



The MFMU Networker

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One FOX Begets Another



Karen Dorman reported this humorous story from UNC-Chapel Hill. One of their first year interns who started another rotation on L&D was driving to work on the highway when he saw a live fox on the side of the road. He blinked and looked again – and sure enough – there it was. He felt it was a ‘sign’, got to the hospital, and recruited his first FOX patient! “This is true story,” claims Karen, “And then I got to stay up all night with her and watch her C-Section at 3:20 AM!”

New NICHD Grants Manager

A new grants manager, Margaret Young, has been appointed to take over responsibilities for the MFMU Network from Mary Ellen Colvin who had this task added to her other duties when grants manager, Chris Myers, left. When corresponding with Ms. Young during this transition period, please make sure also cc: John “Chris” Robey (who is the new Team leader) and Mary Ellen Colvin, as well as Dr. Spong and Susan Pagliaro as needed. Email addresses are: myoung@mail.nih.gov and robeyj@mail.nih.gov. Phone numbers are: 301-435-7008 (Young) and 301-435-6996 (Robey), and the fax is 301-480-4782.

Referring to finances, a revised Recruitment Request Form has been posted on the MFMU web site (Business section – Policies and Procedures). When needed, you may complete the form and submit it on line to Susan Pagliaro for approval.

*Best Wishes for a
Healthy, Peaceful
New Year!*

Doppler Training Scheduled for CAPPs Prediction

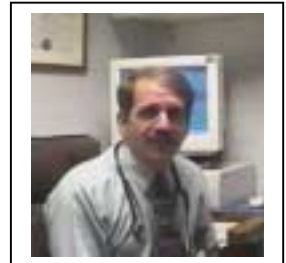
At least eight ultrasonographers, along with BCC staff, are meeting at Columbia University for a hands-on uterine artery Doppler training with Dr. Fergal Malone on January 26. Certification is required for all sonographers participating in the CAPPs Prediction study. The first part of the certification involves reviewing a power point presentation (provided on the MFMU web site), detailing the uterine artery Doppler protocol, answering the ten questions that follow and sending them to Rebecca Gersnoviez at the BCC. For the second part of the certification, sonographers need to take 15 still Doppler waveform images of a uterine artery, each from a separate patient, and submit them to Dr. Malone who will review the images for accuracy.

Meanwhile, centers are working on getting the Prediction protocol approved by their IRBs and completing the rest of the certification process. In addition, nurses are working to improve recruitment to the RCT part of the CAPPs study. Dr. Jim Roberts has scheduled a grand round at UT Houston, and UTSW has beefed up their screening to include four patient clinics rather than just concentrating at their main site. Other suggestions for increasing recruitment include local news releases, mass mailing to area Ob/Gyns, a national press release from the NICHD and NHLBI communication offices and an announcement on the ACOG web site.

More Kudos for BEAM Teams!

Thanks to continued dedication of BEAM research staff, infant follow-up to determine the effects of antenatal magnesium sulfate on cerebral palsy, continues at an exceptionally good rate.

Dr. Marc Collin, BEAM follow-up neurological examiner at Case Western’s MetroHealth Medical Center in Cleveland and pictured on the right, has been praised by Cynthia Milluzzi for service above and beyond the call of duty! One of the infants born to a BEAM study patient is in the custody of another caregiver who was not able to bring the child to the hospital because of numerous issues beyond her control. So that the follow-up data was obtained in the right timeframe, Dr. Collin drove to caregiver’s home (190 miles round trip!) and performed the exam there.



Ester Flores, the BEAM nurse at UTSW, received a call on her cell phone the night before Thanksgiving from a BEAM mother who had driven to Dallas for the Thanksgiving weekend from her new home in Indiana. She wanted to make an appointment for her infant’s follow-up on the Friday after Thanksgiving. The mother said it would be hard for her to return again to Dallas since she could not travel by air or bus because she did not have an ID and did not want to risk being deported.

Since the clinic was closed for the holidays, Esther persuaded her to stay until Monday and then contacted Cathy Boatman, the Bayley examiner, and Dr. Heyne, the pediatric examiner, who were able to accommodate the patient on Monday morning. Finally, Ester confirmed the Monday appointments with the mother. All this was done within half an hour by Ester, while doing last minute shopping with her two children at the Wal-mart!

