



# The MFMU Networker

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## Network Cuts Teeth on New C-Section Study



As with the start up of most new studies in the Network, unfamiliar procedures and requirements have presented challenges to both the BCC and Network Centers. The absolute volume of data generated by enrolling 1700 patients a month and the number of edits

immediately generated was an area of early concern. However, an analysis of the number of edits being created, in comparison to other Network studies, showed that in fact this study does not have a higher percentage of edits per patient.

To help the situation, some changes have been made to normal Network procedures. Due to the large volume of chart requests, some centers indicated that turning around edits within the usual one week timeframe was not possible. As a result, for this study, the centers will now have two weeks to correct and return edits.

As on other data forms, some questions are flagged as being "required" to be answered because of their importance and, if no explanation for missing data is given, an edit is sent. The Cesarean Section Registry may have a higher percentage of these required fields than most studies because there are actually 18 concepts being investigated within the main study. C-Section also differs from most Network studies because all data is

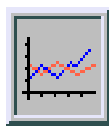
extracted from patient charts. Answers cannot be obtained if they are missing because there is no patient contact. Therefore, to ensure explanations for missing data are entered, a new kind of required field has been developed. Centers can enter the "required" answer as permanently missing without receiving an edit if they also initially enter an explanation. Data forms will be revised to identify the required fields. All these adjustments have been made to maximize efficiency without sacrificing data quality.

A conference call was held on March 18 with the BCC, coordinators and Dr. Landon to discuss general study questions and day-to-day management. Several changes are being made to the manual, including redefining labor to be regular contractions with or without documentation of cervical change. Some data forms are being also being reworded to be more specific about intrapartum antibiotic administration and induction attempts. It was decided that only patients who deliver in the hospital should be included on the registry form. Therefore, deliveries outside the hospital, such as in cabs, are not to be recorded. The charts of patients who have an uterine rupture, cesarean hysterectomy or die should be kept at each institution until the end of the study. The revised manual, data forms and software will be distributed shortly. Meanwhile, Sharon Leindecker has notified everyone of the changes by email.

## Factor V Leiden Study Progresses

The protocol and data forms are in the process of being developed for this observational study evaluating obstetric outcome in women with the factor V Leiden mutation. Principal Investigator, Donna Dizon-Townson, from Utah was at the BCC on March 25 to work on study details.

## Asthma Observational Study Reaches Goal

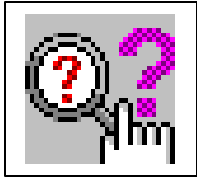


March 15 was the last day for enrolling patients in the Mild Cohort of the Asthma Observational Study which reached its goal of 900 patients! Recruitment to the other two cohorts ended last August with a total of 1824 patients. Forty five more patients are needed for the Asthma RCT. Only two have been recruited, out of 50 needed, to the plasma levels of inhaled corticosteroids study.

A one day Asthma Protocol Subcommittee meeting will be held April 8 in Bethesda. The subcommittee will meet to discuss ideas for follow-up studies on women who participated in these asthma studies and to plan analyses of the observational data.

## Creative Sleuthing Keeps Lost-to-Follow-Up Rates Low

Though the ideal percentage of lost-to-follow-up in a clinical trial is zero, many of the studies performed by the MFMU Network



achieve an acceptable rate of two percent or less. Part of this is due to the fact that most of the

Network trials have, as a relatively simple primary outcome, preterm delivery, which is determined by the date of infant birth. However, obtaining even a date of birth can be challenging for nurses in the Network because of the mobility of the study population. Prodding by the BCC and the sheer creative determination of study nurses help keep the numbers of lost-to-follow-up low.

A number of resources for information have been identified by Network nurses. One of the most profitable sources for Lisa Reynolds in Utah has been the Church of the Latter Day Saints which keeps data on everyone worldwide who has a public record of birth. This information can be obtained from the LDS Church's Family History Library in Salt

Lake City at (801) 240-2584. The library also maintains 3,200 genealogical research centers throughout the world. The exciting news is that the library will soon announce the availability of data online. The Church's web site is [www.lds.org](http://www.lds.org). Lisa tracked an FFN trial patient to Puerto Rico and got her outcome data using this service. She also was able to persuade a phone operator in New Mexico to call a patient who moved there, but had an unlisted phone number, and request she call Lisa collect in Utah. The patient actually called Lisa who got the name of the hospital and then the records.

