



The MFMU Networker

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FOX Trial Continues to Be Crafted

A great amount of work continues being done on the FOX trial. The Subcommittee has approved a major change to the protocol, which revised the study from 3 arms to 2 arms. One arm will be the open device group which will have the fetal pulse oximeter sensor inserted and data available to caregivers. The other arm will be the masked device group which will have the sensor inserted but data will be masked to the caregivers.

The FDA has required that an Investigational Device Exemption (IDE) be submitted for the fetal pulse oximeter. The NICHD, BCC and several other investigators have been busy assembling the materials required for the submission. Nellcor Puritan Bennett, the manufacturers of the Oxifirst Fetal Oxygen Saturation Monitoring System, has granted permission to include its approved Pre-Market Approval Application (PMA) in the Network's IDE, which is very helpful because it contains a great deal of the material required by the IDE. The IDE must be approved before the study can start.

The tentative training session for October 17 has been postponed until near the end of the year or January 2002. The following events, which are necessary to get the study underway, include: approval of the revised protocol by the Steering Committee and DSMC, obtaining IRB approval at centers, Nellcor training and certification at individual centers, completion of software development for the N-400 and Corometrics 128, central training for coordinators and research nurses and, finally, center-wide certification.

Variety of Abstracts Submitted to SMFM

August was a busy month for the writers and reviewers of abstracts prepared for the Society of Maternal Fetal Medicine's 2002 meeting. The Publications Subcommittee approved a total of 18 MFMU Network abstracts for submission. The topics cover the C-Section, Cervical Ultrasound, BV/TV, High Risk Aspirin, HUAM, Preterm Prediction, pPROM and Preterm Labor studies. The next newsletter will report on those abstracts which are accepted.

Work on 13 abstracts for SGI is now underway, with the deadline of October 29 for submission. All data on fluids for the biological fluid abstracts must be sent to the BCC by October 10. October 22 is the deadline for submission to Dr. Paul Meis, with the review taking place by conference call on October 25.



MCP Hahnemann is New Network Center

Drs. Cathy Spong and Elizabeth Thom conducted a site visit at MCP Hahnemann Medical Center (MCPH) on August 14 for the purpose of making an evaluation of a proposed reorganization of facilities in Philadelphia. Prior to the visit, TJU staff, Dr. Ron Wapner, PI, Michelle DiVito, Coordinator, Tracy D'Ambrosia, office coordinator and Joan McAllister, data manager, had relocated to MCPH. Staff, facilities, organizational procedures, and protocol procedures were all reviewed and the recommendation was made that MCPH become the main Network center.

Thomas Jefferson University will become an ancillary site with Christiana Care Hospital System remaining an ancillary site. Both ancillary sites have a designated 'site'-PI and coordinator in addition to two full-time trained research nurses. Weekly staff meetings are held at each site by Michelle and monthly meetings are held with staff from all three sites. Coordination details, such as target recruitment for each site, patient chart maintenance, specimen storage and study documentation, have all been established.

The addition of MCPH will boost deliveries by almost one third (to about 12,000) for the center.

Dr. Leveno Shows 'Grand'-Fatherly Side

Juliana shares her "cullies" with PI, Ken Leveno, at her mother's reception for the Network in July. The large group



enjoyed a delightful get-together, augmented with a delicious spread of salmon, roast pork, shrimp, veggies, dips, sweets and libations. It was nice to have a chance to become acquainted with some of the new members and catch up with the old. Thanks, Dr. Cathy Spong, for a lovely evening!

13th Annual NICHD Aspen Conference Convened

130 students and faculty participated in the annual Conference on Maternal-Fetal/Neonatal/Reproductive Medicine held August 22-25 in Aspen, Colorado. The goal of the Institute each year is to promote investigative careers in OB/GYN and pediatrics to about 85 clinical fellows in maternal fetal medicine, neonatology, and reproductive endocrinology. Topics include sources for research funding, clinical trial design, and elements of a research career.

Dr. Steve Gabbe presented an overview of the issues involved in the use of pulse oximetry during labor in preparation for the clinical trials workshop, which focused on the design of a trial to assess the safety and usefulness of fetal pulse oximetry. Dr. Cathy Spong made several presentations, including one on the prevention of fetal alcohol syndrome in an animal model. Other familiar faces from the NICHD and the Network, who were presenters or led sessions, included Robert Goldenberg, Elizabeth Thom, Charlotte Catz, Linda Wright, Sumner Yaffe, and Duane Alexander.

Dr. David Satcher, Surgeon General of the United States, gave the Joseph Butterfield Lecture on the topic: The Challenge of Eliminating Health Disparities in Perinatal Medicine.

Study Updates

Factor V Leiden: Recruitment for this study ended Friday, August 31, with about 5200 patients enrolled. The enrollment process went very smoothly and was completed more than six months ahead of schedule. Now it is *very* important for each center to be diligent about data collection so that the study can be ensured follow-up information on all patients, but especially the 100 FVL carriers and 200 matched controls. The last patient should deliver in April or May 2002.

