



The MFMU Networker

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Troubleshooting Fox Equipment

Steve Weiner, Angela Swanson, Brendan Broderick and Sandy Weininger visited UT Southwestern on August 18, to troubleshoot problems being encountered Network-wide with the FOX equipment. The resourceful Dallas research nurses were able to enroll two FOX patients on the day of the visit. This was the first opportunity for the FOX team of the BCC to observe the FOX study unit in action with live patients (as opposed to electronic simulators on non-pregnant BCC staff!). The visitors were able to observe randomization, transfer of a patient between rooms, and delivery and equipment shut down. During the day the study equipment performed as intended, and (or fortunately) did not exhibit any strange behavior! This has not deterred the BCC from trying to locate the source of any remaining problems and a second visit to a different site may be arranged.

Network centers can help with the troubleshooting by diligently completing and sending in the weekly error logs. Even if no errors are encountered, the log must be submitted to the BCC. One of the most common data problems is caused by human error when the time on the computer and the time on the L&D clock are verified as correct when in fact they are not. Please take extra care to double check that both the date and time are correct before starting the program. However, if by chance, the nurse discovers after randomization that the date or time is wrong, do NOT try to correct it! This action will only compound the problem. Another common problem involves unintentional disconnection of the laptop from its power source. Please be vigilant about preventing this from happening. Brendan Broderick is handling equipment problems since Angela left, so please contact him with related questions.

More than 20% of the target sample of 10,000 patients have been enrolled in FOX, with recruitment averaging about 200 enrolled patients per month since April. Pauline Breault, FOX study nurse at Brown, has offered to organize a conference call for other FOX study nurses to discuss and share recruitment methods and ways to solve other issues and problems. Information about the call will be coming from Susan Pagliaro.

Drs. Roberts and D'Alton Discuss Preeclampsia on Today Show

When an alert Gwendolyn Norman heard that topic of preeclampsia was to be discussed on NBC's Today Show, she delayed going to work in order to watch. To her surprise, both Dr. James Roberts and Dr. Mary D'Alton were interviewed about what obstetricians and patients can do about the condition. Dr. Roberts was able to put in a big plug for the CAPPS study when he talked about NIH and research on preeclampsia. If you missed the broadcast, you can watch the video at <http://www.msnbc.com/news/970874.asp>, or find the link on the MFMU Network web site.

New 17P Trial Fast Tracked

Work is progressing well on the next trial to be started in the Network, the *RCT of 17 Alpha-Hydroxyprogesterone Caproate to Prevent Preterm Birth in Multifetetal Gestations*. A meeting with the BCC and co-investigators (Drs. Caritis and Rouse and coordinators Northen and Cotroneo) is scheduled for October 8. Nurse training will occur Wednesday, October 22, the day before the Steering Committee meeting. New study drug has been ordered because the drug remaining from the other progesterone trial has expired. Discussions are being held between the NICHD and the FDA regarding the IND that will be required. The protocol and consent form should be distributed within a few weeks so centers can begin their IRB submissions.

NICHD Celebrates 40th Anniversary

In October 1962, President John F. Kennedy signed legislation establishing the National Institute of Child Health and Human Development (NICHD) and on November 14, 1963, members of the National Advisory Child Health and Human Development (NACHHD) Council met for the first time, welcoming NICHD.

NICHD was initially founded to investigate broad aspects of human development as a means to understanding developmental disabilities, including mental retardation, as well as pregnancy. Forty years later, research at NICHD covers all stages of human development from preconception to adulthood and addresses topics related to the health and well-being of children, adults, families, communities and populations.

As a result of NICHD's research efforts during the past 40 years, many significant advances in the field have occurred. Some of these include:

- ◆ Drop in the infant deaths rate by more than 70 percent;
- ◆ Survival rates for respiratory distress syndrome from 5 percent in the 1960s to 95 percent today;
- ◆ Nearly 50 percent drop in sudden infant death syndrome since the Back to Sleep campaign began in 1994;
- ◆ Drop in rate of transmission of HIV from infected mother to fetus and infant from 25 percent to 2 percent;
- ◆ Screening and treatment techniques for congenital hypothyroidism and phenylketonuria that have eliminated their impact on cognitive development.

On September 8th, NICHD held a scientific symposium highlighting numerous advances in the areas of clinical sciences, gene expression, growth and development, cell biology, neurobiology, social and behavioral sciences and reproductive sciences. Dr. Robert Goldenberg, previous PI from U of Alabama, talked about factors influencing perinatal outcomes. The Institute also established the NICHD Hall of Honor to highlight a number of researchers' contributions to the NICHD mission. Other activities related to the 40th anniversary are being planned and can be found on the NICHD web site.

