



The MFMU Networker

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Media Splash for C-Section Study Results

A London newspaper was the first to break the embargo on publishing the results of the MFMU Network's cesarean section study two days before it was to appear in the December 16th issue of the *New England Journal of Medicine*. The media immediately began contacting the Protocol Chair, Dr. Mark Landon, NICHD Program Scientist, Dr. Cathy Spong, and other experts for further information. Dr. Landon was interviewed by Tom Brokaw and Robert Bazell, while Dr. Spong was interviewed live on CBS's Early Show and on Washington DC's 5:00 NBC news on December 15. To see a recording of her appearance, go to the to web: <http://www.cbsnews.com/sections/earlyshow/health/main500165.shtml>. The study results are also the lead item on the main NIH web site.

The Network's study, conducted between 1999 and 2002, was the largest, most comprehensive study (over 70,000 patients) to assess the risks from a vaginal delivery after a prior cesarean delivery compared with a repeat Cesarean delivery. The investigators found that the risks after a cesarean are low but still higher in those patients who

attempted to have a vaginal delivery. Such risks include placental abruption, hypoxic-ischemic encephalopathy and endometritis. However, the overall risk for brain injury to the baby or death is roughly 1 in 2000 trials of labor.

Repeat cesarean deliveries, however, also carry risks beyond delivering vaginally after a prior cesarean delivery, including the risk for infection and other surgical complications. In addition cesarean deliveries may complicate future pregnancies, sometimes causing placenta accreta or placenta previa.

This information is relevant for patients and their physicians when making delivery decisions after a prior cesarean. After peaking at 31 percent in 1998, the rate of natural birth after Cesarean sections dropped to only 11 percent by the end of 2003. The U.S. Public Health Service, in its Health People 2010 Report, has proposed a target rate of 37 percent of vaginal birth after Cesarean delivery. However, many hospitals have stopped doing such deliveries citing liability issues and the need to have surgical teams on standby.

Network Begins Recruitment for Two New Trials



Progesterone Follow-Up Study Starts

The manual of operations and data forms for this study of children born to mothers who participated in the Network's progesterone trial were finalized in November. These documents as well as both the English and Spanish versions of the ASQ questionnaire have been posted on the MFMU web site. All examiners who will be conducting the exams on the children have been certified through one of three conference calls held with Dr. Mark Klebanoff. Four centers are now fully certified and two more have IRB approval. The University of Alabama was the first to submit data forms for a completed exam! The goal is to have all 350 exams completed by April 2005.

Omega-3 Trial Up and Running

A re-training conference call was held in early December with research nurses to review study procedures and highlight changes and additions made since the official training that occurred in July. By the end of December, four centers had been certified and their study drug had been ordered. Columbia was the first to be fully certified. IRB approval from the remaining centers has been delayed because their IRBs required product information that had to be supplied by the manufacturer and Eminent Services. This information was recently compiled and sent to the centers. The centers seem enthusiastic about this new trial and look forward to recruiting their first patients!

Annual DSMC Meeting

Because of the number of trials requiring their review, the Data Safety and Monitoring Committee needs to meet, the first time ever, for than one day to consider the trials conducted by the MFMU Network and the MOMS trial. The MFMU trials to be considered during the February 17-18, 2005, meeting are: GDM, FOX, STTARS, CAPPS and Omega-3. Network centers are being asked to enter all outstanding data for transmission to the BCC by January 12.

Network Continues to Publish Many Research Results

Twelve MFMU Network manuscripts have been published during 2004. Several more have been accepted by journals but have not yet been published. A number of others are in the process of being reviewed in-house (by Network investigators) before being submitted, or are in the process of journal review.

In addition, 15 abstracts were accepted for the 2005 SMFM annual meeting, 4 of which are oral presentations. The five abstracts that were submitted for the 2005 SGI annual meeting have all been accepted as posters. A number of papers are expected to result from these presentations. Following are the manuscripts that appeared in print in 2004. A complete list of Network publications can be found on the MFMU web site.

Mark B. Landon, John C. Hauth, Kenneth J. Leveno, Catherine Y. Spong, Sharon Leindecker, Michael W. Varner, Atef H. Moawad, Steve N. Caritis, Margaret Harper, Ronald J. Wapner, et al. **Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery.** *NEJM*, 351(25): 2581-2589, 2004.

