



The MFMU Networker

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Dr. Don McNellis, MFMU Network Program Officer, Announces Retirement

After 24 years of federal service, of which 17 were at NIH, Dr. Donald McNellis has announced his retirement effective October 1. Of his long and illustrious career, Dr. McNellis says the years as Program Officer of the MFMU Network have been the best in his professional experience because he was able to collaborate with the leading clinical investigators in his specialty. Dr. Jim Roberts, Chair of the Network, says he has been continually impressed with Don's fairness and commitment to the success of the Network. Throughout all the Network's travails, and whether people liked or disliked certain decisions, the success of the Network, according to Dr. Roberts, has been related to his ability to keep everyone's trust even while occasionally "bending" the rules to ensure accomplishments.

In his position at the Pregnancy and Perinatology Branch at NICHD, Dr. McNellis has had the satisfying and rewarding experience of helping to further basic research and also seeing it applied through clinical trial research studies, such as the Network. Dr. Sumner Yaffe points out that he has played a singularly important role in the Center for Research for Mothers and Children as the *only* obstetrician until September 1999. Dr. Yaffe continues to praise Don for assuming, with his quiet efficiency, the responsibility for a multitude of programmatic responsibilities involving women of child-bearing age, pregnant or not, and discharging these tasks in an outstanding low-key manner.

Dr. Charlotte Catz recalls the time when there were only the two of them in the Branch and they supervised each other in their roles as Program Officers for the Networks. She points out that the Networks have been able to achieve tremendous results on a reasonable budget due to the innovative concept of capitation funding, implemented by Don and for which he received an award. She describes him as a very dedicated, reliable colleague who is well recognized by associates in both government and academia as a positive advocate for the profession. He has, for example, served as the NICHD Liaison to ACOG since 1982, where he has a wide range of contacts and continues to be knowledgeable about the practice of maternal medicine.

Even as the Networks have grown in terms of participants and protocols, he continued to carry a full load of grant portfolios in the areas of high risk pregnancy and preterm birth, including fetal physiology. He has especially been involved in the areas of preeclampsia research and perinatal ultrasounds. Don especially delights in assisting junior faculty through the research process. He has been instrumental in developing and promoting research opportunities within NIH, and NICHD in particular, to clinical fellows in all areas of OB/GYN medicine, especially through the annual Aspen Conference and the Medical Specialized Clinical Investigator Development Award. *(Continued on page 2)*

New Program Officer For Network Named

Dr. Susan Meikle has been appointed acting program officer and will replace Dr. Don McNellis, as the Network's program officer upon his retirement on October 1. Dr. Meikle comes to the NICHD from the Centers for Disease Control where she has worked as the medical epidemiologist in the Division of Reproductive Health in a variety of activities related to refugee reproductive health, HIV in women, and a surveillance system of pregnancy success rates for fertility clinics. Her professional experiences include more than five years as OB/GYN technical physician at Denver General where she had clinical duties and practiced clinical research. Over the years, she has had numerous international experiences with women's healthcare programs, including refugee situations in Macedonia, Tanzania, and Azerbaijan and has worked with CARE to reduce maternal mortality in Tanzania. *(Continued on page 2)*

Progesterone Trial to Resume

Six months after this trial was put on hold as a result of the FDA withdrawing the drug from the market, new progesterone study drug has been manufactured and is in the process of being tested. NICHD is sending a letter to all IRBs stating that the study is starting up again, that Diosynth B.V. (Akzo Nobel) is supplying the bulk materials and that the drug is being *(Continued on page 2)*

McNellis, cont.

His career spans many different aspects of maternal medicine, including practicing, teaching, advocating, researching, and managing. After graduating from Dartmouth College and receiving his medical degree from Northwestern Medical School, where he returned to do his residency in OB/GYN, he was a major in the USAF and was posted at the USAF Hospital in Wiesbaden, Germany. Following his service, he attended the School of Public Health at the University of North Carolina where he received a M.S.P.H. He was a professor of OB/GYN at Bowman-Gray and at Rutgers, an associate director of medical research at Ortho Pharmaceutical Corporation, and a chief obstetrics consultant to the Health Services Administration before his appointment at NICHD. He has served on numerous boards and committees and is an editorial consultant and contributor to several publications. He received the PHS Special Recognition Award for Productivity in 1991, the NIH Award of Merit in 1993 and the NIH Directors' award in 1994.

About his retirement, Dr. McNellis says he needs some time to regroup and to attend to some family affairs. He would like to continue to be active professionally, perhaps in an academic setting. Dr. Mark Klebanoff, who has worked with Don on many things for more than 15 years, describes him as a good person to work with, who works hard to get things done. Mark laments that "we who remain behind will be the worse off for his leaving". Dr. Yaffe expresses sentiment for NICHD and the Network when he says simply, "we will miss him." We all wish him the very best and expect he will continue to contribute to the advancement of science in maternal fetal medicine.

