



# The MFMU Networker

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## Site Visits to Subcontractors



On May 28, Mark Klebanoff (project officer), Don McNellis and Kimberly Howell (NICHD) and Liz Thom, Anita Das, Cora MacPherson and Steve Weiner (BCC) visited McKesson Bioservices, the new repository for MFMU biologic fluids. In addition to being an impressive facility with hi-tech equipment, McKesson offers flexibility in labeling, inventorying and processing requests for specimens. It is expected that bar codes will soon replace those handwritten labels that won't stick to vials, and will virtually eliminate errors in sample identification and data entry! Details are being worked out on how to catalog the current inventory of specimens and the process for requesting specimen retrievals.



Don, Kimberly, Liz and Anita also visited Eminent

Services, one of the suppliers for the Network's study drugs on June 1. Though Eminent contracts out many aspects of the actual production of study drugs, it is responsible for obtaining the raw materials for manufacture, and then testing and analysis of the finished drug. Eminent is supplying the study drugs for the terbutaline, asthma and steroids trials.

**SMFM Abstracts Due to Publications Committee by 5 PM, August 12**

## Steroids Trial Start-Up Hits Snag



Once again, problems with the manufacture of study drugs have delayed the start of a MFMU clinical trial. This time, the FDA belatedly questioned the formulation of the placebo, which includes a particular substance that produces the suspension quality that matches the real study drug. This additive is not a FDA approved inactive substance generally recognized as safe (GRAS) that can be used in placebo drugs, and will require full testing and another IND. Once the FDA gives final approval, the placebo will take six weeks to manufacture.

Meanwhile, the Coordinators attended a training session at the BCC on May 12-13, and are currently in the process of completing the certification requirements at each Center. A number of procedures need to be completed, including identifying study pharmacists and conducting a conference call with them, and establishing plans for NICU follow up. The Coordinators also held a conference call on June 3 to discuss completion of the Capitation forms. The completed forms were due to Kimberly Howell at NICHD on June 11

## Cervical U/S Study Recruitment Ends

The 8 participating Network Centers managed to top the goal of 180 participants in the Cervical Ultrasound study with a total of 186 by the enrollment deadline of June 11! On April 19, Dr. John Owen, Dr. Vince Berghella and Cora MacPherson spent a long day reviewing multiple ultrasounds from 17 patients. Detailed queries resulting from the readings were sent back to the ultrasonographers for resolution. It was reported that the quality remains excellent across centers. Thus far, ultrasounds from 68 patients have been reviewed, representing one half of all delivered patients and 38% of all randomized patients. At least one more review will be necessary, which is now scheduled for the end of August.

## Modification Made to Voting Procedures for Study Concepts

At the May Steering Committee meeting, Dr. Mark Klebanoff recommended a change to the voting policy which decides the fate of study concepts introduced at Steering Committee meetings. He proposed that a 2/3 majority vote by secret ballot be used to advance a proposed study concept to the mini proposal phase. Ballots will be counted immediately after they are cast. Investigators may revise concepts that are supported by a majority of votes (but less than 2/3) for reconsideration at a future meeting. However, they are strongly discouraged from re-submitting proposals that fail to obtain a simple majority. The measure was passed by the Steering Committee.



## Kimberly's Coordinating Corner

**A Note from the Network Coordinator:** It was a pleasure meeting many of you during the May Steering Committee meeting. As many of you are now aware, I have replaced Molly Fischer, as the MFMU Network Coordinator. Contrary to Molly's appointment at BCC, my position has been expanded and is based at NICHHD. However, I will continue to coordinate activities at NICHHD, BCC, and the clinical centers. My first and foremost task was working with Mary Ellen Colvin and Dr. McNellis on this year's capitation budgets. Thanks for your support with form development, completion of surveys, and other helpful information. We are currently in the process of reevaluating the Cesarean capitation rate and determining the Steroids capitation rate. In addition to capitation, there are several other projects that I will be exploring to improve the overall efficiency and communication of the Network. Among those are the possibility of moving to "dial-in" conference calls, coordinating a central MFMU Network web site, and moving towards a "paperless" workplace through increased use of electronic mail and the internet. I am very excited about my appointment at NICHHD and look forward to working together with you and the challenge of improving the function of a highly successful network. In that regard, please feel free to contact me with suggestions or areas of concern.

## Room Reservations Necessary for July Steering Committee Meeting

A block of rooms have been reserved for the July 26-27 Steering Committee Meeting. Contrary to previous reservations, **each person must contact the hotel** themselves, to confirm their reservation and obtain a confirmation number. If you do not call, you will lose your reservation. So please contact the Bethesda Holiday Inn reservations (301-652-2000) and confirm your reservation for the "**NICHHD MFMU Steering Committee meeting**".

