



The MFMU Networker

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NICHD MFMU Network Recompetition Nets Six New Centers

On January 26, NICHD announced the results of the recompetition for the Cooperative Multicenter MFMU Network RFA. A total of 14 centers will comprise the Network for the next 5-year project period starting April 1. They are:

Center	Principal Investigator	Coordinator
U of Pittsburgh - Magee-Womens	Steve Caritis	Peggy Cotroneo
U of Alabama - Birmingham	Dwight Rouse	Allison Northen
Wayne State University	Yoram Sorokin	Gwen Norman
Wake Forest University	Paul Meis	Melissa Swain
Ohio State University	Jay Iams	Francee Johnson
University of Texas - Southwest	Kenneth Leveno	Julia McCampbell
University of Utah	Michael Varner	Elaine Taggart
Thomas Jefferson University	Ronald Wapner	Michelle DiVito
Brown University	Marshall Carpenter	JoAnn Tillinghast
Columbia University	Menachem Miodovnik	Vicki Pemberton
Case Western Reserve	Brian Mercer	Cyndi Milluzzi
University of Texas - Houston	Susan Ramin	Mary Clare Day
U of North Carolina - Chapel Hill	John Thorp, Jr.	Karen Dorman
Northwestern University	Alan Peaceman	Gail Mallett

A smooth and speedy induction of the new centers is anticipated. An orientation, on computers, data collection and certification procedures, including training for the Progesterone trial, will be conducted by the BCC for the new coordinators on April 3 and 4.

The NICHD will lead an all-day program on the Network's organization, policies and budgetary matters for all centers on April 5, to be followed by the Steering Committee meeting on April 6. The workstations for data entry will be configured by the BCC and sent to the new centers immediately following the meeting.

The new centers have the necessary documents for requesting IRB approvals for the Progesterone, C-Section and BEAM studies. IRB approval of at least one study is necessary in order to get the Federal Wide Assurance for human subject research before grant funds can be awarded. Meanwhile, a phase-out plan for the centers leaving the Network, which was presented at the January Steering Committee meeting, is being followed.

A new Rolodex soon will be available on the Network's web site. In addition to compiling requests much more quickly, you will have the ability to email directly from it, either by name or by subcommittee. Plans are to have it up and running sometime in April.

SMFM Honors Don McNellis

Dr. Donald McNellis, who retired as NICHD Program Officer for the MFMU Network in 1999, was conferred an Honorary Member by the Society for Maternal Fetal Medicine at its 21st annual meeting in Reno, Nevada, in February. While presenting the award during the President's Champagne Toast and Awards ceremony, Dr. Michael Socol, SMFM President, extolled the exemplary contributions of Dr. McNellis in the field of maternal fetal research. Dr. McNellis also played a role at the conference by serving as a moderator for the Plenary Session.

Twelve abstracts from MFMU Network studies were presented at the meeting, including one selected for the main plenary session on the results of the Asthma trial, reported by Dr. Mitch Dombrowski. Dr. Cathy Spong, MFMU Network Program Officer and Chief, Pregnancy & Perinatology Branch, won an award for the second consecutive year for her research on the *Prevention of alcohol-induced proinflammatory cytokine release and spatial learning deficits with novel peptides: A mouse model of fetal alcohol syndrome.*



Dr. Don McNellis with Dr. Cathy Spong (right) and Kimberly Howell

SMFM Focus Group Addresses Human Research Protection

Peggy Cotroneo, Chair of the SMFM Research Support Personnel Focus Group and Coordinator from Pittsburgh-Magee, organized a seminar addressing an important hot topic for everyone in the field of human research. As a result of national concerns about human safety in clinical trials research, the Office for Protection from Research Risks (OPRR) of the NIH recently was moved to the Office of the DHHS Secretary, expanded and renamed OHRP in order to oversee reforms to strengthen and improve the current system of protections. For the seminar, Peggy invited Dr. Jeffrey Cohen, Associate Director for Education in the Office for Human Research Protections (OHRP) to speak about the system of protection for subjects undergoing human research.