Changes Made to GDM Protocol

The GDM subcommittee has approved two changes relating to study procedures in the GDM trial. The first allows clinicians to test blood glucose when there is a clinical suspicion of hyperglycemia in Group II or III patients. If the patient has either a random blood glucose of > 160 mg/dl or a fasting blood glucose > mg/dl then the patient's caregiver may initiate treatment.

The second change to the protocol and consent form allows a copy of the OGTT results to be sent to the patient and physician, if requested, after completion of the study. The BCC is changing the wording in the protocol and consent form for approval by the GWU IRB. Once approved, the wording will be distributed to the centers for their IRB approval.

Modifications also are being made to the Neonatal Outcome form, MG11. The investigators have decided to collect data related to the *clinical* collection of bilirubin and glucose. Dates, times, levels of both, and the method of collecting glucose, will be recorded on the data forms.

Recruitment has been steadily increasing over the past several months, with 133 recruited as of the end of August. Twenty-six of those were enrolled in August.

Chair Tallies SMFM Effort

The following comments were emailed by Brian Mercer, MD and Chair of the Publications Committee, on August 7, after the second conference call held that week to review abstracts being submitted to SMFM on the following day:

"OK folks, By my count that is 237 e-mails (151 received and 86 sent), 4+ hours of conference calls (plus multiple others), 16 abstracts with 4 pending, 43 trees and 132,465,378,987 excited electrons in 2 weeks for MFMU SMFM only.....so far!!!.....I'm gone on vacation after tomorrow....be careful with those electrons!!!"

In the end, a record number of 19 abstracts were submitted to SMFM by Network investigators. These abstracts will be presented by the authors at the October and January Steering Committee meetings, (in addition to any presentations in New Orleans). SMFM has finished selecting abstracts. Two of the three abstracts selected for oral presentations are also plenaries: Dr. Wapner's *Repeated vs. Single Course Steroids* and Dr. Landon's *Safety of Trial of Labor in Single vs. Multiple Prior C-Section*. The other oral presentation is Dr. Bloom's *Complications of Anesthesia*

for *Cesarean Delivery*. Ten abstracts have been selected for poster presentations.

Less than a month later, the process began again as Network investigators submitted their proposals for SGI. By this time however, the BCC finally had received word from the GWU IRB, based on a response from OHRP, that they must approve proposals for secondary analyses of "old" Network studies. Documents required for the GWU IRB submission include the investigator's own IRB approval, the consent form used in the original study from the investigator's center and the investigator's signed declaration of conflict of interest. Thus far, the BCC has submitted nine SGI proposals to its IRB and hopes to get a response by the first week in October.

Bits & Pieces

NICHD Seeks Clinical Lab: In response to research needs of the Network and other programs, the NICHD has issued a Sources Sought notice seeking a clinical laboratory for microtechnology, microanalysis of blood samples and genomic technology. The lab will be used to test protein expression and gene analysis for factors associated with maternal-fetal and neonatal disease and disease outcomes. Having a selected lab available for testing of the MFMU Network's biological specimens will be a welcome solution for efficiently obtaining timely study results!!

Subcommittee Meeting Venue Change: Hotel loyalty is finally paying off! The Holiday Inn in Bethesda has enticed the NICHD to book reservations for the next year's quarterly Steering Committee meetings at the hotel by offering a free meeting room in which to hold the evening subcommittee meetings. As a result Subcommittee members can return to the hotel and re-energize while waiting for their protocol meeting to begin. Evening subcommittees will meet there beginning with the October S.C. meeting

Correction: The progesterone article in the July issue of the *Networker* mis-stated the availability of Progesterone drug. The pharmacy that manufactures the drug *cannot distribute it to other pharmacies* in the country. However, physicians can order it directly from the manufacturing pharmacy. Please contact Dr. Paul Meis for ordering information if interested.

Another Outlet for Network Publications?

An August 7th *New York Times* Op-Ed editorial heralds a new model for dissemination of research, the Public Library of Science (PLOS). In the opinion of Dr. Harold Varmus, the former director of the National Institutes of Health, the high cost of research publications impedes the distribution of knowledge. Several years ago he and a group of concerned researchers issued an open letter signed by 30,000 colleagues asking the publishers of scientific journals to make their archived research articles available online. Most

journals declined because to do so would undercut their profits made by selling expensive subscriptions to libraries.

Feeling that restriction of results is a basic inequity when much of the research has been financed by public money, Dr. Varmus's group has created the Public Library of Science, a



series of peer-reviewed journals that will be freely available on the Internet. The first ones, published this October, will be PLoS Biology and PLoS Medicine. The journals will pay for themselves by charging a small fee to the organizations and institutions that support the research. The aim is to create a freer flow of data about research and results, both to individuals and doctors.

