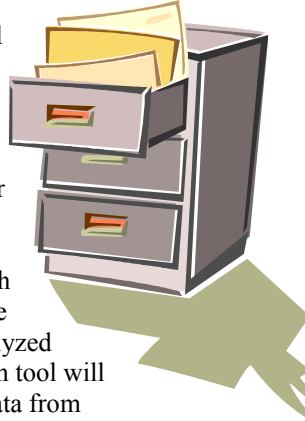


New Protocol In Development

The MFMU Network Steering Committee has approved the next study to be undertaken by the Network. Entitled, *The Measurement of Obstetric Patient Safety*, the aim of the study is to identify about a half-dozen measures that can be used to assess the safety of obstetrical care and be incorporated into medical practice. The impetus for this study comes from the Agency for Health Care Research and Quality and a Congressional mandate that soon doctors will be required to start using quality measures to report on their performance.

A panel of experts will be consulted to help identify the measures that will be studied. A three month pilot study will prospectively collect data related to these measures on about 2500 patients which then will be analyzed to assess their adequacy. Revisions to the data collection tool will be made if required before the study officially starts. Data from approximately 122,500 patient charts are then expected to be extracted over the following 12 months. Because of the vast amount of data, the BCC will be implementing an on-line data entry system. All in all, this will be about a three year study. The co-protocol chairs for this study are Drs. William Grobman from Northwestern University and Jennifer Bailit from Case Western Reserve. The Network's Advisory Board reviewed and approved the protocol on March 20.



BEAM Trial Sets New Standards

The BEAM trial began with an ambitious goal – to complete a two-year follow-up examination on 90% of the children who were born to its participants. Over 9 years and 5,700 neurological exams later, we have met and exceeded that initial objective with two-year outcomes on over 93% of the cohort, due to the tremendous efforts of many individuals.



Achieving this outcome required the dedication, creativity, persistence, resourcefulness, and cooperation of the many follow-up coordinators and examiners. To maintain compliance, varied incentives were used and great efforts were employed to locate lost participants. There was often great flexibility in where and when the children were seen. Examiners saw children at off-hours or with minimal notice; some traveled to the patient's home, whether in town, out of town, or even out of the country. Many families who moved since the child's birth were examined at a different Network center, in some cases even after that center was no longer participating in the Network. The examiners also had to jump through several hoops just to participate. Each had to attend multiple training sessions and then submit annual videotaped exams for central review and evaluation, all to ensure quality and reliability of the primary study endpoint.

At times it was more difficult to achieve our targets, but centers persevered and saw substantial improvements. Some of the more impressive (*cont'd on Page 2*)

SCAN Trial Poised to Start

This trial of 1000 patients will screen women who are pregnant for the first time (or have not had a pregnancy lasting more than 19 weeks) between 16 and 22 weeks' gestation by transvaginal ultrasound to see if their cervix is short (less than 30 mm). If so, they will be asked for their consent to participate in a randomized trial of 17 alpha-hydroxyprogesterone caproate (17P) versus placebo to determine if progesterone will prevent a preterm delivery (less than 37 weeks). One risk factor for preterm delivery that has been consistently demonstrated is short cervical length, especially in nulliparous women.

About half of the Network centers have already received IRB approval for the trial, and the research study staff are beginning the certification process. The sonographers who are being certified to perform the transvaginal ultrasound images are required to submit three transvaginal images from five different patients to the BCC. The BCC will forward them to Dr.



Jay Iams, PI at The Ohio State University for review and approval. At least one sonographer must be study-certified at a center before it can begin the trial. Dr. William Grobman, Co-PI at Northwestern University, is the protocol chair for this trial.

(BEAM, cont'd from Page 1)

gains during the study in terms of follow-up were: UTHSC at San Antonio (from 70% to 85%), UTMB at Galveston (from 79% to 91%), University of Texas Southwestern (from 80% to 90%), UTHSC at Houston (from 83% to 95%), Wake Forest University (from 84% to 93%), and Ohio State University (from 87% to 97%).

Special recognition is appropriate for several individuals. First, for 'endurance', to those follow-up coordinators and examiners who have been involved in this study from the very beginning until the end: Linda Steele (Wake Forest), Sandy Brenner (Ohio State), Dr. Anna Bodnar (Utah), Dr. Virginia Delaney-Black (Wayne State), Dr. Shobhana Desai (Drexel), Dr. Kurt Klinepeter (Wake Forest), Dr. Kathy Nelson (Alabama), Dr. Michael O'Shea (Wake Forest), Dr Myriam Peralta-Carcelen (Alabama), and Becky Selegue (Ohio State). Second, for 'stamina', recognition goes to Dr. Kathy Nelson for completing the most study exams at 400. Lastly, for 'overall performance', recognition goes to the University of Tennessee at Memphis which achieved a follow-up rate of 98% of its 192 participants.

