



# The MFMU Networker

Volume IX Issue 4

December 1999

## BEAM Enters Follow-up Phase

The training of medical staff, who will be doing the follow-up 2 year old pediatric exams, proved to be a useful exercise this fall. The training sessions, led by Peter Blasco from the Oregon Health Sciences University and done at the Kennedy Krieger Institute in Baltimore, focused on the Gross Motor Function Scale to assess the severity of cerebral palsy. As a result of this activity, some changes are being made to the manual of operations and questions added to a follow-up data form. New data audits also have been written for the cerebral palsy diagnosis. As more and more patients are tracked for follow-up exams, please remember that major follow-up costs such as airfare and lodging must be pre-approved with Dr. Deborah Hirtz.

Two ultrasound reviews have been scheduled with three consultants, Dr. Dorothy Bulas who assisted the Network on the High Risk Aspirin trial, and Drs. Michael DiPietro and Joanna Seibert who worked with the NICU Network on the Phenobarbital trial. The reviews will be held February 7-8 and March 20-21 with more than 1500 films to be analyzed.

The possibility of acquiring additional recruiting sites is still being investigated.

## Steroids Trial Start-up Saga Continues

Some last minute hurdles with the FDA have been resolved and the study placebo drugs are scheduled for manufacture in January. Definitions of study outcomes are still being refined, as neonatologists continue to review the protocol and give feedback. As some coordinators and research nurses proceed with certification and examine the study details closely, several issues have surfaced. Consequently, a new form and additional questions to other data forms have been added to cover the collection of data in the event patients receive off-study steroids during the trial. Everyone is encouraged to take this time to look at and think about how the study will be carried out at their center so arrangements can be set up, or details resolved, *before* the study begins. New updated versions the study documents will be distributed before the trial officially begins. Copies of the training video also are being made and will be distributed shortly.



## Advisory Board Operations to Change

NICHD is seeking to improve the ways the Advisory Board fulfills its mission to provide constructive input to proposed MFMU Network studies. To this end, the Board will likely meet more frequently and/or for longer meeting times in order to review the protocols in more depth. In addition, they will review proposed studies earlier in the developmental stage and provide written comments to the investigator. Too often, the Board's input comes "after the fact". Ultimately, this should even shorten the time frame it takes to get the studies on line. It is expected that this improved external review process from experts in diverse but related fields will provide valuable insights to the design of our Network trials.

## SMFM Accepts all Network Abstracts; Two Chosen for Plenaries

For the eighth consecutive year, MFMU Network abstracts have been selected for Plenary Sessions at the annual meeting of the Society of Maternal Fetal Medicine. Only eight out of approximately 1000 submitted abstracts are accepted for the Plenary Sessions each year. This year, Dr. Robert Goldenberg will be presenting results from the Preterm Prediction study: *Toward a multiple marker test for spontaneous preterm birth* (cont. page 2).

## Y2K Reminders

- ❖ Be sure to backup the Network PCs and Spirometers after you do your last work in 1999!!
- ❖ Also, please make sure your center is online for data transmission on January 5, 2000. There will be three weeks worth of data and the Network Software staff would like to verify all Y2K related revisions are working correctly



*(SMFM Abstracts, cont'd)*

Klebanoff will present results from the Trichomonas trial: ***Metronidazole treatment increased the risk of preterm birth in asymptomatic women with Trichomonas***. This will be the first time results from the TV trials and Asthma Observational studies will be publicly presented. Besides the Plenary presentations, there will be three orals and seven posters:

Orals

Iams JD, for the NICHD MFMU Network. ***Self perceived symptoms to predict preterm birth***. (HUAM Prediction Study)

Hauth JC, for the NICHD MFMU Network. ***Mid-trimester threshold vaginal pH and gram stain scores predictive of subsequent preterm birth***. (BV/TV Trial).