Dwight J. Rouse, Mark Landon, Kenneth J. Leveno, Sharon Leindecker, Michael W. Varner, Steve N. Caritis, Mary Jo O'Sullivan, Ronald J. Wapner, Paul J. Meis, Menachem Miodovnik et al. **The maternal-fetal medicine units cesarean registry: chorioamnionitis at term and its duration—relationship to outcomes.** *Am J Obstet Gynecol*, 191(1): 211-216, 2004.

Mitchell P. Dombrowski, Michael Schatz, Robert Wise, Elizabeth A. Thom, Mark Landon, William Mabie, Roger B. Newman, Donald McNellis, John C. Hauth, Marshall Lindheimer et al. **Randomized trial of inhaled beclomethasone dipropionate versus theophylline for moderate asthma during pregnancy.** *Am J Obstet Gynecol*, 190(3): 737-744, 2004.

Mark A. Klebanoff, John C. Hauth, Cora A. MacPherson, J. Christopher Carey, R. Phillips Heine, Ronald J. Wapner, Jay D. Iams, Atef Moawad, Menachem Miodovnik, Baha M. Sibai, et al. **Time course of the regression of asymptomatic bacterial vaginosis in pregnancy with and without treatment.** 190(2): 363-370, 2004.

Eric J. Knudtson, Kenneth Smith, Brian M. Mercer, Menachem Miodovnik, Gary R. Thurnau, Robert L. Goldenberg, Paul J. Meis, Atef H. Moawad, J. Peter Vandorsten, Yoram Sorokin et al. **Serum homocysteine levels after preterm premature rupture of the membranes.** *Am J Obstet Gynecol*, 191(2): 537-541, 2004.

Vincenzo Berghella, Jay D. Iams, Roger B. Newman, Cora MacPherson, Robert L. Goldenberg, Eberhard Mueller-Heubach, Steve N. Caritis, Mitchell P. Dombrowski for the National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units. **Frequency of uterine contractions in asymptomatic pregnant women with or without a short cervix on transvaginal ultrasound scan.** *Am J Obstet Gynecol*, 191(4): 1253-1256, 2004.

Dombrowski MP, Schatz M, Wise R, Momirova V, Landon M, Mabie W, Newman R, McNellis D, Hauth J, Lindheimer M, Caritis S, Leveno K, Meis P, Miodovnik M, Wapner R, Paul R, Varner M, O'Sullivan M, Thurnau G, Conway D for the NICHD Maternal-Fetal Medicine Units Network, and The NHLBI. **Asthma During Pregnancy.** *Am J Obstet Gynecol*, 103(1): 5-12, 2004.

Dombrowski M, Schatz M, Wise R, Thom E, Landon M, Mabie W, Newman R, McNellis D, Hauth J, Lindheimer M, Caritis S, Leveno K, Meis P, Miodovnik M, Wapner R, Varner M, O'Sullivan M, Conway D, for the NICHD Maternal-Fetal Medicine Units Network and The NHLBI. **Randomized trial of inhaled beclomethasone dipropionate versus theophylline for moderate asthma during pregnancy.** *Am J Obstet Gynecol*, 190(3): 737-744, 2004.

Klebanoff M, Hauth JC, MacPherson C, Carey JC, Heine P, Wapner R, Iams J, Moawad A, Miodovnik M, Sibai B, VanDorsten JP, Dombrowski MP for the NICHD Maternal Fetal Medicine Units Network. **Time course of regression of asymptomatic bacterial vaginosis in pregnancy with and without treatment.** *Am J Obstet Gynecol*, 190(2): 363-370, 2004.

Yost NP, Owen J, Berghella V, MacPherson C, Swain M, Dildy GA, Miodovnik M, Langer O, Sibai B for the NICHD Maternal Fetal Medicine Units Network. **Second-trimester cervical sonography: Features other than cervical length for the prediction of spontaneous preterm birth.** *Obstet Gynecol*, 103(3): 457-462, 2004.

Yost NP, Owen J, Berghella V, MacPherson C, Swain M, Dildy GA, Miodovnik M, Langer O, Sibai B for the NICHD Maternal Fetal Medicine Units Network. **Number and gestational age of prior preterm births does not modify the predictive value of a short cervix.** *Am J Obstet Gynecol*, 191: 241-6, 2004.

Owen J, Yost N, Berghella V, MacPherson C, Swain M, Dildy GA, Miodovnik M, Langer O, Sibai B for the Maternal Fetal Medicine Units Network. **Can shortened mid-trimester cervical length predict very early spontaneous preterm birth?** *Am J Obstet Gynecol*, 191:298-303, 2004.

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