Program Officer, cont.

Dr. Meikle was Clinical Assistant Professor of OB/GYN at Emory and was previously assistant professor in the Department of OB/GYN at the University of Colorado where she received her medical degrees, her

M.S.P.H. and did her residency in both OB/GYN and preventive medicine.

Dr. Meikle has been active in research and has numerous publications and presentations to her credit. She is a Fellow in the American College of OB/GYN, board certified in preventive medicine, and a member of the International Society for Technology Assessment in Health Care.

Progesterone, cont.

manufactured by SP Pharmaceutical. October 1 is the projected date for the trial to resume.

The "old" drug is undergoing testing to determine whether patients who received it can still be included in the trial, or whether another 150 women will need to be randomized to replace them. Because of this issue, a new randomization sequence was generated and new randomization logs distributed to be used with the new drug. New data forms also have been distributed implementing the new e-required fields in the data editing. Those questions which require an explanation entered in the comment field, if the value is permanently missing, are now specially marked.

The ancillary study, involving a blood draw at randomization for fatty acids and cortico releasing hormone levels, will also begin with the resumption of the study. A training conference call with coordinators was held in late September.

Steroids Trial to Begin November 1

After several months of trying to find an indistinguishable placebo that would be approved by the FDA, the investigators have decided to use a combination of a cloudy solution to match the active drug, as well as covered syringes and colored shrink wrapped vials. The study meds could be called double-double blind! Waiting passengers at the Denver airport in August were treated to the unusual sight of PIs Ron Wapner and Liz Thom pulling various syringes out of a brown paper bag to test how well they hid the

solutions. They obviously were very suspicious looking. November 1 is the projected start date for this complex, timely trial!

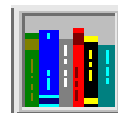
A review of study procedures will be held with the coordinators on October 20, the day before the Steering Committee meeting. All coordinators should come with a completed certification quiz and, meanwhile, try to accelerate their overall center's certification.

Terbutaline Trial Terminated

The Steering Committee voted to stop the Terbutaline Trial at its July meeting because of the continuing inability to recruit enough eligible patients. Though several modifications to study procedures were made during its year-long life, none could overcome the slow recruitment. In all, 1000 patients were screened, 53 patients were randomized to the trial, and 43 were enrolled in the observational component. Both randomized and observational patients will continue to be followed for outcome data. Centers are urged to submit patient follow up data as quickly as possible.

Development of Gestational Diabetes Mellitus RCT Underway

Work has begun at the BCC on the newest study to be approved for implementation in the Network. This trial will examine whether identification and treatment of mild GDM is associated with a lower risk of adverse perinatal outcome. OSU's Dr. Mark Landon and Coordinator Francee Johnson will be meeting with BCC staff on October 12 to work on compiling the protocol and other study details.



Cervical Ultrasound Results to be Announced Soon

The third review consisting of 50 study ultrasounds was done August 23-24 by Drs. John Owen and Vince Berghella and a fourth review will be held at the end of September for the remaining patients. The tapes have been reviewed with the aim of establishing consistent interpretations of findings. Ultrasonographers have been sent detailed queries for resolution. Preliminary results will be presented to the Steering Committee at its October meeting and it is planned to have an abstract submitted to SGI soon after that.

Examiner Training Continues for BEAM

A second set of training sessions for follow-up examiners will be led by Dr. Bruce Shapiro of the Kennedy Krieger Institute and Peter Blasco, now at the University of Oregon. The training will focus on the 2-year exam and will include several 'hands on' sessions with toddlers. In addition, Dr. Robert Palisano will present the Gross Motor Functional Scale which is used specially at the 2-year exam to assess the severity of cerebral palsy.

Meanwhile, plans are being made to begin the central review of the neonatal ultrasounds later this fall. More than 1325 (512 sets) of ultrasounds already exist!

11th NICHD Conference Held

For the eleventh straight year, the annual Aspen Conference on Maternal Fetal Neonatal Reproductive Medicine, sponsored by NICHD, was held in August. Its goal is to promote investigative careers in OB/GYN to clinical fellows in maternal fetal medicine, neonatology, and reproductive endocrinology. Outstanding clinical scientists, including several from the Network, lectured and presented

workshops in study sections and clinical trial design during the intensive 3 day conference. Familiar faces from the Network who presented talks or led sessions included Don McNellis, Jim Roberts, Ron Wapner, Susie Mickle, Elizabeth Thom, Kathy Nelson, Robert Goldenberg, Duane Alexander, Sumner Yaffe and Linda Wright. Ray Bain, former BCC Co-PI, also returned to participate.

Factor V Leiden Study Gears Up

This protocol, the Network's first genetic study, aims to screen five thousand pregnant women before 14 weeks gestation for the factor V Leiden mutation. Women with the mutation have an increased risk for deep vein thrombosis (DVT), a leading cause of maternal morbidity. It is expected that one hundred patients out of the five thousand will be identified as being positive. All neonates of the screened women will also be tested for the mutation. The data forms and manual of operations are being finalized and a Coordinator training session is planned for October 20, the day before the Steering Committee meeting.