Other individuals provided essential support throughout the study: Dr. Peter Blasco, formerly from the Kennedy Krieger Institute, led the training of all neurologic examiners and has been a continual resource in maintaining the consistency and uniformity of the diagnoses, and Dr. Deborah Hirtz of the NIH National Institute of Neurological Disorders and Stroke (NINDS) who has been the primary force behind this study from design through completion and provided significant funding throughout the trial.

Through the joint accomplishments demonstrated by the successful completion of the follow-up portion of BEAM, a new standard has been set, against which future Network studies will be judged, and for which all who participated can take credit.

Submitted by Steven Weiner

Other Study Updates

Omega-3 - The investigators for this trial are eagerly waiting for outcome data on the remaining 13 patients out of the 852 enrolled subjects. It appears that this will be the first trial conducted in the Network with **100% primary outcome obtained** on every randomized patient, setting another new standard!! Congratulations are due to each and every nurse who worked on this study. Nevertheless, data clean-up is now in high gear, so please keep up your hard work until all the data queries are answered.

CAPPS - as of March 28, 320 patients have been randomized to this trial. With 1680 patients left to randomize, the trial is expected to be finish recruitment sometime this Fall (September – October). At the end of March, 271 subjects had been declared lost (meaning no date of delivery is available).

After the January Steering Committee meeting when the higher than acceptable loss rate was announced, the BCC and NICHD had conference call with the four Network centers with the highest lost-to-follow-up rates. Since then, these centers have pushed very hard to track these patients, to the extent of using the internet and detective agencies, with good success. The BCC is encouraging centers to use every available means to trace delivery information on those women.

GDM - Over 16,300 women with a GLT ≥ 135 and < 200 mg/dl have had the 3-hour oral glucose tolerance test performed for this trial. Of these, 1644 have been enrolled into the trial, leaving 256 still to be randomized to meet the sample size of 1900. It is expected that this trial will be finished enrolling by late fall of this year.

TSH Trial Well Underway

With most of the Network centers now certified and screening pregnant women for a mild imbalance of thyroid hormones, over 4235 patients have been screened as of March 28. 219 have been identified as eligible for the subclinical hypothyroidism stratum and 113 for the hypothyroxinemia stratum, with a total of 55 patients randomized. The current consent rate is about 30%, which is about what was expected. The investigators feel it is better for these women to decline participating in the trial now if they don't want to commit to the 5 year follow-up, rather than being lost to follow-up in the future.

A conference call is being scheduled for the follow-up Bayley examiners, follow-up coordinators, and other research staff for April or May. Details for training and certification and general guidelines for follow-up will be reviewed during this call. A hands-on training for the Bayley III is being planned for late fall. The first baby born to a mother participating in this trial was delivered in mid-March; therefore, the Network needs to make sure follow-up procedures are in place very soon.

A revised protocol, covering some minor updates, including to the informed consent form, will be distributed soon, and will need IRB approval. In addition, the manual of operations is being updated to clarify some procedures and to correct some formatting issues. Be on the look-out for an email alert about these new documents.



Dr. Roger Newman congratulates Drs. Elizabeth Thom and Jay Iams on their awards at the annual SMFM meeting



Network PIs Drs. Iams and Thom Honored at SMFM

Early in the first morning of the annual meeting of SMFM this past February, prior to the plenary session, the audience listened to the current President of the Society, Dr. Roger Newman, expound on the accomplishments of someone sitting in the audience. This person had mentored Dr. Newman, been a past President of the Society (2003-2004), as well as being a Principal Investigator of the MF MU Network. Before long, Dr. Jay Iams, the Network's Principal Investigator at Ohio State University, was acknowledged as the winner of the SMFM 2007 Achievement Award.

Later, the following day at the annual Presidential awards presentation, Dr. Elizabeth Thom, Principal Investigator at the GWU Biostatistics Center, was recognized by Dr. Newman and given an Honorary Membership in the Society for Maternal Fetal Medicine. This honor is bestowed on an individual who is engaged in the practice, research,

teaching, or administration of perinatology, whose activities are thought to influence perinatology in a significant and positive manner but who is not a maternal-fetal medicine specialist.

CAPPS PATIENT GOES BELLY UP FOR BEARS TICKETS

A CAPPS study patient in Chicago made the Bears' recent Super Bowl bid even more memorable, by auctioning off advertising space on her pregnant tummy in exchange for 2 tickets to Super Bowl XLI for her and her husband. Posted as "My Body for Super Bowl Tickets" on Craigslist, this CAPPS patient and life-long Bears fan decided that desperate times called for desperate measures.

Her bold move not only scored her 2 tickets on the 50-yard line, but also invitations to pre-game interviews on the field and other festivities. She was quoted as calling it "...a remarkable experience and one we'll never forget." On March 9, she and her husband welcomed the newest Bears fan to their family, a little boy who weighed in at 7lbs 11oz!

Submitted by Gail Mallett

Network Slides Posted on Web

Looking for information on Network studies for a presentation? An updated power point presentation is available on the Network's "Members Only" web site that presents research results of recent Network studies and background information on currently recruiting studies.

