



The MFMU Networker

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MFMU Network Continues to Make Headlines

The MFMU Network again was very productive this year, with nine major publications, including one in *The New England Journal of Medicine*. Four additional papers have been accepted for publication including one by the *New England Journal of Medicine*. Seven have been submitted to various journals for publication. See page 2 for the list of 2008 published manuscripts.

Twenty-one abstracts were submitted to the Society for Maternal-Fetal Medicine (SMFM) and five to the Society for Gynecological Investigation (SGI) for their respective 2009 annual meetings. Eight of the SMFM and two of the SGI abstracts have been chosen as orals. The primary results of two major Network trials - CAPPS (Dr. James Roberts) and GDM (Dr. Mark Landon) - will be presented in the opening plenary session of SMFM, tying the last two years in which the results of two Network studies each were awarded a spot in the plenary session.

Following Network policy, the primary authors of the SMFM abstracts will present their analyses at the January 2009 MFMU Steering Committee meeting to receive suggestions prior to presentation in San Diego. Preparation of manuscripts from accepted SMFM oral presentations should be underway as, per MFMU Network policy, manuscripts resulting from these should be submitted to the Protocol Subcommittee for review shortly before their presentation at the meeting. All accepted presentations (orals and posters) are expected to result in manuscripts within six weeks of the meeting for which they were submitted. For SMFM 2009, the deadline is March 15. Should the author fail to meet this deadline, the authors will be considered delinquent and forfeit the right to submit further analysis requests, concepts or Ancillary Protocols until this issue is resolved.



All Abstracts Accepted by SGI

Four Network investigators will be traveling to Glasgow Scotland in March to present the results of Network research at the 2009 annual meeting of the Society for Gynecologic Investigation. Two of the five submitted abstracts were selected to be orals: Dr. Erin Clark (Association of repeated dose antenatal steroids with neurodevelopmental outcomes at age 2 in infants with IL-6-174 genotype) and Dr. Cynthia Gyamfi (The rate of recurrent preterm birth analyzed by indication for prior spontaneous preterm birth).

Also attending to present posters are: Dr. Amanda Horton (Role of family history in identifying FVL carriers during pregnancy), and Dr. Tracy Manuck (The relationship between polymorphisms in a truncated progesterone receptor [R-M] and clinical response to 17OHPC) for the treatment of recurrent spontaneous preterm birth). Dr. Gyamfi also will be presenting a poster on steroids and RDS in late preterm babies.

Free DVD on MOMS Trial

A free DVD about the Management of Myelomeningocele Study (MOMS) is available to physicians and their patients who may be considering participation in this study, a national NIH-sponsored clinical trial comparing two treatment approaches to spina bifida -- prenatal surgical repair versus postnatal surgical repair, the current standard of care. The DVD features an overview of the study and the patient experience by members of the MOMS steering committee and nurses at the participating centers.

To spur new awareness of the trial, over 8,000 DVDs were sent to genetics counselors, obstetric ultrasonographers, maternal-fetal medicine specialists and obstetricians this past fall. It also has been posted on several websites, including MOMS (www.spinabifidamoms.com) and The Children's Hospital of Philadelphia.

Of the 200 patients needed for the sample size, 147 have been enrolled. A number of recruitment efforts continue, including an exhibit at the First World Conference on Spina Bifida, March 15-18, 2009, in Orlando, Florida. Please contact Jessica Ratay, Study Coordinator, at 1-866-ASK-MOMS (275-6667) or email her at MOMS@biostat.bsc.gwu.edu for information or a free DVD.

Results of BEAM Trial – One of Time Magazine's Top 2008 Medical Breakthroughs

The findings of the Network's BEAM trial were given recognition by Time Magazine in its annual list of the latest medical breakthroughs and discoveries. In this clinical trial of 2,241 pregnant women at risk for early preterm birth (between 24 and 31 weeks of gestation) in those who received magnesium sulfate - commonly known as Epsom salts - shortly before giving preterm birth at 24 to 31 weeks of gestation, the rate of moderate to severe cerebral palsy (CP) in their infants dropped by almost half. Currently, preterm birth accounts for about a third of all cases of cerebral palsy, a developmental disorder that strikes two out of every 1,000 U.S. newborns.