Goldenberg RL, for the NICHD MFMU Network. ***Vaginal fetal fibronectin levels at 8-22 weeks and subsequent spontaneous preterm birth***. (FFN Cohort Study)

Posters

Goepfert AR, Mestecky J, Andrews WW, for the NICHD MFMU Network. ***The Preterm Prediction Study: Mucosal immune factors in pregnant women with bacterial vaginosis***. (Preterm Prediction Study)

Sibai B, for the NICHD MFMU Network. ***Hypertensive disorder in twin versus singleton pregnancies***. (High Risk Aspirin Trial)

How H, for the NICHD MFMU Network. ***Is "incipient nephropathy" associated with an increased rate of preeclampsia in women with pregestational diabetes?*** (High Risk Aspirin Trial)

Sibai BM, for the NICHD MFMU Network. ***Preterm delivery in women with chronic hypertension or pregestational diabetes versus normal pregnancy***. (High Risk Aspirin Trial)

Ernest JM, for the NICHD MFMU Network. ***Frequency of congenital varicella syndrome in a prospective cohort of 347 pregnant women***. (Varicella Study)

Hauth JC, for the NICHD MFMU Network. ***Response of the three components of a vaginal gram stain score to metronidazole treatment and in relation to preterm birth***. (BV/TV Trial)

Dombrowski MP, for the NICHD MFMU Network. ***An observational cohort study to evaluate the effects of asthma on perinatal outcome***. (Asthma Observational Study)

Dombrowski MP, for the NICHD MFMU Network. ***Should the definitions of asthma severity be modified during pregnancy?*** (Asthma Observational Study)

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## Progesterone Trial Progressing Well

Resumption of the trial has gone very well, with November having the highest monthly recruiting rate yet, with fifteen randomized. Meanwhile, Wake Forest has finished piloting the ancillary study. They have determined that a refrigerated centrifuge is *not* necessary for processing the blood drawn

to test for fatty acids and cortico releasing hormone levels. A conference call with the coordinators is being scheduled to discuss implementation.

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## Asthma Trial Drugs Expire

With only about 10 patients left to be randomized to the Asthma RCT, Glaxo Wellcome pharmaceuticals notified the BCC this fall that the date for expiration of the oral study drugs had been revised backwards from 2001 to November 1999. They also stated they were not able to manufacture more drugs for the trial until January 2000. Fortunately, with NICHD and NHLBI approval, Paul Thadikonda at Eminent Services has been able to quickly procure and encapsulate the drugs so that there was no time when patients on the protocol had to go without drugs or randomization had to be delayed. The drug kits will be sent out on a case by case basis, as new patients are randomized.

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## Factor V Leiden Update

The Subcommittee is considering comments made by the Advisory Board, which reviewed the protocol at their October meeting. Once issues are resolved during a conference call, the data forms can be finalized and software programming can proceed more quickly. It is anticipated that screening for patients will begin early next year.

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## Gestational Diabetes Update

Dr. Mark Landon and Francee Johnson will be meeting with BCC staff January 18 to work further on the protocol and draft forms.

## Coordinators Corner

Just a note to thank you for your helpfulness and support throughout the ongoing staff transitions at NICHD. I am especially grateful for those of you who have taken the time to call or e-mail, to fill me in on various issues that would have been otherwise unknown since Dr. McNellis retired. Your "memories" are most appreciated.

In the next millenium, we look forward to visiting several of the Network sites for the first time. It is always exciting and informative to see the Network centers "in action". Site visits are not necessarily made because centers have poor performances; but rather to gain information which is used in many constructive ways.

Enjoy your holidays!

Kimberly Howell, MA

## Data Review Visit Made to Wayne State

Wayne State University was the site of a data review visit by BCC staff on September 29-30. Visits were made to the two hospitals that are used by that Center: Hutzel and Sinai Grace. The staff were especially impressed by the incredible computer system at Sinai Grace, where all the intrapartum data in L&D is captured on computer - no paper and no board! The only hitch to the visit was the two traffic tickets

Coordinator Gwen Norman received while parked to show off the two facilities!

## Features Added to the Network Web Site

A couple of new components have been added to the Network's web site. Starting with the Factor V Leiden and the Repetitive Steroids protocols, examples of study consent forms are available for downloading so that each center can edit them to conform with their individual IRB requirements. They are in MS Word format and can be accessed at the Study Documents site in the Business Center.