Dr. Cohen's talk covered many things, including the ethical principles contained in the Belmont Report of which, he said, every researcher should possess a well-thumbed copy. He also discussed the federal regulations and policy related to 45 CFR 46 (DHHS policy for protection of human research subjects, including the subparts pertaining to fetuses, pregnant women, prisoners and children) and regulations containing the three basic protections for human subjects. The first of these are the Institutional Assurances, which is documentation of institutional commitment to comply with the Common Rule. The second is the Institutional Review Board and its decision matrix addressing beneficence, justice and respect for persons when it reviews proposed research. The third basic protection is the informed consent, which is more than merely a piece of paper. Dr. Cohen described informed consent as the educational process that takes place between the investigator and the prospective subject that includes full disclosure of the nature of the research and the subject's participation, adequate comprehension on the part of the potential subjects, and the subject's voluntary choice to participate.

One of the many steps being taken by the DHHS includes the requirement that all clinical investigators receive training in bioethics and other issues related to human research. The BCC has required its MFMU staff to take the on-line educational course required by NIH for all NIH employees who conduct or support research involving human research. Dr. Cohen encouraged anyone to call his office at (301) 402-5552 with questions or concerns, or consult the web site at <http://ohrp.osophs.dhhs.gov/> for more information.

Mary Talucci, research nurse at Thomas Jefferson University, volunteered to chair the SMFM Research Support Personnel Focus Group for the next two-year term.

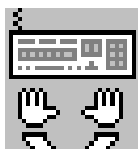
Major Results from 2 Network Trials Announced

Results from the four year randomized trial of inhaled beclomethasone vs theophylline for asthma during pregnancy were presented by Dr. Mitch Dombrowski at the SMFM annual meeting in February. The objective of this double-blind, double-placebo-controlled trial of 398 singleton gravidas with moderate persistent asthma was to determine whether beclomethasone, which has greater anti-inflammatory effects, would decrease exacerbations compared to theophylline. Analysis of the results, however, showed similar rates of asthma exacerbations requiring medical intervention and pregnancy outcomes in both treatment regimes.

Findings from another four year randomized trial to determine if antibiotic treatment of women with a positive cervical/vaginal fetal fibronectin (FFN) would reduce the risk of spontaneous preterm delivery (SPD) were presented by Dr. Bill Andrews at the annual meeting of SGI in March. The analyses showed that metronidazole plus erythromycin does not decrease the risk of SPD in women with a positive FFN test.

C-Section Goal Achieved

Congratulations to Network centers for entering all C-Section forms by February 28th for patients enrolled through June 30, 2000. Analyses of this data will be submitted to the 2001 SMFM annual meeting. More than 1800 forms were entered in the week between February 21 and 28. Less than 1% of forms are missing for the study through last June. However, more than 18,000 forms are outstanding for the period July - December 2000.



Software Corner

In response to many Coordinators' requests to have a hand-held unit containing the Network's Calculator software for the Pregnancy Wheel, Project EDC, BEAM Study Corrected Age, and Dates to use in clinics, Ralph Kolva at the BCC has developed this capability. If you would like to take advantage of this convenience, you can purchase any hand held unit that operates on the Palm Pilot Operating System and send it to Ralph who will install the programs on it. Please call Ralph at 301/881-9260 for further information.

People in the News

Congratulations to our Program Officer, **Dr. Cathy Spong**, who was selected to succeed Dr. Charlotte Catz as NICHD Branch Chief of the Pregnancy and Perinatology Branch (PPB) Center for Research for Mothers and Children (CRMC). Although Cathy will take on many other responsibilities, she will remain the Program Officer for the NICHD MFMU Network. **Dr. Catz** has been named as Clinical Research Coordinator for the Director of NICHD.

Heather Juliussen-Stevenson is a new Research Assistant at the BCC working on the C-Section study. She is a recent graduate of American University with a degree in Anthropology. She is particularly interested in osteology and how the differences between cultures influence medical practice. She has several pets, enjoys running and reading, and aspires to play the bagpipes.