MFMU Fellow Wins Recognition for Network Research

The analysis of DNA samples collected from the Network's progesterone trial, conducted by Tracy Manuck, MD, was selected for presentation at the Fellows Plenary Session during the 2009 annual meeting of the Society for Maternal-Fetal Medicine. Additionally, this abstract has been awarded the "Best Research in Prematurity" award from the March of Dimes! The research evaluated evidence of genetic predisposition to respond to 17 alpha-hydroxyprogesterone caproate (17OHPC), the drug used in the progesterone trial.

Dr. Manuck is a native of Farmington, Connecticut and attended Wake Forest University in Winston-Salem, NC where she earned a B.A. in Chemistry. She also received her M.D. and completed residency training in Obstetrics and Gynecology at Wake Forest University/Baptist Medical Center. Dr. Manuck moved to Salt Lake City in 2007 and is a current Maternal Fetal Medicine fellow. Her research interests include previable preterm premature rupture of membranes, preterm labor, and multiple gestations.



2008 NICHD MFMU Network Publications

Mercer BM, Gilbert S, Landon MB, Spong CY, Leveno KJ, Rouse DJ, Varner MW, Moawad AH, Simhan HN, Harper M, Wapner RJ, Sorokin Y, Miodovnik M, Carpenter MW, Peaceman AM, O'Sullivan MJ, Sibai BM, Langer O, Thorp JM, Ramin SM; for the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. **Labor outcomes with increasing number of prior vaginal births after cesarean delivery.** *Obstetrics and Gynecology*, 111:285-291, 2008.

Sciscione A, Landon MB, Leveno KJ, Spong CY, MacPherson C, Varner MW, Rouse DJ, Moawad AH, Caritis SN, Harper M, Sorokin Y, Miodovnik M, Carpenter M, Peaceman AM, O'Sullivan MJ, Sibai BM, Langer O, Thorp JM, Ramin SM, and Mercer BM for the National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU). **Previous preterm cesarean delivery and risk of subsequent uterine rupture.** *Obstetrics and Gynecology*, 111:648-653, 2008.

Carroll MA, Vidaeff AC, Mele L, Wapner RJ, Mercer BM, Peaceman AM, Sorokin Y, Dudley DJ, Spong CY, Leveno KJ, Harper M, Caritis SN, Miodovnik M, Thorp JM, Moawad AH, O'Sullivan MJ, Carpenter MW, Rouse DJ, Sibai BM, and the National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units Network (MFMU). **Bone Metabolism in Pregnant Women Exposed to Single Compared With Multiple Courses of Corticosteroids.** *Obstetrics and Gynecology*, 111:1352-1358, 2008.

Mastrobattista JM, Klebanoff MA, Carey JC, Hauth JC, Thom EA, Ernest JM, Cotroneo M, Wapner RJ, Varner M, Iams JD, Moawad AH, Sibai BM, Miodovnik M, Dombrowski MP, O'Sullivan MJ, VanDorsten JP, Langer O, for the National Institute of Child Health and Development Maternal-Fetal Medicine Units Network. **The effect of body mass index on therapeutic response to bacterial vaginosis in pregnancy.** *American Journal of Perinatology*, 25: 233-237, 2008.

Grobman WA, Lai Y, Landon MB, Spong CY, Leveno KJ, Rouse DJ, Varner MW, Moawad AH, Caritis SN, Harper M, Wapner RJ, Sorokin Y, Miodovnik M, Carpenter MW, O'Sullivan MJ, Sibai BM, Langer O, Thorp JM, Ramin SM, Mercer BM, for the National Institute of Child Health and Human Development Maternal Fetal Medicine Units Network. **Prediction of uterine rupture associated with attempted vaginal birth after cesarean delivery.** *American Journal of Obstetrics and Gynecology*, 199: 30.e1-30.e5, 2008.

