



The MFMU Networker

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Leadership Changes Within NICHD MFMU Network

During the past few months, leadership of the MFMU Network has changed, both at the top and at the investigator levels. Dr. Catherine Spong has succeeded Dr. Susie Meikle, who replaced Dr. Don McNellis, as Program Officer for the Network, and Dr. Steven Gabbe has replaced Dr. James Roberts as Chairman of the Network. Investigators from various Network centers have also moved on to new positions at MFMU research centers both within and outside the Network.

New Project Officer Named for Network

Dr. Catherine Spong has been named the new Project Officer for the NICHD MFMU Network. She comes to the position with an impressive list of qualifications. A native of Missouri and a graduate of the University of Missouri-Kansas City Six Year Medical Program, she did her OB/GYN Internship and residency at Harbor-UCLA Medical Center, and her Fellowship in MFM at the Perinatal Research Branch, NICHD and Georgetown University Medical Center.

Dr. Spong is a clinical instructor at Georgetown and also a Senior Staff Fellow at the NICHD's Developmental Neurobiology Lab, Section on Developmental and Molecular Pharmacology. She has two patents pending, one on the prevention of fetal alcohol syndrome and neuronal cell death with ADNF peptides and the other on orally active peptides that prevent cell damage and death. She is the recipient of numerous awards and honors and has over 100 papers, book chapters and abstracts. She is an editorial consultant to two journals, on the editorial board of a third, and is active in several professional societies.

She and her husband are the proud parents of a one year old daughter, Juliana. A person of seemingly varied talents Dr. Spong also used her calligraphy skills to put the finishing touches on the book of tributes created by the Network for Dr. Don McNellis.

Steering Committee Chair Steps Down; Dr. Steven Gabbe Appointed

After nearly 10 years as Chairman of the NICHD MFMU Network, Dr. James Roberts has returned to "normal" life as a Network investigator. He will continue to pursue his focus on preeclampsia research, both within the Network and at Magee-Womens Research Institute where he heads the nation's largest

research program in preeclampsia. The Network honored him at a dinner at the Steering Committee meeting in February.

Dr. Steven Gabbe, was installed as the new Chair during the February meeting. World renowned in the area of diabetes in pregnancy, Dr. Gabbe has been the Department Chair at the University of Washington (Seattle) since July 1996, following nine years as the Chair of the OB/GYN Department and Director of the residency training program at the Ohio State University and, prior to that, nine years at the University of Pennsylvania.

Dr. Gabbe is a graduate of Princeton University and Cornell University Medical College. His postgraduate training and Fellowship appointments were at Cornell University Medical College, the New York Hospital, Harvard University and the Boston Lying-In Hospital. He is a member of the Institute of Medicine, National Academy of Sciences and many other professional and scientific societies and committees. Dr. Gabbe has held numerous editorial positions, authored many papers and received many awards and honors, the most recent being the Distinguished Teacher Award from the 1999 graduating class of UW's School of Medicine and being named as one of Seattle's Best Doctors. He and his wife, Dr. Patricia Temple, are the parents of four children.

Network Investigators Job Swap

Three centers have new Principal Investigators, albeit ones with Network experience: Alabama, Wayne State, and San Antonio. Four centers have changed personnel at the Alternate PI level: Tennessee, Wayne State, Chicago and Utah. See page 2 for a current listing of PIs, Alternates and Coordinators at all thirteen centers.

Network RFA Deadlines Delayed

- Letter of Intent Receipt Date: April 14, 2000
- Application Receipt Date: July 7, 2000

Who's Who at Network Centers

	<u>PI</u>	<u>ALT PI</u>	<u>Coordinator</u>
Magee-Womens	Steve Caritis	Phil Heine	Peggy Cotroneo
Tennessee	Baha Sibai	Bill Mabie	Risa Ramsey
Alabama	Bill Andrews	John Hauth	Allison Northen
Wayne State	Yoram Sorokin	Mitch Dombrowski	Gwendolyn Norman
Cincinnati	Menachem Miodovnik	Tariq Siddiqi	Nancy Elder
Wake Forest	Paul Meis	Margaret Harper	Missy Swain
Chicago	Atef Moawad	To Be Named	Phyllis Jones
Ohio State	Jay Iams	Mark Landon	Francee Johnson
Miami	Mary Jo O'Sullivan	Samir Beydoun	Faith Doyle
UTSW	Ken Leveno	George Wendel	Julia McCampbell
UTSA	Deborah Conway	Don Dudley	Susan Barker
Utah	Michael Varner	Michael Belfort	Elaine Taggart
Thomas Jefferson	Ron Wapner	Jorge Tolosa	Michelle DiVito

Steroid Drugs Finally Shipped

While the trials and tribulations of formulating the placebo drug for the Steroid trial had been resolved, as reported in last issue of the *Networker*, its manufacture had not. When the issues of product sterilization, stopper validation and other quality assurance procedures proved too much for the proposed manufacturer, the pharmacy department at the University of Tennessee, which has a FDA license, was approached and rose to the challenge. Four professors went to work and the placebo was made, sterilized and bottled. Paul Thadikonda, President of Eminent Services, personally watched over the process and brought the placebo back to Maryland for labeling and shipping. The drug was shipped on March 15.