Leadership Changes

Dr. Ron Wapner from Drexel University has stepped down as PI, but will remain as PI Alternate. **Dr. Anthony Sciscione**, formerly the local PI at Christiana Care Health System, a satellite of Drexel, has been named as the new PI at Drexel. **Dr. Philip Shlossman** has replaced Dr. Sciscione as local PI at Christiana Care.

Dr. Sciscione received his medical degree from the University of New England College of Osteopathic Medicine and did a rotating internship in New Jersey between Union Hospital and St. Joseph's Hospital, Seton Hall University School of Graduate Medical Education. His residency was at the Medical Center of Delaware and his MFM Fellowship was performed at Johns Hopkins Medical Institution. Among other responsibilities at Christiana Care, he was director of perinatal research, the Fetal Assessment Center and the residency program. Since July he has been director of OB/GYN research and also director of the MFM division at Drexel University.

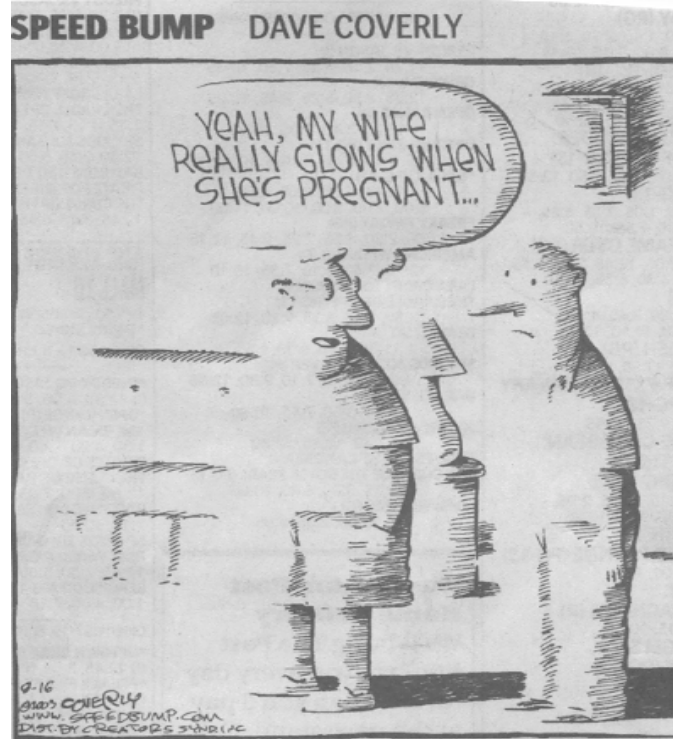
After completing a M.S. in Marine Fisheries at Texas A&M University, **Dr. Shlossman** continued his studies in medicine at Texas A&M. He was an intern and resident in OB/GYN at Christiana Care and a MFM Fellow at Pennsylvania Hospital. He is Associate Director of MFM, Director of Medical Student Education

and Director of Perinatal Research, in addition to being active in state and local societies, organizations and hospital committees.

Dr. Menachem Miodovnik has left his post as PI at Columbia University to work at the Washington Hospital Center in Washington, DC. The new PI, **Dr. Fergal Malone**, received his undergraduate and postgraduate education (M.D.) at the University College Dublin where he graduated first in his class. His OB/GYN residency was at Tufts University School of Medicine, where he also was administrative Chief Resident, and performed his MFM Fellowship. Since 1999, he has been at Columbia University College of Physicians/Surgeons as associate professor of OB/GYN, attending perinatologist, director of OB/GYN ultrasonography and director of perinatal research. He has taught postgraduate courses on ultrasound at the last two SMFM annual meetings, in addition to a number of other continuing medical education courses around the country.

In August, **Vicki Pemberton** resigned as Nurse Coordinator at Columbia and **Sabine Bousleiman**, Vicki's second in command, has been named as her replacement. Sabine has attended a number of meetings and is a familiar face to most of us. We welcome all new participants to the Network and wish those that have left the best of luck.

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Editorial Disclosure Policies Expanded

According to a September 30 editorial in the *New York Times*, the publisher of some of the world's most influential scientific journals is expanding its disclosure policies. The Nature Publishing Group of Macmillan Publishers has announced that it now requires the

authors of review articles to disclose any financial ties to the products or therapies they evaluate. This disclosure policy has already been applied to authors of research reports, but has been lacking for authors of review articles that evaluate progress in a particular field. Authors of letters written

to journals are still not required to disclose such ties. Medical journals have made numerous efforts to reduce the potential for commercial bias and this is another step in the process.

People in the News

Two new research assistants have joined the BCC staff, since Angela Swanson and Maureen Hoover departed.

