

100% of Network SMFM Abstracts Accepted

All twenty of the Network's abstracts that were submitted for the 2006 annual meeting of the Society for Maternal-Fetal Medicine (SMFM) were accepted, with the FOX trial selected as the lead presentation in the Plenary session and two C-Section and one BEARS secondary analyses designated for the oral sessions. Only 60% of all the abstracts submitted were accepted by the Society for presentation this year so the Network should be proud of its work.

The investigators are currently working on their posters and orals and will be presenting them at the January Steering Committee meeting for review and critique. In addition, many of the investigators are writing manuscripts, based on their research, for submission to the SMFM meeting issue of the *American Journal of Obstetrics and Gynecology* or another professional journal.

The Network has developed a specific manuscript review process that must be followed before manuscripts can be submitted for publication. The steps for manuscript development, review and approval are posted on the MFMU Network's internal web site. Please contact Susan Pagliaro, Network Coordinator, for further information.



CDC Releases Statistics on Births in 2004

The CDC recently released the following statistics on births in 2004. The cesarean delivery rate rose six percent to 29.1 percent of all births, the highest rate ever reported in the U.S. For 2003-04, the primary cesarean rate rose 8 percent, and the rate of vaginal birth after cesarean delivery (VBAC) dropped 13 percent. Since 1996, the primary rate has climbed 41 percent and the VBAC rate has dropped 67 percent.

No improvement in timely receipt of prenatal care in 2004 was reported, although the percentage of women beginning care within the first three months of pregnancy has been increasing steadily. Tobacco use during pregnancy continued to decline slightly with 10.2 percent of all mothers smoking in 2004. The rate of twins increased, but the rate of triplet and higher order multiple births was essentially stable. Eight and one tenth percent of all infants were more likely to be born low birth weight (< 2,500 grams), a 16 percent increase since 1990.

More than a half million infants (12.3 percent), or one of every eight live-born infants, were born preterm (≤ 37 weeks) in 2004. The preterm birth rate has climbed 18 percent since only 1990. The U.S. Public Health Service has set a goal of reducing the preterm delivery rate to 7.6% by 2010, but the

figures show the rate is headed in the wrong direction. While a number of factors contribute to preterm delivery, according to the March of Dimes, 50% of premature deliveries remain unknown and research into the molecular biology of pregnancy is called for.

MFMU Network Makes First Cut in IECRN Project

Last spring, The Inventory and Evaluation of Clinical Research Networks (IECRN), a component of the NIH Roadmap project to "re-engineer the clinical research enterprise", solicited nominations for clinical research networks (CRN) that embody best practices. The Roadmap effort was initiated in 2002 by NIH to identify major opportunities and gaps in biomedical research that no single institute at NIH could tackle alone, but that the agency as a whole must address to make the biggest impact on the progress of medical research. NICHD's Dr. Spang and the BCC's Dr. Thom submitted an application detailing specific areas of successes in the NICHD MFMU Network. The project seeks to identify and examine CRN practices that contribute to demonstrated success in six different areas. Early in December, NICHD received notification that, based on the deliberations of the IECRN Best Practices Selection and Review Committee, the MFMU Network was selected to participate in the next assessment phase involving an in-depth review of its practices.

The results of the best practices competition will be presented at the NIH's National Leadership Forum, to be held in Rockville, Maryland, May 31 through June 1, 2006. Selected CRNs will be invited to share their ideas about the best ways to organize and run networks and be recognized for promoting the NIH Roadmap's primary goal – accelerating medical discovery to improve health.

NICHD MFMU Network to Celebrate 20th Anniversary

The NICHD MFMU Network will be celebrating its 20th anniversary during the annual SMFM meeting in Miami, Florida. Anyone who has been associated with NICHD MFMU Network research has been cordially invited to attend a celebratory dinner on Friday, February 3. The location and cost will be announced shortly.

A history of the Network, including participating centers for each of the 5-year cycles and timelines for the over 25 studies conducted by the Network, will be available on the MFMU web site in the near future.



Computer Corner



NIH Goes Electronic

On August 19, 2005, the NIH announced that it will:

1) transition from the PHS398 application to the SF424 Research and Related (R&R) application; and 2) simultaneously transition to electronic submission via Grants.gov by the end of 2007. Funding Opportunity Announcements will continue to be issued in the NIH Guide and also be posted in Grants.gov as mechanisms are transitioned. Applications in response to these announcements will require electronic submission through Grants.gov.

In order to provide security, the submission of electronic applications to NIH requires all organizations to register with both Grants.gov and the NIH eRA Commons. Grants.gov registration provides the ability to submit applications electronically to 26 Federal grant-making agencies.

Commons registration allows NIH to receive applications submitted through Grants.gov. It also provides a way for NIH and registered users to communicate electronically after submission. Organizations should prepare themselves by completing registration in both Grants.gov and the NIH eRA Commons now. Please go to www.grants.nih.gov/grants/forms for further information.