A new link has been added which takes you directly to PubMed, the National Library of Medicine's search service which accesses the 9 million citations in MEDLINE and Pre-Medline (with links to participating on-line journals and other related databases). Many of the Network's abstracts can be accessed this way.

Also, please note that some of the Network's manuals of operation (i.e., BEAM and Asthma) have gotten so large that your browser may have problems reading them. There is now a link to Netscape.com where you can download the new free Netscape Communicator 4.7, which will be able to access the manuals.

## Four Abstracts Submitted to SGI

The first abstract from the Cervical Ultrasound study was among the four abstracts which were submitted to the 47<sup>th</sup> annual meeting of the Society of Gynecological Investigators. They are:

Ramsey PS, Tamura T, for the NICHD MFMU Network. *Elevated cervical ferritin levels at 24 weeks gestation are associated with spontaneous preterm birth in asymptomatic pregnant women.* (Preterm Prediction Study)

Meis PJ, for the NICHD MFMU Network. *Does fetal stress cause spontaneous preterm birth?* (High Risk Aspirin Trial)

Mabie W for the NICHD MFMU Network. *Maternal complications of Asthma in Pregnancy.* (Asthma Observational Study)

Owen J, for the NICHD MFMU Network. *Endovaginal sonography at 16-18 weeks of gestation predicts subsequent spontaneous preterm delivery in high risk women.* (Cervical Ultrasound Study)

## MFMU Calendar

### MFMU Network RFA

RFA Release: February/March 2000  
Letter of Intent Due: April 2000  
Applications Due: July 2000

### Steering Committee Meetings

February 17-18, 2000  
May 1-2, 2000  
July 17-18, 2000  
October 16-17, 2000

## People in the News

Investigators moving on...**Dr. Oded Langer** has left UTSW to be the Chairman of the OB/GYN Department at St. Luke's Roosevelt Hospital Center in New York City. His new phone number is 212/523-5750. As of December 1, **Dr. Brian Mercer** is the new Director of Maternal Fetal Medicine at Metrohealth Medical Center (part of Case Western University) in Cleveland, Ohio. This is his first move since finishing his Fellowship at the U. of Tennessee a number of years ago. His phone number is 216/778-7341.

**Mary Ellen Colvin**, the Network Grants Manager, has been promoted and **Carolyn Kofa** has taken her place. She can be reached at 301/435-7006 (phone) or 301/402-0915 (fax). Mary Ellen will be working with Carolyn as she learns the ropes.

Congratulations to **Shleema Smith**, research nurse at Thomas Jefferson, on the birth of her 8 lb. 3 oz. daughter, Deja Simone, on September 1. On her first day back after maternity leave, Shleema screened a FFN Elisa positive patient and then had several more soon after. Perhaps it is that motherly touch that helps!

Cora MacPherson, listening to a local Washington news talk show, was surprised to hear the voice of **Dr. Mark Klebanoff**, who was being interviewed about the results of a new study concerning caffeine and pregnancy. The study, published in the *NEJM*, allayed Cora's concern

about the amount of coffee she is drinking, while working *and* finishing her dissertation, during her pregnancy.

**Dr. Jim Roberts**, has announced that he is resigning as Chair of the MFMU Network Steering Committee. It is intended that there will be an overlap with Dr. Roberts and the new Chair for a couple of months.

**Anita Das** has returned from her 22 day trek in the mountains of Nepal, with no apparent loss of brain cells from the high altitude. Though a snow storm prevented them from getting to base camp for Mt. Everest, she climbed to a higher point from which she could look down on the camp. One vivid memory is of a tour of the hospital in Kunde, started by Edmund Hillary, and run by two volunteer doctors. Situated in a room no larger than one's office, was the examining area, laboratory, two beds for in-patients, and x ray area. Stocked only with a few donated supplies, Anita left all the medications she no longer needed for her trip. She hopes to organize the sending of leftover study medications and supplies, etc. in the future.

**Jenny Mark**, RA on the C Section protocol at the BCC, will be leaving at the end of December to pursue a career in health information technology. We appreciate all her efforts and wish her the best of luck.

# Happy Holidays



And All Best Wishes for A Healthy,  
Peaceful Year 2000!