Record Number of SGI Abstracts

A total of seven Network abstracts, the most ever submitted to SGI, were presented at the Society for Gynecologic Investigators' mid-March Annual Meeting in Toronto, Canada. Following is a list of authors, titles and related studies delivered on behalf of the MFMU Network:

From the High Risk Aspirin Study

- B Sibai and R Romero. *Changes in the maternal plasma concentrations of two angiogenic factors - placental growth factor and angiogenin - precede the development of preeclampsia.*
- B Sibai and R Romero. *Plasma concentrations of the soluble tumor necrosis factor receptor 2 are increased prior to the development of preeclampsia.*
- CA Hubel and JM Roberts. *Serum ferritin and transferrin saturation are increased in early gestation in women who subsequently develop preeclampsia with preterm but not term delivery: potential markers of inflammation.*
- A Buchbinder. *Adverse perinatal outcomes are significantly higher in women with severe gestational hypertension compared to mild preeclampsia.*

From the High Risk and Low Risk Aspirin Studies

- KY Lain and JM Roberts. *The protection of smoking against preeclampsia is lost in older women.*

From the Preterm Prediction study

- PS Ramsey. *Cervical markers at 22-24 weeks' gestation improved the prediction of subsequent spontaneous preterm birth.*

From the Fetal Fibronectin trial

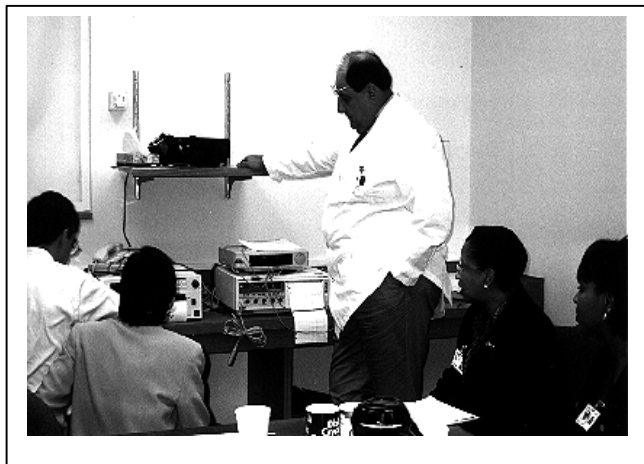
- WW Andrews. *Randomized clinical trial of metronidazole plus erythromycin to prevent spontaneous preterm delivery in fetal fibronectin positive women.*

Oximetry Trial Pulses with Energy

A very productive two day meeting was held at UT-Southwestern March 19-20, with representatives from the BCC and the FDA conferring with Drs. Ken Leveno and Steve Bloom and their research nurses, Julia McCampbell and Shirley Williams, on the design

of the Fetal Pulse Oximetry (FOX) trial. Two prototypical Fetal Pulse Oximeter set-ups were compared and evaluated for feasibility in conducting the three arms of the FOX trial: 1) No Device, 2) Open Device (oximetry data collected and used by clinician), and 3) Masked Device (oximetry data collected, but blinded to clinician). Sandy Weinberger, PhD, a biomedical engineer from the FDA's Center for Devices and Radiological Health, is providing his expertise to configure software to collect data from the devices.

The second day of the meeting was spent refining the protocol and deciding what information to collect on the data forms. It is hoped that the prototype model can be demonstrated at the July Steering Committee meeting, with coordinator training to coincide with the October Steering Committee meeting. This will be approximately a two-year trial of 10,000 women to determine whether the use of fetal pulse oximetry, as an adjunct of conventional electronic fetal heart rate monitoring, reduces the risk of a cesarean delivery.