Rouse DJ, Hirtz DG, Thom E, Varner MW, Spong CY, Mercer BM, Iams JD, Wapner RJ, Sorokin Y, Alexander JM, Harper M, Thorp JM Jr, Ramin SM, Malone FD, Carpenter M, Miodovnik M, Moawad A, O'Sullivan MJ, Peaceman AM, Hankins GD, Langer O, Caritis SN, Roberts JM; Eunice Kennedy Shriver NICHD Maternal-Fetal Medicine Units Network. **A randomized, controlled trial of magnesium sulfate for the prevention of cerebral palsy.** *New England Journal of Medicine*, 359: 895-905, 2008.

Newman RB, Goldenberg RL, Iams JD, Meis PJ, Mercer BM, Moawad AH, Thom E, Miodovnik M, Caritis SN, Dombrowski M, for the National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. **Preterm Prediction Study Comparison of the Cervical Score and Bishop Score for Prediction of Spontaneous Preterm Delivery.** *Obstetrics and Gynecology*, 112: 508-515, 2008.

Alexander JM, Leveno KJ, Rouse D, Landon MB, Gilbert SA, Spong CY, Varner MW, Caritis SN, Harper M, Wapner RJ, Sorokin Y, Miodovnik M, O'Sullivan MJ, Sibai BM, Langer O, Gabbe SG, for the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. **Cesarean Delivery for the Second Twin.** *Obstetrics and Gynecology*, 112:748-752, 2008.

Klebanoff MA, Meis PJ, Dombrowski MP, Zhao Y, Moawad AH, Northen A, Sibai BM, Iams JD, Varner MW, Caritis SN, O'Sullivan MJ, Leveno KJ, Miodovnik M, Conway D, Wapner RJ, Carpenter M, Mercer BM, Ramin SM, Thorp JM, Peaceman AM and National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network. **Salivary progesterone and estradiol among pregnant women treated with 17- α -hydroxyprogesterone caproate or placebo.** *American Journal of Obstetrics and Gynecology*, 199: 506.e1 - 506.e7, 2008.

Important Messages for Network Authors

Please note that, as of April 7, 2008, any paper published in a peer-reviewed journal resulting from NIH-funded research must be submitted to the new PubMed Central (which is not the same as PubMed). Please send Susan Pagliaro the "postprint" (**the final manuscript as a Word document after peer-review and acceptance for publication, but prior to the publisher's copyediting, design, formatting, and other services**). In the meantime, if you receive a message with the subject line: "[nihms] NIHMH#1234: Approve Submission of Manuscript", please forward it to Ms. Pagliaro because this is the request from the NIH Library of Medicine to submit it to PubMed Central.

Also note that the MFMU Network has adopted a formal policy for authorship that is in line with the strict rules for author acknowledgement required by most medical journals. An authorship template has been created for each completed Network study, along with a set of instructions. These are posted on the MFMU website and recently have been updated. They must be followed when listing those investigators who are eligible for listing as an author / contributor to your manuscript.



New Coordinator Hired at OHSU

A warm welcome is extended to the new MFMU Network coordinator at OHSU, **Beth Schafer**, who is learning the ropes from Ellen Lairson who will depart from that post on January 1. Beth has had a diverse medical career since receiving her BSN from Kent State. She was a floor nurse in the cardiac unit at the Cleveland Clinic for a few years before relocating to Boston and Brigham and Women's Hospital where she nursed post-op cardiac surgical patients and conducted patient education programs.

Beth then became the product representative in Boston for a Texas company that develops products for wound care. In that role she was responsible for clinical education and training for the company's products, and for developing new marketing opportunities.