Meanwhile, most centers have completed their certification. Separate conference calls have been held with the study pharmacists and coordinators. Pharmacy notebooks and final versions of study documents have been sent. The first screening data was sent by three centers on March 22, with the primary exclusion being patients were not at risk for SPTD by study definition.

BEAM Keeps Network Busy

For the first time in Network history, unrelated external sites will be added to help with recruitment. Brown University, the University of Texas Medical Branch at Galveston and Columbia University are being considered. Staff from the NICHD and the BCC and Allison Northen, coordinator at Alabama, will be making site visits in April and May to determine their suitability. Data from external sites will be keyed centrally at the BCC.

Six hundred eight cranial ultrasounds from 237 infants were read by three consultants, Drs. Dorothy Bulas, Mike DiPietro and Joanna Seibert, over a two day period in February at the National Childrens Medical Center in Washington, DC. Each ultrasound was read by two reviewers and, if there was a

discrepancy, the findings were adjudicated by all three. Considerable effort was required to prepare for and execute the review session. As a result of variation in the quality and readability of ultrasounds among centers, the BCC issued guidelines which were distributed at the Coordinator's meeting. These should be reviewed by the coordinators before submitting the films to the BCC. All data from the reviews (134 fields) will be keyed at the BCC. Another review session is scheduled for March 20-21.

It is already time for the first infants born in the study to begin having their two year follow-up neurological and Bayley exams. Each center must have a certified Bayley examiner who must submit a video taped Bayley exam to a central reviewer before (s)he can qualify as a Network examiner.

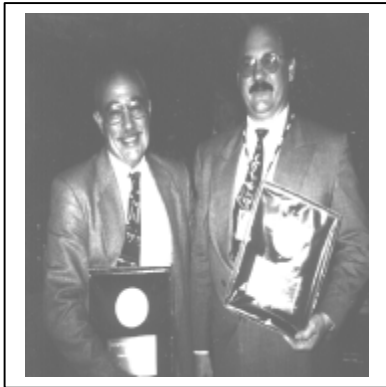
Asthma Trial Stopped

The Asthma Trial ended recruitment on March 3, just two patients short of the 400 sample size target. One of the study drugs will be expiring soon and additional supplies are not available. This made it necessary to stop the trial before patients were randomized who would require drugs past the expiration date. Ten patients remain who have yet to deliver. Data clean-up is starting on the baseline data from the trial. Meanwhile, the BCC has finished sending the centers all the remaining queries on data from the Observational study

Factor V Leiden

The Factor V Leiden study is poised to start as soon as the final budgeting and approval is received from NICHD. Several centers have already completed certification. Certification problems continue at some centers as they deal with getting IRB approval for their patient's informed consent form and fluids banking because of the ethical issues of genetics involved.

Network Investigators Sweep SMFM Honors



Two of the eight papers presented at the main plenary session of the annual meeting of the Society of Maternal Fetal Medicine, held this January in Miami, Florida, were from the NICHD MFMU Network studies. Dr. Chris Carey, (pictured on the right in the photo) received an award for the best paper of the meeting for his reporting of the TV trial results in the plenary session. Dr. Robert Goldenberg (on the left in the photo) also received an award for his oral presentation on the FFN Cohort study. Three other

investigators won awards for their work on studies outside the Network: Drs. Cathy Spong, Donna Dizon-Townson and Deborah Conway.

In addition to the two plenary session presentations, there were three oral presentations and eight posters given on Network studies. See the December issue of the *Networker* for a listing of the abstracts.

Network Forms New Genetics Committee

In response to the increasing number of issues being raised in genetic related maternal research, the MFMU Network has formed the Genetics Committee, chaired by Dr. Ron Wapner. Its purpose is to investigate current regulations and ethical issues surrounding concerns such as DNA and blood banks, informed consents, and reporting results to patients. The Committee will develop guidelines and be a resource for Network investigators when developing genetic related trials. Two of the country's most distinguished geneticists have agreed to serve as consultants to the Committee: Drs. Sherman Elias and George Annas. Dr. Annas will be making a presentation on genetic ethics to the Steering Committee at its July meeting.