BEAM Trial: January 28, 2002 has been selected as the date for the next training session for *all new* pediatric examiners working on the BEAM trial. This includes examiners from both "new" and "old" centers and will be held, as normal, at the Kennedy Krieger Institute at Johns Hopkins University in Baltimore, Maryland.

Steroids Trial: The study drug, betamethasone, continues to remain in short supply and clinical centers can only be re-supplied on an as-needed basis. Recruitment slowed over the summer. However, Ohio State enrolled almost half their total number of 15 in the months of June and July. MCP Hahnemann (TJU) still leads the pack with a total of 31 enrolled. As of September 12, there have been 117 patients enrolled in this trial. About 10% of those screened are eventually randomized.

Dr. Ron Wapner has been invited by UNC - Chapel Hill to make his presentation on multiple courses of steroids to their staff on October 3. While in North Carolina, he will also visit Wake Forest for the same purpose. Other centers are encouraged to invite Dr. Wapner to talk with their staff. Those places where he has made his presentation have reported a positive effect on study recruitment.

Bits & Pieces

◆ **The results of the TV trial** were published in the August 16 edition of the New England Journal of Medicine. Entitled, *Failure of Metronidazole to Prevent Preterm Delivery among Pregnant Women with Asymptomatic Trichomonas vaginalis Infection*, the publication concluded that routine screening and treatment of asymptomatic pregnant women for this condition cannot be recommended.

◆ **Dr. Langer's RCT concept** to study diet, insulin and oral hypoglycemic agents as alternatives in the management of gestational diabetes in pregnant women, which was presented at the July Steering Committee meeting and voted on by email, did not receive the required 2/3 vote to progress to the mini-protocol stage.

◆ **The MFMU web site** soon will have a new updated look! We hope you will find it easier to navigate. Also, check out the new on-line calendar. If you have suggestions, please contact the webminder.

NAS to Hold Roundtable on Environmental Toxicants in PT Birth

The Roundtable on Environmental Health Sciences, Research, and Medicine is holding a two-day workshop entitled *The Role of Environmental Toxicants in Premature Delivery*, at the National Academy of Sciences in Washington DC on October 2 and 3. A number of Network PIs will be presenting. Recent research have suggested that some environmental factors (e.g. genital tract infection, stress, anxiety, depression) may play important, but as yet unspecified roles in determining a woman's risk of delivering a preterm baby. This workshop will build on previous research, and focus on the role of environmental toxins, an area often overlooked, as a risk factor. The third in a series, this workshop is sponsored by the Roundtable, to discuss issues related to the environment and our health. Those who cannot attend the workshop are invited to participate by listening to a live audio Webcast of the event and submitting questions using an e-mail form. Both the Webcast link and the form will become available at the time of the event at <http://www.national-academies.org>. Further information may also be found at this website. Registration is free.

LO1 Research Opportunity Deadline Nearing

NICHHD intends to commit approximately \$5 million in total costs in FY 2002 to fund 3 supplemental grants within the NICHHD's MFMU, NICU and Reproductive multicenter research networks. The objective is to stimulate investigators with expertise in the design and conduct of clinical trials to focus on ethnic disparities in preterm birth and its sequelae. Investigators from all Network centers are invited to submit concepts to Dr. Spong before October in response to the LO1 entitled: Health Disparity in Preterm Birth: Clinical Trials to Prevent Preterm Birth and Adverse Neonatal Outcomes Associated with Infectious/Inflammatory Disease Process. At least eight concepts will be presented at the October Steering Committee meeting.

This effort is focused on reducing the large difference in infant mortality rates between different ethnic populations, in many cases related to infection-induced preterm birth. This area is one of the major disparities in health outcomes as listed in the NIH's Areas of Emphasis. Because of the complex issues

surrounding the meaning and assessment of race and ethnicity, investigators are encouraged to collaborate with scientists in other disciplines and consider the new Office of Management and Budget directives on classifying race and ethnicity.

Applicants may request a project period of up to two years and a budget for direct costs of up to \$700,000 per year, excluding Facilities and Administrative (F&A) costs on consortium arrangements.

MFMU CALENDAR

Steering Committee Meetings

October 18-19, 2001
 February 7-8, 2002
 May 20-21, 2002
 July 29-30, 2002
 November 18-19, 2002

Publications

October 25 (tentative)- Review Conference Call
 October 29 - SGI Deadline for Submission

Software Corner

Software programmers at the BCC have been working for the past year on a new PC data entry program to be used at the Network centers. The new system utilizes the Visual FoxPro (VFP) programming language and is Windows based. Data entry will be more efficient and user friendly. Current protocols will remain in the old data entry mode, but new studies, starting with the FOX trial (coincidentally named!), will be designed in VFP.

Network coordinators will preview the system at their October meeting and will be asked to offer comments and suggestions. The BCC will hold a full training on the new system for data entry people before the FOX trial is implemented.

