

Women & Infants/Brown to Continue Participation in NIH's Maternal Fetal Medicine Units Network (MFMU) and Neonatal Research Network (NRN)

PROVIDENCE – Since 1986, a great deal of research to improve the care and outcomes of high-risk pregnant women and newborns, especially very low birth weight infants, has been organized and conducted through two networks in the National Institute of Health's (NIH) *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) – the 12-center Maternal Fetal Medicine Units Network (MFMU) and the 15-center Neonatal Research Network (NRN).

Following a rigorous review process, Women & Infants Hospital and The Warren Alpert Medical School of Brown University, have recently received notification that their participation in both research networks has been renewed for the five-year cycle that begins in 2016. Women & Infants/Brown is one of only a few sites nationwide – and the only one in New England – to be part of both networks simultaneously.

DWIGHT ROUSE, MD, of the Division of Maternal-Fetal Medicine at Women & Infants Hospital and a professor of obstetrics and gynecology at the Alpert Medical School, is the Brown/Women & Infants principal investigator for the MFMU.

The Network conducts large randomized clinical trials aimed at improving outcomes for pregnant women and their offspring. With 140,000 births spread among its 12 centers, the Network is able to perform trials of sufficient size to reach definitive conclusions that result in health-improving practice changes locally, nationally and internationally. These trials directly inform the guidelines of the American College of Obstetricians and Gynecologists and clinical obstetric practice in the U.S. and abroad. As a result of MFMU Network trials, in the U.S. it is now routine to:

- Use weekly 17-alpha hydroxyprogesterone caproate to prevent repeat preterm birth.
- Administer antibiotics to women with preterm premature rupture of membranes to improve neonatal health.
- Give women in early preterm labor magnesium sulfate to lower the chance that their baby will suffer from cerebral palsy.
- Treat mild gestational diabetes to improve maternal and neonatal health.

Dr. Rouse said, "The two most recently completed MFMU Network studies will also directly improve practice. The Antenatal Late Preterm Steroids (ALPS) study showed that betamethasone administered to mothers delivering in the late preterm period (from 34 to 36 weeks gestation) lowers the risk of respiratory problems in their babies. Of the 2,800 women in this study, 290 were enrolled at Women & Infants. The TSH study, presented orally at this year's Society for Maternal Fetal Medicine Meeting but not yet published, showed that treating pregnant women with subclinical hypothyroidism does not improve the intelligence of their children at age five (as had been claimed), and therefore screening pregnant women for this condition is not warranted."

Neonatal Research Network conduct studies of newborn medicine

ABBOT LAPTOOK, MD, medical director of the neonatal intensive care unit (NICU), professor of pediatrics at the Alpert Medical School, and principal investigator for the Women & Infants/Brown Neonatal Research Network, said, "The Neonatal Research Network has conducted a number of important

clinical trials which have improved the outcomes of sick newborns and changed how neonatologists care for their patients. Not all trials performed by the NRN have changed clinical practice; even when this occurs, the results are important to guide neonatologists as to what treatments are not helpful and should not be used."

Treatments that have been demonstrated in NRN trials to help newborn infants include:

Therapeutic hypothermia: This trial demonstrated that cooling the brain from a normal temperature to 92.3°F for three days is the only treatment to be of benefit for infants with a serious brain condition at birth, encephalopathy.

Targeted oxygen saturations: This trial showed the risks and benefits of maintaining oxygen levels either high or low in extremely preterm infants requiring supplemental oxygen.

Aggressive phototherapy: This trial demonstrated better outcomes of extremely preterm infants when phototherapy for yellow jaundice was used aggressively compared to conservative use.

Vitamin A supplementation: This trial demonstrated that administration of vitamin A over the first month of life decreased the risk of Bronchopulmonary Dysplasia (BPD, a form of chronic lung disease) among extremely low birth weight infants.

Prophylactic Indocin: Administration of low doses of Indocin (similar to aspirin) in the first 24 hours of life reduces the extent of severe intracranial hemorrhage among extremely low birth weight infants.

Inhaled nitric oxide: This trial helped clinicians understand when to start nitric oxide therapy for serious conditions affecting the circulation to and within the lungs among infants born at term. ❖