Article Cites NICHD OB/GYN Research Opportunities

An article by Drs. Don McNellis and Duane Alexander describing new exciting opportunities for researchers in OB/GYN at NIH, and NICHD in particular, has been published in the July 1999 issue of the *American Journal of Obstetrics and Gynecology*. The writers present an overview of the organization and funding policies of the institutions, and review OB/GYN opportunities for research training and career development for both young and established investigators. They stress that for these new opportunities to survive and expand, it is extremely important for the OB/GYN academic community to actively apply and productively use them.

Two Centers Site Visited

The University of Tennessee at Memphis was the focus of a "data review" site visit July 15-16. Conducted by Liz Thom and Steve Weiner of the BCC and Deborah Hirtz, Program Officer at NINDS, the visit concentrated on data quality. Many charts and data forms were reviewed and discussions were held concerning data issues and procedures. The impressive BEAM recruitment at U. T. was attributed to the work of their 24 hour "BEAM Machine", a pair of research assistants who spend day and night in Labor and delivery screening and enrolling patients at all hours. Even Dr. Sibai's daughter was a member of the team this summer. The highlight of the trip was witnessing a 19 minute C-Section performed by Dr. Baha Sibai (see photo of Liz, Steve and Deborah). The Memphis BBQ was a big hit, too.

An "official" site visit was conducted at the University of Texas, Southwest, in mid September by Don McNellis, Susie Meikle, Deborah Hirtz, Kimberly Howell, Liz Thom, Cora MacPherson, Sharon Leindecker, Steve Weiner and Rachel Copper. In addition to chart reviews and discussions about study procedures, meetings were held with heads of the OB/GYN department and tours were made of the hospital and outlying clinics. The team was highly impressed with how successfully the clinics were run, from both patient and research management points of view. They were treated to Dr. Leveno's favorite German restaurant one evening and, at the last meeting in the hometown of Washington's football team's arch rival, Dr. McNellis presented him a Washington Redskins banner. Wait until next time, Dallas!!

A data review site visit is scheduled for Wayne State at the end of September.



People in the News

❖ Welcome to **Diane Scholl**, the new MFMU secretary at NICHD. She brings more than nine years of government experience, including working for the Public Health Services, the Budget Office, and Dr. Yaffe, to the job. She has spent a large part of her life as an artist and raising three children, now grown. Belonging to a number of art organizations, Diane is a painter, photographer and plays the classical guitar.

❖ The BCC has two new research assistants. **Christa Iamiceli** is a native of Arizona and a recent graduate of Villanova University. Before entering the graduate program in biostatistics at GWU, she worked as a surgical assistant in ophthalmology. She plays the violin and enjoys running. **Michele Therrien**, also a GWU graduate student, but in epidemiology, is from the Boston area. She graduated from

Bates College in Maine with a biochemistry degree. She plays the clarinet and enjoys softball and volleyball.

❖ Congratulations to **Rhonda Carrasquilla**, research nurse at Memphis who was married July 31. She is now the mom of FIVE kids, four girls (including two who are both 13) and a boy. She says they are one big, happy family!

❖ Three long time Network research nurses have moved on to other OB/GYN and nursing jobs. **May Scott** at Miami, **Barb Alexander** at Cincinnati and **Margo Brown** at Chicago, all left this summer. We thank them for their dedication and hard work on Network protocols and wish them all the best in their new positions.

Bits & Pieces

Y2K Update: The BCC has distributed a BIOS upgrade for the spirometers used in the Asthma trial. Most centers have already installed this upgrade. Data entry personnel may call Brendan Broderick at the BCC for help with installation.

Network Abstracts Submitted to SMFM: On August 13, the Publications Committee approved thirteen abstracts for submission to the annual meeting of the Society of Maternal Fetal Medicine (SMFM). Look for more details in the next issue of the *Networker*.

New Address for Web Site: Beginning October 15, the MFMU Web Site will have a new address:

www.bsc.gwu.edu/mfmu. Please be sure to change your bookmark on that date. The reason for the change is that the web site is being moved to a new, more secure server. Remember, you can find the latest MFMU staff directory (Rolodex), study documents, certification materials and Steering Committee reports on the web!

New Phone # for Supplies & Results at Adeza Lab: (877) 945-0208

MFMU Network Calendar

◆ **Steering Committee Meetings**

October 21-22, 1999
February 17-18, 2000
May 1-2, 2000
July 17-18, 2000
October 16-17, 2000

◆ **Data and Safety Monitoring Committee**

October 5, 1999

◆ **Data Review Visit**

Wayne State University: September 29-30, 1999

◆ **BEAM Examiner Training - Kennedy Krieger Institute**

October 25, 1999
November 8, 1999

◆ **MFMU Network RFA**

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