## Rolodex Now Available Online

The MFMU directory, known as the Rolodex, is now available on the MFMU Network web site. Each coordinator was given a printout of their center staff and addresses at the May Steering Committee meeting, and asked to verify the information and inform the BCC if discrepancies existed. The BCC will be making all corrections, additions and deletions to center staff on the Rolodex until further notice. However, centers may create their own reports and print the listings from the web site. The BCC has the ability to print address labels from the Rolodex and is willing to continue providing labels for centers upon their request.

While most of the information entered for MFMU staff is straightforward (name, and contact information), protocol assignment, titles and subcommittee options need some explaining since they are more arbitrarily used in order to create specific reports. The assignment of titles may be particularly confusing. Titles are meant

to describe functions rather than positions within an organization. Therefore, staff who work on specific protocols (research nurses, research assistants/associates/fellows) are grouped together under the title "study research staff". The only titles, in addition to research study staff, that should be assigned to protocols are: pharmacists, statisticians, consultants, ultrasonographers and pathologists. The administrators of the Rolodex also prefer only one education degree, perhaps the latest or highest, be used with each name.

The Rolodex promises to be an efficient, "paperless" method for supplying the Network with the latest staff contact information. For it to work properly, all Network staff are reminded to keep the BCC informed of changes in staff, addresses, phone numbers, etc.

## MFMU Network Calendar

Factor V Leiden Protocol Subcommittee Conference Call:	June 23
Data & Safety Monitoring Committee Conference Call:	June 29
Data & Safety Monitoring Committee Meeting:	October 4-5
Steering Committee Meetings:	July 26-27 & October 21-22
SMFM Abstracts Due to Publications Committee:	August 12, 5 PM
SMFM Abstract Review Conference Call:	August 16, 9 AM
SMFM Deadline for Submission:	August 19
BEAM Follow-up Examiner Training:	October 25 & November 8

## People in the News

### A Tribute

All best wishes to **Dr. Marshall Lindheimer**, who is retiring from both the MFMU Network and his professorship at the University of Chicago. A dinner at the May Steering Committee meeting, which was Dr. Lindheimer's last meeting as the Alternate PI, provided friends and colleagues an opportunity to share stories, "Lindheimerisms" and thank yous to a man dedicated to the science and art of medicine.

As an "honorary obstetrician" this world renowned nephrologist's career has been dedicated to solving the medical problems of women with renal diseases and toxemia of pregnancy. From July 1999 to December 1999, the Lindheimers will reside in Leuven, Belgium, where he is the recipient of the Francqui Foundation "Interuniversity Foreign Francqui Chair". He will lecture and meet with prominent scientists from all Belgian universities in a number of informal contacts and symposia. The last time anyone associated with obstetrics and gynecology was awarded a chair was ten years ago. He has invited anyone who is in Belgium for the summer to look him up. He will be residing in the "old city" in a 4 bedroom townhouse.

Upon his return to the US, Dr. Lindheimer will become Professor Emeritus and plans to still be exploring many scientific opportunities at the age of 68. Rumor has it he also may be available for special assignments. **Dr. Atef Moawad** will replace Dr. Lindheimer on the Network's Capitation Committee.

◆ **Dr. Michael Belfort** is the new Alternate PI from the University of Utah, replacing Dr. Dudley who is moving to the UT – San Antonio. Dr. Belfort is an Associate Professor of OB/GYN at the University of Utah Health Sciences Center and the Co-Director of the Department of MFMU at Utah Valley Regional Medical Center. He received his basic medical degree from the University of Witwatersrand, Johannesburg, South Africa and, his M.D. from the University of Cape Town, S.A. He did his Internal Medicine and General Surgery Internship at Witwatersrand Medical School and his Residencies in OB/GYN at the University of Cape Town Medical School and at Baylor College of Medicine. His Fellowship in MFMU was also done at Baylor. He is the author or coauthor of more than 230 articles, abstracts, book chapters and presentations and a member of numerous medical associations

◆ **Kimberly Howell** is the new NICHD Network Coordinator. A native of Maryland, she graduated from Hampton College and received her graduate degree in organizational psychology from Columbia University. By coincidence, she worked at the Biostatistics Center from 1995-1997 on diabetes related clinical trials. After leaving the BCC she was a research coordinator for a private research organization. She feels it may be divine fate that drew her to NICHD, which she learned about while working at the National Opinion Research Center on a research project funded by NICHD. Kimberly enjoys all kinds of athletic activities and travel. She says she is always ready for a new adventure and challenge. Please read her message in the Coordinating Corner feature.