In keeping with the government's swing to paperless operations, please note that the Maggie Young, the NICHD Grants Manager for the MFMU Network, now has an e-FAX number that should be used when transmitting forms to her. The number is 301-451-5510.

New Reports Available on MFMU Data Entry System

In response to center requests for specific reporting options, the BCC has added three new reports to the MFMU Data Entry System. The first is an update on the race and age report that lists patients screened at each site by race with totals and percentages, by maternal age at each site in age categories, including mean maternal age, and by gestational age categories.

The second report is a listing of patients, showing randomization/enrollment dates and drug codes. The third report is the number of DNA samples collected for the CAPPS study.

Software reports are designed to help centers with their study and data management. The BCC develops the reports in response to specific requests from the clinical centers. Please contact Julia Zachary at the BCC if a special report is needed to help with managing patients or data.

News Flash



All eight abstracts submitted by the Network for the SGI annual meeting have been accepted!

Fetal Oximeters No Longer Marketed

On November 1, 2005, Nellcor (a subsidiary of TYCO Healthcare) officially announced that it will no longer offer the OxiFirst® fetal pulse oximetry system, which is comprised of the N-400 fetal pulse oximeter and the FS-14 series fetal sensor. Citing lack of widespread acceptance, along with ongoing component obsolescence challenges, Nellcor decided to discontinue the system.

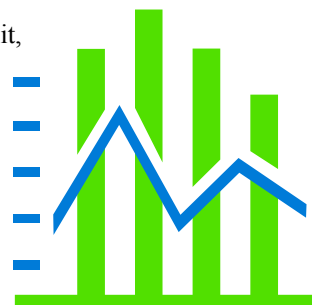
As of the announcement date, the N-400 was no longer for sale, although the sensors are available through January 31, 2006, or until the inventory is gone. The company plans to offer parts and factory service only through January 31, 2009. Other lines of pulse oximeters and sensors continue to be marketed.

ACOG News Release Cites Research Results Regarding Night Time Deliveries

A news release from the American College of Obstetrics and Gynecology (ACOG) in August 2005 reported on the results of a California study that found neonatal deaths were higher for infants born between 7 PM and 7 AM than for infants born between 7 AM and 7 PM. Published in *Obstetrics & Gynecology*, the scientific journal of ACOG, the study was based on more than 3 million infants born in the state between 1992 and 1997. Based on the analysis of deaths per 1,000 births, there were 1.88 infant deaths for daytime births, 2.37 infant deaths for early night (7 PM to 1 AM) and 2.31 infant deaths for late-night births (1 AM to 7 AM).

After controlling for various factors, this was a 12 % increase in infant deaths during the night, although there was little significance in mortality between early and late night. According to the researchers, the increase in infant deaths may be attributed to the availability and quality of the physicians, nurses and support personnel as well as accessibility of diagnostic tests and procedures. However, they concluded that more research is needed.

Interestingly, Jennifer Bailit, MD, Network investigator from Case Western Reserve, did an analysis of complications by delivery shift in the Network's C-Section study for 2006 SMFM. She hypothesized that outcomes would be worse during 11 PM – 7 AM. However, the data showed that there was no trend to increased risk with night time deliveries. She will present the findings at the annual SMFM meeting in February.



2005 Tally of Network Publications

15 published in peer-review journals
4 accepted
8 submitted
18 drafts in active progress

Study Notes



CAPPS: While recruitment into the trial is maintaining a steady pace of about 225 a month, enrollment into the observational arm is lagging behind. In an effort to identify problems that may be hindering enrollment into CAPPS Prediction, research nurses kept a log for a month to record reasons patients did not enroll. The results of this log did not indicate any specific barriers and, therefore, the subcommittee has decided that no changes will be made to the protocol at this time.

Several questions have been raised by nurses over the past couple of months including whether patients who have a high blood pressure recorded at an emergency room visit should be excluded from screening. The subcommittee decided that if these patients have no other high blood pressures during pregnancy, including at screening, they may be included in the study.

It also should be noted that the screening blood pressures for all patients **must** be taken with an aneroid sphygmomanometer. This blood pressure reading is the one used to determine eligibility. The coordinator is responsible for making sure that the research nurses have been certified to take sphygmomanometer readings by watching the training video. Taking blood pressure with a Dynamap machine is allowed only for later study visits and during delivery.

Two studies looking at the effects of vitamin C and E on preeclampsia have been completed and results are pending. One was a high-risk study in England and the other study was performed in Australia. The subcommittee is looking forward to hearing the results.

The application for the CAPPS Prediction Certificate of Confidentiality was submitted to the NIH in early December and is awaiting official sign-off. Please notify Susan Pagliaro if center IRBs and/or institutional officials are asking about its status.

GDM: Recruitment for the GDM trial met its half-way mark in October and, at the current rate, should take about two more years to finish. The event was celebrated with delicious chocolates for the coordinators and the BCC from Dr. Mark Landon, study PI, and a special cake for the coordinator's meeting from the BCC study staff.