The BCC also offers full training for any new data entry person or anyone experiencing difficulty navigating the existing system. Please call Julia Zachary if you would like to schedule a training date. Also, if you have misplaced your Users' Manual, which contains detailed information on how to use the current system, please call for a replacement.

Certification Efforts Continue at New Centers

The six new MFMU centers have been working hard to achieve certification on the four recruiting studies currently being run in the Network. In less than six months, all centers have been certified for the Progesterone study and have begun screening patients. Four centers have randomized patients. Many issues are involved in setting up the infrastructure to conduct studies at the new centers, including budgets, staffing and IRB approvals. The table records the status of certification for each center as of 9/26/01.

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Rules for Certification:

1. Progesterone screening must be started and BEAM certification materials must be received before C-section may begin.
2. Two randomized trials must have enrolled at least one patient each before C-section may be expanded to a second site.

	Brown	Columbia	Case Western	Houston	UNC	North-western
Progesterone						
Certified	8/15/01	4/26/01	7/19/01	5/2/01/	5/2/01	7/3/01
Scening	8/22/01	4/26/01	7/23/01	5/29/01	6/11/01	8/20/01
Randomizing		6/27/01	8/29/01	8/24/01	8/15/01	
BEAM						
Certified	6/26/00	2/28/01			8/27/01	
Screening	7/18/00	3/29/01			8/30/01	
Randomizing	8/02/00	3/31/01			9/3/01	
C-section						
Certified	9/1/01	7/1/01		8/1/01	8/1/01	
Steroids						
Certified						
Screening						
Randomizing						

People in the News

Kimberly Howell, Network Coordinator, resigned her post to take a position with the National Institute on Aging to work in the area of Health Disparities as a Program Analysis. Her last day was July 31 and she has been sorely missed. Applicants for the position have been interviewed and it is hoped that a person will be selected very shortly.

Cora McPherson, PhD, BCC statistician who worked on the aspirin and BV/TV trials, the ODNs and cervical ultrasound studies, and did a lot of the initial work on the FOX trial, wanted to spend more time with her 1-1/2 year old son and found work as a consultant with research trials conducted at Georgetown University. She will continue to do some work for the BCC, helping to write abstracts and publications related to her studies. Her cheerfulness, thoroughness and expertise will also be missed.

Our heartfelt thoughts, prayers and best wishes go to **Marshall Lindheimer** and his wife who were in an auto accident early in September. Dr. Lindheimer has been released from the hospital but his wife remains in critical condition.

Two New RAs at the BCC - Maureen Hoover expects to finish her MPH by the end of this year. She is a graduate of the University of Notre Dame where she majored in biology and Environmental Science. She has done basic research experiments on amphibians and has health-related experience working in a clinic and medical center as patient advocate and intake worker, and a health care services coordinator and resident care assistant in a respite center. Maureen has volunteered in a number of public service organizations and also enjoys running, having participated recently in the Marine Corps Marathon. She is working on the BEAM trial. **Angela Swanson** plans to graduate from GWU next May with a MS in Epidemiology. A native of Iowa, she graduated from the University of Colorado with a degree in kinesiology. She assisted in the lab at CU and has been a graduate assistant at GWU, working with surveys and databases. Angela is an emergency medical technician and enjoys playing tennis and running. She is working on the C-Section study and also will be the RA on the FOX trial.

Columbia welcomes new staff - Lisa Paley has been hired as the follow-up coordinator. She is a DO having done her residency in Pediatrics and Family Practice at NYC hospitals. She has an interest in research activities and previously coordinated a neonatal statistical study. Lisa is the mother of 3 children and her husband, Dr. Charles Paley, is the follow-up pediatrician.

Villmarie Carmona is the new data entry coordinator at Columbia. She recently left active duty in the US Army after 6 years as a medical specialist. Villmarie was hired on September 6 and then was called to duty as a reservist right after the WTC tragedy. She worked long, hard hours in a variety of capacities. Her center is grateful for the many, like Villmarie, who were available to help in this time of crisis. They hope (like her family and 2 babies) that she will not be called up for active duty again.

Medical Journals Issue New Publication Rules

The September 13 issue of the New England Journal of Medicine contains a joint editorial, issued by 12 of the world's most prominent medical journals, stating that they will reject scientific studies that do not come with an assurance that the sponsor gave the researchers complete access to the data and freedom to report the findings.

Under the new policy, journals "will routinely require authors to disclose details of their own and the sponsor's role in the study," the editorial states. "Many of us will ask the responsible author to sign a statement indicating that he or she accepts full responsibility for the conduct for the trial, had access to the data, and controlled the decision to publish." Sponsors will be able to review a manuscript for only 30 to 60 days before allowing it to be published. They also will not be able to suppress aspects of the study that may be detrimental to a product.

The new publication rules are in response to growing concern about increasing industry influence on the conduct and reporting of company-sponsored studies. Funding for studies to test new drugs, vaccines and devices has increasingly come from industry rather than the federal government. As the cost of developing new products has grown, companies have tightened their control over all aspects of the research they sponsor. The new rules seek to exert pressure on behalf of academic researchers.

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