Robert Blanchard received a BS in Biology at the University of Colorado, Boulder, where he conducted research in the neuroscience laboratory. Following graduation, he served for more than 2 years as a U.S. Peace Corps volunteer in The Gambia, West Africa, where he taught classes on health and environmental issues. Upon his return to the U.S., Rob was a Forester at two National Forests in California assisting in forest ecology projects and responding to emergency fire and medical incidents throughout the nation. Before coming to the BCC, he volunteered at the Red Cross doing stem cell research and DNA synthesis and sequencing. He is pursuing a MPH degree at GWU, likes to kayak in his free time, and is trying to teach his Weimaraner puppy not to chew!

Jeremy Drehmer majored in psychology, with a minor in marketing, at DePaul University. He also has obtained a computer career program post-graduate certificate. Jeremy expresses a passion for research and recently worked on a NCI grant designed to reduce the prevalence of youth smoking, including evaluating the impact of community laws and police enforcement on youth tobacco use. One of his responsibilities was data manager for over 25,000 parental consent forms from 41 different schools. He is interested in environmental issues and led a group responsible for preserving Chicago Park District parks. He enjoys playing tennis and plans to pursue a PhD in psychology.

In case any of you wondered where our fearless leader, **Dr. Cathy Spong**, went during the second day of the July Steering Committee, she was

appearing live on PBS's Diane Rehm show. Dr. Spong was asked to join with Dr. David Barker, University of South Hampton, England, author of *The Best Start in Life*, to talk about fetal origins of adult disease. The discussion centered on how the prenatal environment may trigger public health problems such as heart disease, diabetes and obesity.

Congratulations to **Dr.**

Margaret Harper, PI, who received a Master of Science Degree from Wake Forest University last December. Her degree in Health Research and Epidemiology should serve her well in her work at Wake Forest and in the Network!

Warmest wishes go to **Theresa Dix**, the night nurse for FOX at Wake Forest, who went to China for two weeks in August to adopt her second child, nine month old daughter, Hollie Yan-Noel Dix. While they were in China they celebrated big sister Hannah's 4th birthday, who also was adopted from China. The family is adapting well and Theresa returned to work on September 7.

The staff and OB/GYN department at MetroHealth system are not looking forward to the end of September when **Elinor Bayse** retires. Elinor has worked on the Network projects, especially the FOX trial, since Case Western became a participating Network center. She served the OB/GYN department at MetroHealth system for 31 years and is known as a truly dedicated nurse and will be greatly missed. Thanks for your work and dedication, Elinor. Everyone wishes you a very happy retirement!

Karen Dorman, from UNC-Chapel Hill, was selected to be the next Chair of the Nurse Coordinators at their last meeting. **Missy Swain** has been their

leader over the past two years and was roundly applauded for the great job she did. Karen has already taken the lead in bringing several issues to the fore and is working to make sure the MFMU Coordinators keep the Special Focus Group for Research Personnel functioning for the SMFM annual meetings.

Two new staff have been appointed as BEAM follow-up coordinators at Drexel University. **Stacy Vagelaras**, working at the TJU/Drexel site, has a strong research background and has worked with the Drexel Neonatology Physicians on past projects. She recently completed the CRA/CRC Training program and is certified in clinical research. Stacy coordinates the on-call research team and has taken on responsibility for most of night call.

Marilyn Sherman has joined the Network team at the Christiana Hospital site where she also coordinates daily recruitment. She has extensive background in providing nursing care for patients in L&D and has certifications in Parent Education, Inpatient Obstetrical Nursing and Neonatal Resuscitation.

The MFMU Network again has shown what a great bunch of caring, sharing people they are. Upon the news that **Phyllis Jones'** home had burned down, **Francee Johnson** offered to collect donations from the coordinators and BCC staff who knew her when the U of Chicago was in the Network and she was the coordinator. Not only did those people contribute, but also so did coordinators and staff who did not know her. \$450 was raised which will be divided between a gift certificate from Target and cash so Phyllis can replace at least some of the essentials.

MFMU Calendar



Steering Committee Meetings

- October 23-24, 2003
- January 22-23, 2004
- April 15-16, 2004 (with Neonatal Network)
- July 12-13, 2004
- October 21-22, 2004

Training

Progesterone/Multifetal trial October 22; 11:30 am - 5:30 pm
BEAM Follow-up Examiners – March 15-16, 2004

Site Visits

Case Western Reserve University: October 16-17
Brown University: November 3-4

Publications

SGI abstract submission to Dr. Mercer, October 17
Publications Subcommittee SGI Conference Call, October 21
Abstract submission to SGI, October 24

Professional Meetings

SMFM Annual Meeting, New Orleans, February 2-7, 2004

