two-thirds of his life. Guy has lots of hobbies, but particularly enjoys playing tennis, basketball and his violin.
- ❖ Farewell wishes go to **Gwendolyn Norman**, who has served as the nurse coordinator at Wayne State since it became part of the Network in 1991. Gwendolyn has taken a position as the OB Core coordinator for the NIH National Children's Study that is designed to look at all of the aspects that may impact the health of children from pre-conception until 21 years of age. She will be responsible for the identification and recruitment of 1,000 participants over five years. Her near-term goal is to complete her doctorate for her PhD in medical anthropology. Thanks for all of your dedication and contributions to the Network, Gwendolyn, and best of luck – we will miss you!
- ❖ The Network welcomes **Nancy Hauff** as Gwendolyn's replacement. Nancy has extensive management and research experience, most recently working as the coordinator for the NIH Perinatal Research Branch with Dr. Roberto Romero. She has a BSN and MSN in nursing from Wayne State University, is certified by the Association of Womens Health, Obstetric and Neonatal Nursing (AWHONN), and also is working on her doctorate in medical anthropology. Nancy has served as Director of Hutzel Hospital's Community Outreach for Women's Services and for its Outpatient Services, taught at its Department of Nursing Education and Research and also served as adjunct faculty at WSU. She has earned numerous honors for community-related work. Nancy states that her personal interests are first, and foremost, her husband Gary, four children, and three and one quarter grandchildren! She enjoys traveling, snorkeling, golf, and cooking. Nancy attended training at the BCC in February and already is hard at work on Network studies!

### PRESIDENT ELECT

Solve this "cross-number" puzzle and be the first person to submit the winning solution to [Lucy.L@bsc.gwu.edu](mailto:Lucy.L@bsc.gwu.edu) to win recognition in the next Networker.

Across


- 1. A Prime Number
- 5. George H W Bush
- 6. Andrew Johnson
- 7. George W Bush

Down

- 1. A Palindrome
- 2. Abraham Lincoln
- 3. Ronald Reagan
- 4. John Tyler

1	2	3	4
5			
6			
7			

NOTE: a palidrome is a number that reads the same forwards and backwards.



## MFMU CALENDAR

**Network Meeting dates for 2008**  
 April 10 – 11  
 July 10 – 11  
 October 23 – 24

**Network Meeting dates for 2009**  
 January 8 – 9  
 April 23 – 24  
 July 9 – 10  
 October 22 – 23

**2008 SMFM Abstract Deadlines**  
 Proposed Abstracts for SMFM: April 15  
 Subcommittee Approved Abstracts for SMFM: April 30