Sandy Weinberger, PhD, demonstrating a fetal oximetry unit to Dr. Ken Leveno, Cora MacPherson, PhD, and research nurses, Julia McCampbell and Shirley Williams in Dallas

Meet the New Coordinators

* **Mary Clare Day (UT-Houston)** - received a BA in history with minors in classics and architectural history before getting a BSN from UT-Houston and, more recently, her ACRP certification as clinical research coordinator. She coordinated NIH and industry-funded research, primarily focused on pharmacologic treatment modalities for substance abuse, including pregnant women. Recently, Mary Clare has been coordinating MFM and general OB research. Her professional interests include substance abuse in pregnancy, neonatal abstinence syndrome (specifically in regards to maternal methadone use and breastfeeding), and human lactation. She has 2 young children and is expecting a baby girl in early July. Her husband just graduated from law school and took the Bar Exam early in March. She is looking forward to the peace and quiet of her hotel room while attending the Network orientation meeting in April!

* **Karen Dorman (UNC-Chapel Hill)** - started her career in Houston, where she worked in critical care for 6 years before transferring to L&D and setting up two of the first critical care units. She then worked in research and was the transport/perinatal outreach nurse at Baylor College of Medicine. In 1998 she moved to UNC-Chapel Hill to "get out of the big city" and also to continue working for her boss, Ken Moise, MF Division Director at UNC. She has 2 great boys, 9 and 14, who keep her busy with cub scouts and the outdoor activities which she loves.

* **Gail Mallett (Northwestern)** - is an experienced NICHD MFMU Network research nurse, having worked at the U of Chicago for the past 6 years under Phyllis Jones. She obtained a BSN from Northwestern in 1988 and is a registered nurse. Gail is the mother of three children and aspires to obtain a Masters of Public Health. She is actively involved in church lay ministries and enjoys gourmet cooking, gardening, jazz and classical music, and cardio-kickboxing.

* **Cyndi Milluzzi (Interim Coordinator, Case Western)** - has a background in Perinatal Nursing for approximately 15 years at MetroHealth Medical Center in the areas of L&D, as a RN and as a nurse manager, and currently is the Perinatal Coordinator for the Dept. of MFM. Through her involvement with the high-risk antepartum service, she has been able to

develop data bases to assist the residents, fellows and faculty with identifying specific patients who may be appropriate subjects for on-going studies. She is a former educator in the fine arts, has a BSN and has taken graduate studies. Her two school-age children keep her active and she also enjoys any type of physical fitness, including biking, roller-blading and ice skating. She can't wait until her June wedding in Bermuda.

* **Vicki Pemberton (Columbia)** - was a research nurse on the NICHD MFMU Network at the U of Cincinnati before going to work in the department of neonatology, where she had the opportunity to do research with the NICHD NICU Network and coordinated a NIH grant focusing on preterm infant skin adaptation. Vicki is pleased to be going back to her first love - OB. She presented a poster at the SMFM annual meeting in Reno on her research project *Cervical dilation at admission for preterm labor and time interval to delivery*. Her personal interests include renovating a 75 year-old house using her skills developed from volunteer work with Habitat for Humanity. She enjoys running, biking, water skiing and travel.

* **Sophia Scarpelli (Columbia)** is a board certified Diabetes Educator. She was the Project Coordinator of the Diabetes in Pregnancy Program at Albert Einstein/Montefiore Medical Center in JY for over 10 years. Most recently she has worked as the MFM Services Coordinator at Our Lady of Mercy Medical Center and at St. Luke's Roosevelt Hospital Center. The proud mom of two teenage daughters and an avid scuba diver, Sophia loves to explore the many shipwrecks that lay on the bottom of the Atlantic Ocean.

* **JoAnn Tillinghast (Brown)** - has been in nursing for 27 years, starting as a LPN. She graduated from Rhode Island College with a BS in 1984 and from the University of Rhode Island with a MSN in 1996. Her clinical nursing experience includes medical nursing, home care and critical care. She worked in nursing education for 7 years and has been a research nurse in MFM at Women & Infants Hospital for 3 years. JoAnn is an animal and beach lover and is learning to sail.

Calendar of Events



April 3-4, 2001, New Coordinator Training
 April 5-6, 2001, Steering Committee Meeting
 July 16-17, 2001, Steering Committee Meeting
 October 18-19, 2001, Steering Committee Meeting