People in the News

- ◆ Congratulations to BCC research assistant, *Barbara Jones-Binns*, who delivered her first child, 8lb 4 oz Cale Alexander Binns, by C-Section on December 18. Their discharge was delayed a few days because both had fevers, Barbara's blood pressure spiked and Cale had aspirated meconium. Barbara went home December 22, Cale on Christmas Eve and all are doing just fine!
- ◆ Best wishes to two newlyweds at UTSW: *Paula (Mesa) Orduno*, Follow-up Coordinator, and *Desheila (Young) Weightman*, Research Nurse. We wish them and their spouses many, many years of happiness.
- ◆ Kris Anderson regrets the loss of two longtime nurses at her University site, *Lori Williams and Melanie Fuller*. Lori was the infant follow-up coordinator and Melanie recruited for BEAM and BEARS and was working to get the GDM and CAPPS studies going. *Lisa Fullmer* is filling in as the follow-up coordinator (along with her duties at the UVRMC site) until a replacement is found. A new nurse has been hired at the University site, *Tina Winn*, who is being certified for CAPPS and GDM. She has a strong L&D background, and looks forward to being involved in research and learning new things.

Steroid's 3-Year Follow-up Cancelled

As previously reported, the Antenatal Corticosteroids trial (BEARS) was stopped in April following a recommendation by the DSMC to the NICHD and after extensive discussions among the DSMC and Drs. Willoughby and Alexander.

During subsequent discussions at NICHD, it has been decided that follow-up of the children would be limited to the 2-year visit because further data collected at a 3-year follow-up visit, as designed in the protocol, would most likely not be able to discriminate differences as a result of the trial.

Consequently, it is important that all Network centers make sure to get all infants back for the two-year follow-up exam.

GDM and Quest Concerns

Both the BCC and centers have encountered ongoing problems with the services contracted for the GDM study with Quest Diagnostics. The BCC has written a letter of dissatisfaction covering issues such as not being contacted when values are out of range, delays in receiving results, and tops to tubes that come off in the centrifuge.

Quest has responded to some of these issues, including the gray tops. They claim that there has not been a change in the tops and should still be #VCN 026858. If centers are not receiving the same top as before, please let the BCC know as soon as possible. A conference call is being scheduled with Quest in January to discuss these problems further.

A GDM subcommittee call was held December 17 to discuss several issues, including recruitment, aberrant OGTT test results from Quest and whether patients in Group II were learning their group assignment. Coordinators from the subcommittee will be contacting other coordinators about these items. However, the subcommittee re-emphasized that the protocol, which states Group II patients should not know their group assignment, should be followed.

STTARS Status

By conference call on December 16, the DSMC approved the protocol for the 17-Alpha-Hydroxyprogesterone Caproate for Prevention of Preterm Birth in Multifetal Gestation randomized trial with some minor changes. The changes, including definitions of neonatal outcome, are being made to the protocol before it is distributed to the Steering Committee for final approval and vote. The manual of operations is being written and a number of the data forms are in software development. The certification quiz is also being developed.

The major delay, unfortunately, has been in the collection of the chemical, manufacturing and control data required for the FDA IND, including certificates of analysis and analytical test procedures for the initial lots of the progesterone and placebo. The University of Tennessee, the manufacturer of the study meds, has encountered a problem with the filtration of the injection solution. Until this and several other items are resolved, the IND cannot be submitted. While some centers have submitted the materials to their IRB, most IRBs will not consider approving the protocol until IND approval has been received.

A Software Programmer's Nightmare

On December 1, Margie Jimenez, the data entry operator at Brown University, telephoned the Network Software Programmers to say that her computer would not start. It was quickly determined that her hard drive had failed. A service call was made and a new hard drive was installed on the 2nd, but in the process of restoring from Brown's back-up tapes, it was discovered that they only contained "incrementally" backed-up data, not a full backup of the PC as required for a smooth recovery process.

Margie sent her PC and all her tapes to the BCC and Brendan Broderick put the Emergency Restore System into high gear. By December 10th, Brown had their PC back with the VFP software restored, along with about 99% of their data. Shortly thereafter the BEAM database was restored to Brown's PC via the phone line.

By December 18, following data transmission, the BCC was able to verify that Brown databases were once again complete. As always, lessons are learned from emergencies and the BCC has already checked the tape backup configuration at all centers and distributed disaster recovery disks to each center to use in the event of a hard disk crash.

The BCC really appreciates the fact that Margie and JoAnn Tillinghast were calm and relaxed during this crisis. Because of their help and understanding, the BCC was able to completely restore their computer and verify their databases within eighteen days!



NOTE: Coordinators, please remember to pass on study information and updates that you receive from the BCC and NICHD to your nurses. While the BCC encourages people to call with questions, many of the nurses are calling with questions about new study procedures that should have been communicated to them. Thanks!

Record set for Manuscripts and Publications in 1 Year

In keeping with a renewed effort to publish the results of research projects, Network investigators have published 14 manuscripts and had another 9 accepted by journals, for a total of 23 articles this year. Six additional papers have been submitted, but have not yet been reviewed by the journal. The 23 represent one fifth of the total number of publications that have been published since the very first Network manuscript appeared in the *New England Journal of Medicine* in 1993. Following are the papers that appeared in print in 2003.