Opportunity for Research with NICHD's Network Specialized Clinical Fellowship

Dr. John Rosnes from Wake the Forest Medical Center is the latest recipient of the NICHD Specialized Clinical Fellowship and is seeking participation from all the Network centers in his project. His research seeks to characterize the maternal plasma CRH response to neonatal administered glucocorticoid in patients with preterm labor. After patients are consented and demographic data collected, they will receive the steroid and have two blood samples drawn 24 hours apart. The sample size is 225 patients. This is an excellent research opportunity for MFMU Fellows, and participants will share in the authorship. If interested, please contact Dr. Rosnes at 336/716-4615.

Coordinator's Corner

A special thanks to the Nurse Coordinators for your help with the Factor V Leiden capitation. Of course capitation is just not the same without Dr. McNellis, so I sent it off to him for his review. It came back with his seal of approval and is currently awaiting final approval.

Next on the capitation agenda:

- ACTH - Steroids
- ABR - Steroids
- Gestational Diabetes

On the horizon, we will be meeting with Grants Management to discuss many of the capitation and budgetary concerns raised, as well as addressing issues concerning study implementation. Once again, thanks for your continued support throughout the transitions here at NIH and within the Network.

Kimberly Howell, MA

BV Trial Results Published

The results of the BV Trial were published in the February 23 issue of the *New England Journal of Medicine*. The findings concluded that, while metronidazole cured bacterial vaginosis, the primary objective of reducing the incidence of preterm labor was not achieved. These results were also rather broadly interpreted and reported in the Washington Post's Health magazine in early March.

Coordinators Discussion Listserv New on Web Site



To facilitate discussion among Coordinators and BCC staff on protocol related issues and procedures, a new listserv just for these staff has been implemented on the MFMU web site. Protocol questions will be forwarded to the appropriate PI, if necessary, and the answers disseminated to everyone at once. We hope this tool will keep our communications to each other up to date with the latest information!

Computer Corner

New upgraded computers and printers have been ordered for all 13 centers, which will be distributed in the next couple of months after they are shipped to the BCC and configured with the Network software. They will be loaded with Windows 98 and a new communications package, which will allow faster processing and improved technical support leading to easier trouble shooting and sending of software updates.

Only a few centers responded positively to a survey asking if they wanted to keep their old PC to use as a second workstation for keying Network data. In order to do this, the old computer would have to be set up with the same Network requirements for security and transmission lines. This program will be piloted, but only allowing C-Section data to be keyed on the old PC.

Meanwhile, Miami and Thomas Jefferson have accomplished a highly successful catch-up of C Section data keying using a second non-Network PC. Data was then uploaded to the Network PC for data transfer to the BCC. If other centers would like to use this method for catch-up, contact Brendan Broderick at the BCC for help.

The BCC has been working on the development of a new windows-based MFMU data entry system using Visual Fox Pro software. At the February Coordinators meeting, programmer Alysia Jones and Julia Zachary presented several prototypes of data entry screens and were pleased with the good feedback and ideas they received from the coordinators.

The new system is still in the development phase.

MFMU Calendar

Steering Committee Meetings

- May 1-2, Rockville, MD
- July 17-18, Rockville, MD
- October 16-17, Rockville, MD

Advisory Board Meetings

- March 29, 2-3:00 pm, Conference Call re the Antioxidant trial
- June 28, 8:30-4:30 pm, Rockville, MD
- August 2, 10-12:00 pm, Conference Call
- November 1, 8:30-4:30 pm, Rockville, MD

Site Visits

- University of Utah, Data Review Visit, April 3-5
- Brown University, Site Visit, April 6
- Galveston University Site Visit, May 18

People in the News

◆ The *Above and Beyond Award* goes to research nurse **Liz Daugherty** at Magee-Womens for climbing to a second floor office and giving a patient her progesterone injection in a bathroom stall while chauffeur **Peggy Cotroneo** cruised around the block.

◆ We say farewell and thanks to **Lisa Reynolds**, past coordinator and research nurse at Utah who has left MFMU research to work with Dr. Jeffrey Anderson, world renown for his contributions to cardiovascular research. Lisa enjoys being a clinical nurse again but says she misses the C Section Database!

◆ Congratulations to **Cora MacPherson** and **Anita Das**, BCC statisticians, who received their Doctor of Philosophy degrees in mid-January. Anita's dissertation was on reproductive risk factors for Human Papillomavirus Seropositivity in Pregnant Women, which investigated whether previous vaginal birth increased the seroprevalence of HPV-16, in addition to determining the risk factors associated with HPV-16. Cora's dissertation investigated whether low to moderate alcohol use during pregnancy resulted in a decreased incidence of preterm delivery. Cora celebrated her degree with the birth of a son, Jack Buckley, on February 11. Mom, baby and dad are all doing great!

◆ Best wishes are extended to **Melanie Allison**, BEAM follow-up nurse, who eloped to Jamaica in December and is now known as Melanie Cantley. Coordinator Allison Northen is thankful that Melanie and her husband will continue to live in Birmingham.