◆ **Faith Doyle**, is the newly appointed coordinator at the University of Miami. After a 3 year absence, during

which she lived in North Carolina, Faith is returning to the University where she previously worked on the AIDS clinical trials and also some MFMU Network studies. She has also worked as a clinical site monitor for NIH vaccine trials. A native of South Florida, though she also lived in Maryland for 10 years and graduated from the University of MD, she is happy to be back among family. She loves reading, especially Celtic history and archeology, and sports, including swimming, long distance biking, and roller blading.

◆ A big thank you goes to **Anita Das** who is participating in her third annual bike ride for AIDS. She will be riding nearly 350 miles from Raleigh, NC to Washington, DC in four days, beginning June 23. She has personally raised more than \$2100 and will be among 2500 registered participants, up by almost 1000 from last year. Thousands more will be part of the support staff providing food, shelter and medical attention (including massages!) Go Anita!

◆ **Dr. Michael Varner**, his wife **Dr. Kathleen Digre**, and **Dr. Michael Belfort** are part of a five member team of medical professionals from the University of Utah who are visiting Tibet from June 29 through July 18. They are participating in a medical exchange program in women's health care with other Tibet and Chinese health professionals. Perhaps they will return with some novel insights for MFMU studies! We wish them a safe and successful journey.

◆ Announcing a name change for **Valerija Smith**, statistician at the BCC. She is changing her surname back to her maiden name of Momirova, which means "Momir's daughter" in Macedonia, the country where she was born.

## People Moving On

**Sarah McLaughlin**, Research Assistant at the BCC for the last six years, has received her masters degree in Epidemiology and is leaving in July to be a Senior Programmer Analyst with the Rand Corporation. Thanks, Sarah, for all the programming assistance and tips over the years! **April Burton**, Network secretary at NICHD, has accepted an assignment with the Child Development and Behavior Branch of NICHD where she will be able to pursue her career in the behavioral sciences as she continues her education in the field of psychology. Thanks for those many hours spent coordinating conference calls and putting together

Network mailings! Until April's replacement is found, please address all questions and requests to the Network Coordinator, Kimberly Howell. **Jody Dax**, research nurse at UTSW-Dallas, is leaving after twelve years in her position to return to working with patients at the hospital level. We appreciate all her efforts coordinating the various sites at Dallas and the many hours she put in correcting edits and audits! **Tony Fuller**, a software programmer at the BCC, left us to expand his horizons on June 11. His work, including keying, data transmission and updating the Users Manual, along with his friendly smile, will be missed.

## Study Updates

### BEAM Trial Given Go Ahead

Based on the feasibility report prepared by selected members of the Data Safety and Monitoring Committee and other reviewers, NICHD and NINDS have recommended continuing the BEAM trial. Several changes to the study are being implemented following suggestions made by the review committee. These include adding two or three recruiting centers outside the Network, and rewording the consent form to mention the results of the Mittendorf magnesium trial in Chicago. Other training sessions for follow up coordinators, focusing on the diagnosis of cerebral palsy at the two year pediatric exam, are being scheduled for October and November at the Kennedy-Krieger Institute in Baltimore. It was determined that it is not feasible to include staff from the NICU Network in these sessions.

### More Changes Made to Terb Trial

Following the May Steering Committee meeting, the protocol definition of preterm labor (PTL) for the trial was relaxed, allowing each center to clinically diagnose patients in PTL. New forms, manual and protocol, reflecting this and several other changes have

been distributed and also are available on the web. Centers are doing a better job on screening log entries, which now are more reflective of the population. There is still a 20% exclusion rate for patients who don't meet contraction criteria.

### Progesterone Study Suspended

The Progesterone trial was put on hold in March when the FDA ordered immediate discontinuation of the 17  $\alpha$ -hydroxyprogesterone and a recall of remaining study drug. A new manufacturer of study drug is being sought and the trial will continue once the new batch is produced. Meanwhile, each center will receive "relief funding" at a percentage level of its average recruitment.

## Bits & Pieces

**Reminder:** All materials needed for Steroids trial certification may be found on the MFMU Web Site at:

[www.biostat.bsc.gwu/~mfmuweb](http://www.biostat.bsc.gwu/~mfmuweb).

In fact, the most recent forms, manual of operations and protocol for ALL studies may be found on the web site.

**"E-Required" Field Implemented on Data Forms:** A new type of "required" data field was introduced on the C Section study forms and will be used on future

MFMU study data forms, including the Steroids trial. E-Required fields are identified by a box around the answer space and must have a comment entered if an "\*" is used to answer the question. If no comment is entered to explain why the answer is permanently missing, an edit will be sent. The existing BEAM trial data forms have been revised to implement this new system of data checking.