Lynne Sherman at UT-Dallas has been able to trace patients through [www.publicdata.com](http://www.publicdata.com), a database of information in Texas obtained from public sources available through the Freedom of Information Act and Open Records Laws. Patients (or relatives and friends) can be found through their drivers licenses, voter registration, criminal and parole records, etc.

Nurses at the University of Florida have had success getting patient outcomes because Jackson Memorial Hospital is a distribution

center for WIC, a Federal nutrition supplement program. Many of their patients use this resource so the nurses monitor the appointment screens and catch up with them at social service/benefit appointments.

Constantly changing health care policy and providers also result in tracking difficulties. Some centers find help through their physicians who have dual privileges with other hospitals in the area. If patients deliver at another hospital, nurses can give the doctors patient names and social security numbers and have the doctors gain access to delivery records. Birth dates are also obtainable through the Bureau of Vital Statistics.

Clinical trials in the United States may have problems achieving the follow-up success of trials in Great Britain and other European countries because of the differences in health care. However, with the access of public information ever more available and with the persistence and persuasive powers of Network study nurses, MFMU trials can strive for that zero percent lost-to-follow-up.

## Feasibility of BEAM Trial Being Assessed

Selected members of the Data Safety and Monitoring Committee (DSMC) and other reviewers chosen by NINDS examined BEAM data at a meeting on February 23. The committee looked at how well the procedures, such as study drug dosing and infant follow-up, are being carried out. A report is being prepared for the Directors of NICHD and NINDS, who will decide whether continuing the trial is feasible. A decision from NICHD and NINDS is expected in April.

A single center ancillary is being conducted at Texas Southwest Medical Center on fetal cerebral blood flow. Wayne State has proposed an ancillary study which will collect cerebral spinal fluid if a spinal tap is already scheduled.

## More Changes to Design of Steroids Trial

The Steering Committee approved several more changes to the protocol for the Steroids Trial at its February meeting. Among the major modifications were the elimination of the rescue course of corticosteroids/placebo, the addition of maternal and neonatal blood collection for a variety of assays, an adrenocorticotrophic hormone (ACTH) stimulation test on 60 patients, and an auditory brainstem response (ABR) on 130 patients. The sample size is 2,400 patients (1,200 in each group). Three separate consents will be required for patients who are enrolled in the trial and also the ACTH, and ABR ancillaries.

Meanwhile, Eminent Services, manufacturer of the placebo, has been able to resolve production problems. The challenge was that the placebo emulsion needed to maintain a cloudy appearance in order to match the study drug, but also needed to be sterilized. The sterilization process resulted in a clarification of the solution. However, a successful formula has been devised and manufacturing should be completed by mid April.

A two day nurse training meeting for this complicated trial is being planned for May.



## MFMU Rolodex Directory Available Soon

The MFMU Directory will soon be available on-line through the BCC's MFMU Network web site. This service will initially be available as "read" only, where the user can look and print from the web site. Once new security measures are initiated, each center will be able to access the directory online and update the personnel listings at their site.

The Rolodex has several options for reporting, including by job title, protocol or committee. Information can be printed by designating several different listings and options for data. Watch for a notice which will let you know the Rolodex is ready to be used. It will be nice to have up-to-date MFMU directory information available at all times!

## Y2K Update

The BCC has distributed to all Centers a BIOS upgrade which allows the Network PC hardware handle the century conversion correctly. Most centers have already installed this upgrade. Data entry personnel were to call Brendan Broderick at the BCC for help with installation. Meanwhile, the BCC has not received Y2K reports from all the Centers. Samples of the completed report are available from Julia Zachary. Please persist in getting these reports completed and returned to the BCC.

## Modifications Made to Terb Trial

Ways to help the low recruitment rate were discussed at a subcommittee meeting held during the February Steering Committee meeting. Several modifications were adopted, including temporarily expanding screening entries on the log to get a better idea of the potential population, and changes to the inclusion and exclusion criteria. Patients can now be started on study medications within 2 hours of stopping tocolytics. The definition of uterine quiescence was also changed to include patients who have no cervical changes for 6 hours though contractions may still occur.