Most recently Beth was a clinical reviewer for the Harvard Clinical Research Institute where she reviewed data from coronary stent trials and prepared reports for physician committees. In her spare time Beth enjoys hiking, biking, reading and cooking.

The Network also wishes to extend heartfelt thanks to Ellen Lairson for her work as the Network research coordinator at OHSU. We wish you all the best, Ellen!

APEX Study Update

Since the beginning of the APEX study last March a total of 2,263 days have been randomly selected for data collection at the 25 participating hospitals, and a total of 30,721 patients have been identified as eligible. By the end of the study (estimated to be February 2011) with approximately 120,000 patients enrolled, APEX will be one of the largest databases ever collected regarding labor and delivery.

The objective of the study is to evaluate the quality of obstetric care, defined as adherence to process measures (i.e., clinical guidelines) associated with five obstetric outcomes: 1) thromboembolism in cesarean deliveries, 2) uterine hemorrhage, 3) maternal infection, 4) maternal third and fourth degree lacerations in vaginal deliveries, and 5) neonatal trauma or HIE in term, non-anomalous neonates.

BCC staff recently conducted data review visits at Northwestern University, UT Southwestern and Wayne State to monitor the quality of the abstraction process. Dr. Jennifer Bailit, protocol co-investigator, participated in the Wayne State review to get an overview of the data that is available for abstraction at a different Network center and to answer questions.

Some of the issues uncovered during these data reviews will be discussed at the Network coordinator's 'APEX Refresher' session on Wednesday, January 7.

MISSING SCREENING LOGS

The following is a true incident...only some details have been changed to protect the innocent. No one can figure out why anyone would want a listing of patients who were screened for a Network trial. Please consider this a word of caution when handling research records entrusted to your care.

On Wednesday, November 26th, the research nurse working at a Network recruiting site locked the office at 3:00 pm and left for the Thanksgiving Holiday. She returned to the office on Monday, December 1st at 8:30 am and realized that the binder containing screening forms for a Network trial was not on her desk where she had left it. She searched the office but did not find the binder.

The nurse contacted the site Manager and the security officer and reported a security breach incident. No other items were missing from the office. The research nurse and the site manager were the only individuals who had access to that office besides the cleaning crew. No one else was seen or known to enter this office during that period. The study screening log contained the names and medical record numbers of about 330 patients. Fortunately a copy of the log was also kept in the main Network office. The research team,

security and cleaning crew were unable to explain what happened to the three inch binder. The incident was reported to the local IRB, NICHD and the BCC. The research staff now places the binder in a locked drawer inside the locked office at the end of each day.



Winner of the "Unusual Year" Puzzle

Partial credit goes to *Donna Allard*, research nurse at Brown University, who knew the answer to question 2 and got 7 of the 23 correct for question 1! No doubt she just didn't have time to finish because she was on the right track to solve the rest. The answers:

- 23, and they are: 1, 11, 101, 111, 1001, 1111, 8, 88, 888, 181, 808, 818, 1881, 69, 96, 609, 906, 619, 916, 689, 986, 1691, and 1961 (unless you want to count the year 0 AD also)
- 6009

Solve the following puzzle and be the first to submit the solution to Lucy.L@bsc.gwu.edu to win recognition in the next newsletter.

DOLLARS AND CENTS PUZZLE

Joe cashed a check at the bank. The absent-minded teller switched the amount of dollars and cents in the check when she cashed it, but Joe didn't notice. Later, he bought a piece of bubble-gum for 5 cents and then noticed that he now had twice as much as the original check amount.

What was the amount on the check?



MFMU CALENDAR

Network Meeting dates for 2009

January 8 – 9
April 23 – 24
July 9 – 10
October 22 – 23

Other Important 2009 Dates

SMFM Annual Meeting, San Diego: January 26 - 31, 2009
SGI Annual Meeting, Glasgow, Scotland: March 17 – 21, 2009