These may be useful when giving grand rounds or a talk about the research undertaken by the Network. Please note that prior to presenting them, the slides may need to be updated with the latest recruitment numbers.

Gestiva® Awarded Orphan Drug Status

On February 26, 2007, the FDA gave Gestiva®, the trade name for 17 alpha-hydroxyprogesterone caproate (17P), orphan designation status for the prevention of preterm birth in singleton pregnancies. This is the same drug that was used in the Network's positive progesterone trial and which Adeza Biomedical used in their application for a new drug application to the FDA.

The granting of orphan drug status is designed to encourage the development of drugs which are necessary but would be prohibitively expensive/un-profitable to develop under normal circumstances. Under the Orphan Drug Act, companies are given tax reductions and marketing exclusivity on that drug for seven years post-approval. This period of time is supposed to encourage more companies to invest money in research.

Update on MOMS Trial

The NICHD's Management of Myelomeningocele study (MOMS) has recruited 116 patients to date, leaving 84 to still randomize. This trial is comparing the safety and efficacy of prenatal surgical repair of spina bificia with the standard postnatal repair.

A major publicity campaign is underway to make this trial more visible to practicing obstetricians nation-wide, including advertising on the Society for Fetal-Maternal Medicine's updated web site with a link to the MOMS web page where physicians can get further information.

People in the News

Sean Blackwell MD has been named **New PI at the University of Texas-Houston**, and in June 2007 will be moving from William Beaumont Hospital in Royal Oak, Michigan to take his new post there. He will succeed Dr. Susan Ramin as the MFMU PI since she became chairperson at University of Texas-Houston last Fall. Sean completed medical school at University of Illinois, then OB/GYN residency & MFM fellowship training at Wayne State University. He joined the WSU faculty in 2001 and worked closely with Yoram Sorokin and Gwendolyn Norman as the Alternate PI for MFMU from 2003-2006. Sean has been involved in other Network activities as well, such as ancillaries studies for BEAM and FOX. In collaboration with John Thorp from UNC, he has presented a primary study related to Cord Blood Gas Values and Neurodevelopment, which is currently in the queue as an approved protocol. In addition to his responsibilities with the MFMU, Sean will be completing a 3-year Masters of Science Program in Clinical Research at UT-Houston.

Jennifer Bailit MD, MPH has been appointed as the **New Co-PI at Case Western Reserve University**. She is an Assistant Professor of Reproductive Biology at CWR and holds a secondary appointment as a Senior Scholar at the Center for Health Care Policy and Research at Case. Jennifer received her undergraduate degree in political science from Brown University and her medical degree from Tufts University. She went on to do her OB/GYN residency at Northwestern and then the Robert Wood Johnson Clinical Scholars program, receiving her MPH from the University of North Carolina at Chapel Hill. She stayed on at Chapel Hill to finish her Maternal-Fetal Medicine fellowship. Clinically, she is a practicing Maternal-Fetal Medicine specialist at

MetroHealth Medical Center. Her research interests focus on measuring and improving the quality of inpatient obstetrical care. Outside of work, she is the proud mother of twins and enjoys reading and hiking.

The BCC is sad to report that **Karla Lawrence** is leaving her position as Executive Coordinator for the Network. Karla received her Masters degree in Community Counseling from GWU earlier this year and has found a wonderful new position as a counselor with the Montgomery County Coalition for the Homeless. We appreciate all her hard work and dedication for the past 2 ½ years.

Shapla Choudhury has been hired as the new Executive Assistant for the BCC MFMU and MOMS staff. She graduated from Occidental College in Los Angeles with a major in Diplomacy and World Affairs and a minor in Psychology. For the past five years she has worked for several organizations, including California Peace Action, a non-profit focusing on peace and social justice; and as an intern with the Nobel Prize winning poverty alleviation NGO, Grameen Bank, in Bangladesh. Shapla intends to pursue a master's degree from GWU, either in neuropsychology and neuropharmacology; focusing on the interpretation of brain scans to diagnose mental illnesses, or in International Development, Asian Studies. Her hobbies include modern and jazz dance, swimming, creating stained glass mosaics, and international travel mostly to Asia and the Indian Subcontinent.



MFMU CALENDAR

Steering Committee Meetings

April 26 – 27, 2007
 July 12 – 13, 2007
 October 11 – 12, 2007
 January 10 – 11, 2008
 April 10 – 11, 2008
 July 10 – 11, 2008
 October 23- 24, 2008

Abstracts/Publications

April 15 – SMFM proposals due to protocol subcommittee for approval
 April 30 – Prioritized proposals from protocol subcommittee due to Pubs Comm.
 May 4 – Publications Committee call to prioritize SMFM proposals
 August 10 – Tentative deadline for SMFM abstracts

Professional Meetings

January 28 – February 2, 2008, SMFM Annual Meeting, Dallas