Omega-3: A newly updated and revised manual of operations for the OMEGA-3 Trial has been released and is available on the MFMU website. All centers are reminded to submit a revised informed consent form, indicating that the trial is under a NIH Certificate of Confidentiality, to their IRBs and to get the application letter signed by the PI and institutional official. UTSW will not be able to recruit patients until the NIH grants approval for the Confidentiality certificate.

The last of the children being followed-up from the 17 α -Hydroxyprogesterone Caproate trial was seen on November 15. A remarkable 78% of the children born in this trial at the current Network centers were found and evaluated, six years after the trial began. Data are undergoing final clean-up and analysis will begin shortly.

BEAM: Centers are reminded that follow-up examiners for the BEAM trial must submit certifying videos to Dr. Bruce Shapiro at the Kennedy Krieger Institute before the end of January. Follow-up exams for all BEAM infants should be finished by the end of 2006. Subcommittee discussions are underway regarding research proposals for the remaining study fluid specimens.



SLC Tribune Features Network Studies in March of Dimes Article

In honor of the March of Dimes third annual awareness month, an article in the November 2, 2005, Salt Lake City Tribune featured Network PI, Dr. Michael Varner, describing various NICHD MFMU Network trials. Prior to 2003, the March of Dimes focused on preventing birth defects and infant mortality. Beginning in 2003, it launched a campaign to address the increasing rate of premature births. During the previous decade in Utah, there had been an increase of about 3 percent, with 4,662 babies born preterm in 2002.

Dr. Varner's statement attributed this increase to assisted reproductive technology and a trend toward having children at a later age. He also indicated that doctors are more likely to deliver premature babies than previously because of better care in newborn intensive care units. The article publicizes the MFMU Network trials being conducted at Utah's four sites.

Funeral Services Held for UAB Laptop

The following was submitted on November 3, by Dr. William Andrews at UAB in honor of his deceased hard drive.

"Thank you all. Funeral services for my hard drive will be held this week in Birmingham. Internment will follow. We are hoping to save the actual desk top with a transplant. Unfortunately, extensive rehab will be necessary for it to learn how to walk again. Regardless, I fear that it will never be the same. Life is fragile. Here I was conversing with my hard drive on a sunny morning and, BAM, I had a black screen with DOS-like stuff written all over it. I didn't even have a chance to say good-bye. Even now, I don't think my old keyboard even knows that I am here holding its hand."

Dear Bill – the entire Network sends its sincere condolences and hopes you have found a wonderful transplant that is healthy and resistant to viruses.

UT Houston Hires New Coordinator

Brenda Glenn-Cole, RN, MBA, BSN, brings a diverse background of experience to the coordinator position recently vacated by Marci Kerr. Most recently she was the clinical manager for IntelliStaf Healthcare, supervising a staff of 64 nurses. She has been a nurse surveyor/compliance reviewer for the state of Texas, a case manager, a director of nursing for various organizations and also has had direct patient care experience. Brenda also has knowledge of Medicare and Medicaid regulation, HIPAA and JACHO Regulations and budget management. She has a grown daughter and enjoys traveling with her husband who is an engineer for Boeing working on NASA contracts. She is active in her church and does community volunteer work. Brenda started her new position just in time to host a data review visit by the BCC. She will travel to UNC-Chapel Hill for hands-on training with Karen Dorman before receiving additional training and certification at the BCC in January.

BEAM Baby Wins Pageant

A BEAM baby, born at just 25 weeks gestation, was recently selected as Wee Miss East Coast 2005-2006. The proud MFMU Network staff at UNC-Chapel Hill say the two-year old, pictured in the photo to the right, has completed all three of her BEAM follow-up exams.



Coordinator Gwendolyn Norman Featured in Rosa Parks Article

An article written by a reporter for the Cleveland's *Plain Dealer* newspaper in the November 3, 2005 issue highlighted her meeting with another Rosa Park mourner, Gwendolyn Norman, Wayne State's coordinator in Detroit, Michigan. All this was the culmination of the newspaper writer's pilgrimage with her young children from Cleveland, on a chilly November evening, to pay respects to recently deceased Rosa Parks at the Charles H. Wright Museum of African American History, where Mrs. Parks' body was on view until 5 a.m.

The writer and her family met Gwendolyn about 10:30 PM, who was in line with about 5,000 others, where they discussed the reasons for their pilgrimage. Gwen recalled a trip down to the segregated South when she was a child and was bitten by a rat. Her Georgia relatives took her to the hospital where she clearly remembered being shunted off to the "colored-only" waiting room. More than four hours later (almost 3 AM), the reported stated that she, her children and Gwendolyn and her family finally made it into the museum, where they were allowed to view Mrs. Parks for about one minute. Gwen reported the experiences of that night were worth more than the lost night of sleep.



MUFMU CALENDAR

2005 – 2006 Steering Committee Meetings

January 19-20, 2006	April 27-28, 2006
July 20-21, 2006	October 19-20, 2006

Professional Meetings

SMFM.....	January 30-February 4, 2006, Miami, FL
SGL.....	March 22-25, 2006, Toronto, Canada



Best Wishes for a Happy and Healthy New Year!