Hauth J, Carey JC, Klebanoff M, Hillier S, MacPherson C, Ernest JM, Fischer ML, Heine P, Nugent R, Wapner RJ, Trout W, Moawad A, Leveno K, Miodovnik M, Sibai B, Van Dorsten JP, Dombroski M, O'Sullivan M, Varner M, Langer O and the NICHD Maternal Fetal Medicine Units Network. **Early pregnancy threshold vaginal pH and gram stain scores predictive of subsequent preterm birth.** *Am J Obstet Gynecol*, 188(3): 831-5, 2003.

Andrews WW, Sibai BM, Thom EA, Dudley D, Ernest JM, McNellis D, Leveno KJ, Wapner R, Moawad A, O'Sullivan MJ, Caritis SN, Iams JD, Langer O, Miodovnik M, Dombrowski M and the NICHD Maternal Fetal Medicine Units Network: **A randomized clinical trial of metronidazole plus erythromycin to prevent spontaneous preterm delivery in fetal fibronectin-positive women.** *Obstet Gynecol*, 101: 847-855, 2003.

Meis P, Spong C and Thom EA (eds). **Introduction.** *Seminars in Perinatology*, Vol 27, No 3 (June), 2003:183-184.

Das A, Copper R, Goldenberg RL, Iams JD, Johnson F, Meis, P, Mercer BM, Moawad A for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about the predictors of preterm birth.** *Seminars in Perinatology*, Vol 27, No 3 (June), 2003: 185-193.

Iams JD and Owen J for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about cervical ultrasound.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 194-203.

Iams JD for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about uterine contractions and preterm birth. The HUAM Prediction Study.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 204-211.

Carey JC and Klebanoff MA for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about vaginal infections and preterm birth.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 212-216.

Bendon RW, Das AF, Goldenberg RL, Mercer BM, Miodovnik M, Ramsey RD, Rabello YA, Thurnau GR for the NICHD Maternal Fetal Medicine Units Network. **What we have learned regarding antibiotic therapy for the reduction of infant morbidity after preterm premature rupture of the membranes.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 217-230.

Andrews WW and Goldenberg RL for the NICHD Maternal Fetal Medicine Units Network. **What we have learned from an antibiotic trial in fetal fibronectin positive women.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 231-238.

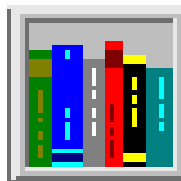
Caritis S, Hauth J and Sibai BM for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about preeclampsia.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 239-246.

Iams, JD and Mercer BM for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about antenatal prediction of neonatal morbidity and mortality.** *Seminars in Perinatology*, Vol. 27, No 3 (June), 2003: 247-252.

Thom E, Rouse D for the NICHD Maternal Fetal Medicine Units Network. **What we have learned about conducting randomized controlled trials in the NICHD MFMU Network.** *Seminars in Perinatology*, Vol 27, No 3 (June), 2003:253-260

Schatz M, Dombrowski M, Wise R, Thom EA, Landon M, Mabie W, Newman R, Hauth J, Lindheimer M, Caritis S, Leveno K, Meis P, Miodovnik M, Wapner R, Paul R, Verner M, O'Sullivan M, Thurnau G, Conway D, McNellis D for the NICHD Maternal Fetal Medicine Units Network. **Asthma morbidity during pregnancy can be predicted by asthma severity classification.** *J Allergy Clin Immunol*, 112(2):283-8, 2003.

Meis P, Klebanoff M, Thom E, Dombrowski M, Sibai S, Moawad A, Spong C, Hauth J, Miodovnik M, Varner M, Leveno K, Caritis S, Iams J, Wapner R, Conway D, O'Sullivan M, Carpenter M, Mercer B, Ramin S, Thorp J, Peaceman A, for the NICHD Maternal Fetal Medicine Units Network. **Prevention of recurrent preterm delivery by 17 alpha-hydroxyprogesterone caproate.** *N Eng J Med*, 348: 2379-85, 2003.



MFMU CALENDAR

Steering Committee Meetings

- January 22 - 23, 2004
- April 15 - 16, 2004 (overlap with Neonatal Research Network)
- July 12 - 13, 2004
- October 21 - 22, 2004

Training

- CAPPS Prediction Protocol January 21, 2004
- CAPPS Prediction Doppler: January 26, 2004
- BEAM Follow-up Examiners, March 15-16, 2004

Ultrasound Reviews

January 29-30, 2004

Site Visits

- Columbia University: January 26-27, 2004
- University of Utah: February 23-24, 2004

Professional Meetings

SMFM Annual Meeting, New Orleans, February 2-7, 2004

MFMU DSMC Meeting

March 12, 2004

On the Light Side