## BCC Web Site Update

Problems have been identified with "reading" MFMU Network documents on the Web (i.e., data forms and manuals). The BCC upgraded to MS Office 97 last fall and any documents created or updated since then can not be viewed by older versions of MS Word Viewer. The BCC is currently reformatting documents back to Word 6.0, so any difficulties you may have had, should be corrected. The BCC will soon be moving its web site to a new server, which will require a slight change in the address (URL). Documents will then be available in PDF format with the site providing a link to download the Acrobat Reader. Keep your eyes open for the announcement. Please call Lucy Leuchtenburg if you encounter further problems.

## Network Presentations Continue to Spring Forth

Following the ten presentations and posters at the Annual Meeting of the Society for Maternal Fetal Medicine in January, including a well received plenary session by Dr. Mark Klebanoff on the results of the BV Trial, four presentations are planned for this Spring. Two are being made in March at the Annual Meeting of the Society for Gynecological Investigation in Atlanta:

- Dr. H. How. *Neonatal outcome following preterm premature rupture of membranes: Indicated compared to spontaneous delivery*, (pPROM trial), and
- Drs. Wang, Woodruff and Moawad. *Plasma activin concentration does not predict preterm birth* (Preterm Prediction study).

Two presentations will be made at the Annual Meeting of the Society for Clinical Trials in Anaheim in May:

- Dr. Elizabeth Thom. *Comparison of central vs. local review of cranial ultrasound in a multicenter trial* (High Risk Aspirin trial), and
- Julia Zachary. *Computer applications: Experiences with the NICHD Maternal Fetal Medicine Units (MFMU) Network*.

## NICHD Makes Biological Repository Award

In January, NICHD awarded the Biological Fluids Specimen Repository Bank contract to McKesson Bioservices, replacing BBI-Biotech Research Laboratories as the storage facility for MFMU Network fluids. All fluids were transferred from Biotech to McKesson in March.



## Bits & Pieces

Remember to check the expiration date on the FFN dipsticks and medium! Rhonda Carrasquilla at Tennessee used a dip stick which registered negative. She then noticed it had expired the day before and re-swabbed the patient with a new dipstick, which had a positive reaction.

## People in the News

Welcome to **Julia McCampbell** who took over as Coordinator at the University of Texas Southwestern Medical Center in January. She has been associated with OB/GYN and the medical school for the past 25 years in their Department of Maternal Health and Family Planning, so she brings lots of expertise in this move to the research department. Julia is a native Texan and received her BS from Texas Womens College and her certificate in education as a nurse practitioner in women's health care from Southwestern Medical Center in 1981. She has two daughters and writes poems and contemporary music, which she also performs. On April 15, she will be recognized by the University for her 25 years of service and inducted as a member of the Quarter Century Club.

Best wishes to **Amy Grubbs** who married Billy Martin on February 27 in Birmingham, Alabama. After a honeymoon to Gatlinburg, Tennessee, Amy is back in the lab at the University of Alabama making sure the biological specimens are handled, stored and shipped correctly!

Though **Dr. Don Dudley** is moving, he can't get away from the Network and the Steroids Trial! After a successful tenure at Utah, he is returning to his roots and relocating to the University of Texas at San Antonio in July. He and his wife both studied and met at the Medical School and are looking forward to being back near their families in Texas.

Congratulations to **Tawanda Johnson nee Campbell**, software programmer at the BCC, on the birth of her second child, January 18. Predictions were for a daughter, but another son, Cheyenne Elijah, joined the family. She also changed her name to match her husband's. Her co-workers were very glad to have her back to work March 15.

**Dr. Ray Bain**, who served as the BCC's Principal Investigator and then as Co-PI with Dr. Liz Thom on the MFMU Network, has left the BCC, accepting the position of Executive Director of Clinical Biostatistics and Research Data Systems at Merck Laboratories in Philadelphia. We wish him all the best.



### Calendar of Events

#### Steering Committee Meetings

May 10 - 11, 1999 - Rockville, MD

July 26 - 27, 1999 - Rockville, MD

#### Nurse Coordinator Steroids Training

May 12 - 13, 1999 - Rockville, MD