



# The MFMU Networker

The Newsletter of the Eunice Kennedy Shriver NICHD Maternal-Fetal Units Network

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## Results of 2 Major Network Trials Announced

The primary results from two Network trials were presented in the opening plenary session of the 29<sup>th</sup> annual meeting of the Society for Maternal-Fetal Medicine this past January. This was the third straight year that two Network studies were selected for the plenary session.

*The Multicenter Randomized Treatment Trial of Mild Gestational Diabetes (GDM)* was conducted to evaluate whether treatment of mild GDM improved pregnancy outcomes, including a composite of neonatal morbidity, stillbirth/perinatal death, bilirubin, glycemia and insulin problems. Women with mild GDM (abnormal oral glucose tolerance test (OGTT), but with fasting glucose < 95 mg/dl) were randomized at 24 to 31 weeks gestation to the usual prenatal care (no treatment group, N=473) or dietary counseling, self blood glucose monitoring, and insulin if necessary (treatment group, N=485). The data showed that, while treatment of mild GDM did not reduce the frequency of the composite outcome, it did reduce the risk for fetal overgrowth, shoulder dystocia, cesarean delivery and hypertensive disorders.

*The Randomized Controlled Trial of Antioxidant Vitamins to Prevent Serious Complications Associated with Pregnancy Related Hypertension in Low Risk, Nulliparous Women (CAPPS)* tested the hypothesis that antioxidant therapy, using Vitamins C and E, would reduce serious problems associated with pregnancy-related hypertension. Over five years 10,154 nulliparous low risk women were enrolled between 9 and 16 weeks gestation to receive 1000 mg of

Vitamin C and 400 mcg of Vitamin E or matching placebo. The investigators concluded that antioxidant therapy with Vitamins C and E neither reduced the frequency of serious complications associated with pregnancy-related hypertension, nor did it reduce the diagnosis of preeclampsia.



## Update on TSH Trial

The end to recruitment is almost within sight, with 125 more patients required for the S stratum and 111 more for the H stratum as of April 8. It is anticipated that enrollment for the S stratum (and maybe the H stratum) could end by the end of this year! Meanwhile, nurses have been reminded to ask randomized patients to consider participating in the ancillary study focused on emotional well-being (121 are enrolled out of the target 300). Nurses are also reminded to encourage study participants to take their study medications in order to improve the rate of compliance for the trial.

As the trial progresses the five-year follow-up of the children, including keeping in contact with the family and scheduling the annual testing of the child, is gaining increased attention. Training for the 24-month Bayley III exam will be conducted with more than 30 developmental examiners and coordinators on Monday, April 27, from 12:30 – 3:30 EDT. For the first

time, training will be provided by the BCC via video broadcasting using AT&T Web Meeting Service which combines audio conferencing and data-sharing through the internet. Copies of the DVD showing a live 24-month Bayley III exam, which will be viewed during the broadcast, will be distributed to the participants prior to the training.

Training for the 36-month exam utilizing the Differential Ability Scales (DAS II) is anticipated for this fall. MFMU coordinators have been asked to identify who will perform this exam at their centers and to provide their names and contact information to the TSH staff at the BCC. The training will be an in-person event held at the Biostatistics Center in Rockville, Maryland.

Examiners and study staff have been reminded by Drs. Cathy Spong and Brian Casey that, by protocol, the results of these developmental tests can neither be shared with the participants nor should they encourage parents to pursue further testing. The only exception is if the cognitive, language or motor development portion of the Bayley III test at 24 months falls more than 2 standard deviations below the mean (i.e., < 70). In this event, the BCC will notify the MFMU coordinator who can then contact the family. The follow-up exams are being conducted as part of a research trial, not clinical practice, and if the family and/or their health care providers are concerned about the child's development, they can have testing done outside the trial.



If there are problems bringing participants back to the center for the follow-up visits, nurses should speak with Dr. Spong to discuss a plan of action.

## BCC Assumes Center Capitation Payments

As many Network participants heard at the January Steering Committee meeting, the GWU Biostatistics Center, the data coordinating center for the NICHD MFMU Network, has been asked by NICHD to now administer the payment of patient capitation costs to the participating Network centers beginning April 1, 2009. The NICHD will continue



to pay the center's base costs, including staff salaries. The BCC will establish sub-award agreements with each university's fiscal office in order to provide payments for capitation expenses.

The BCC will present their plans for managing the administration of capitation procedures at the April Steering Committee meeting.

## NICHD Launches New Health Education Program

In an effort to address the challenges and opportunities of applying new knowledge from evidence based research into practice, the Eunice Kennedy Shriver National Institute of Child Health and Human Development is launching a new National Child and Maternal Health Education Program (NCMHEP) beginning this summer. The program will identify significant unresolved challenges in the maternal-child health arena and develop novel ways of applying new knowledge to the issue, one topic at a time, over the course of 18-24 months.

Topics will be identified based on their prominence in the field, identifiable knowledge gaps and associated scientific advances. Initially the NCMHEP will convene a Coordinating Committee of representatives from professional medical and scientific societies and federal agencies. The Committee will work to address key challenges in the field using new knowledge gained from current research findings. Then they will work to communicate this new knowledge to various audiences by creating and distributing educational products. Preterm birth and health problems associated with low birth weight will be the first topic to be addressed. Future topics will include pediatric obesity, infant mortality and environmental influences on child health and development, among others.

## News You Can Use

MedWatch, the FDA Safety Information and Adverse Event Reporting Program ([www.fda.gov/medwatch/](http://www.fda.gov/medwatch/)), serves both healthcare professionals and the public who use medical products. It provides important and timely clinical information about safety issues involving products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements and infant formulas). Consider subscribing to the MedWatch E-List ([www.fda.gov/medwatch/elist.htm](http://www.fda.gov/medwatch/elist.htm)) which will send you immediate news concerning medical product safety alerts, recalls, withdrawals and important labeling changes that may affect the public's health.

The Drug Safety Newsletter (DSN), published online quarterly (<http://www.fda.gov/cder/dsn/default.htm>), provides information for healthcare professionals about the findings of selected post-marketing drug safety reviews, important emerging drug safety issues and recently approved new drugs. The FDA hopes the newsletter will raise awareness of reported adverse events and stimulate additional adverse event reporting by healthcare professionals.

## MFMU CALENDAR

### Network Meeting dates for 2009

April 23 – 24  
 July 9 – 10  
 October 22 – 23

### Other Important Dates

3<sup>rd</sup> SGI International Summit – Preeclampsia: November 12-14, 2009, in Sendai, Japan  
 SMFM Annual Meeting: February 1 - 6, 2010, in Chicago, IL  
 SGI Annual Meeting: March 24 - 27, 2010, in Orlando, FL

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## News Flash

A new MFMU Network Calculator was just posted on the Web! Check it out on the MFMU MIDAS Home Page under "Resources" and on the MFMU web site's Members Page under "Data Mgmt".