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NEONATOLOGY TODAY

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Neonatology Today (NT) is a monthly newsletter for BC/BE neonatologists and perinatologists that provides timely news and information regarding the care of newborns and the diagnosis and treatment of premature and/or sick infants.

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Surfaxin® (Lucinactant): A Synthetic Peptide-Containing Surfactant

By Russell G. Clayton Sr., DO

Russell G. Clayton Sr., DO, Vice President, Academic and Medical Affairs- Discovery Laboratories, Inc.

The introduction of surfactant replacement therapy (SRT) in 1990 had an immediate impact on the potential for survival of preterm infants. The first commercially available exogenous surfactant in the United States (Exosurf®; colfosceril palmitate) demonstrated a significant reduction in mortality related to Respiratory Distress Syndrome (RDS) and all cause mortality in preterm infants[1]. Although the administration of liquid via an endotracheal tube was unconventional at the time, preterm infants with RDS tolerated the 5 mL/kg dosing volume of Exosurf, a synthetic surfactant containing only phospholipids.

Over the next decade, three other surfactants were introduced into the US market. These surfactants (Survanta®; beractant; Infasurf®; calfactant; Curosurf®; poractant alfa) all contained phospholipids, as well as small amounts of surfactant proteins that are harvested from an animal source. In comparative trials with Exosurf, use of these animal-derived surfactants in preterm infants facilitated a significantly faster reduction in ventilatory pressures and supplemental oxygen use compared with infants treated with Exosurf[2-3]. However, despite these findings, there was no difference in the incidence of bronchopulmonary dysplasia (BPD) in infants treated with Exosurf compared with infants treated with the other surfactants, even when the comparative trials were combined in meta-analysis[4].

Despite the introduction of these surfactants, nearly 10% of deaths in preterm infants are attributed to RDS, and another 3% of deaths are related to chronic respiratory disease originating in the perinatal period[5]. Indeed, since 2000, preterm mortality has risen year by year[6]. In addition, there are concerns related to the purity of medicinal products that are derived from animal sources, including surfactants[7].

> ***"The introduction of surfactant replacement therapy (SRT) in 1990 had an immediate impact on the potential for survival of preterm infants."***

Surfaxin® (lucinactant; Discovery Laboratories, Inc.) is a peptide-containing, synthetic surfactant consisting of phospholipids, a fatty acid, and sinapultide (KL4), a synthetic 21 amino acid peptide with structural similarities to that of pulmonary surfactant protein B. The amount of KL4 in Surfaxin is 2.9% relative to the amount of total phospholipids. In contrast, the relative amount of surfactant

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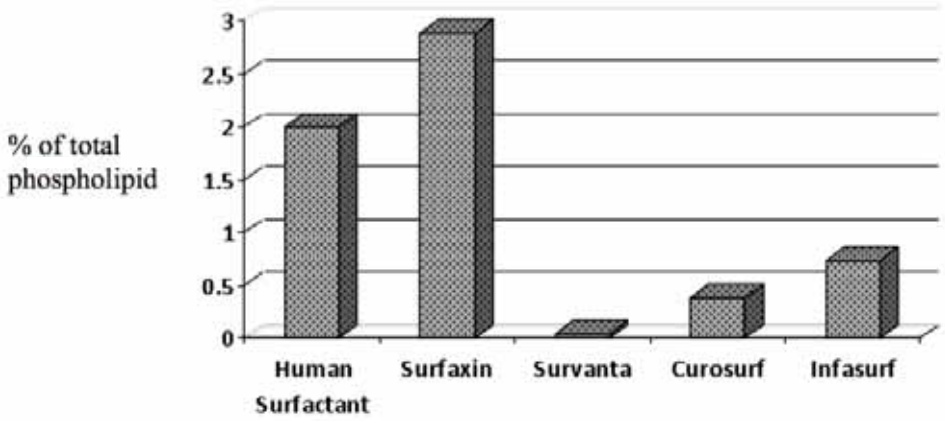

Figure 1. Percent of surfactant protein B (or KL4) relative to the total phospholipid content. Sources: Manufacturer's prescribing information (Curosurf and Infasurf), Notter, et. al., 2002,Chemistry & Physics of Lipids 114, 21-34 (Survanta).

protein B in other currently available surfactants is less than 1%. The relative amount of surfactant protein B in humans is 2% (Figure 1).

The minimum surface tension (STmin) of Surfaxin is comparable to the STmin of surfactants that contain surfactant protein B. In vitro studies have demonstrated that Surfaxin maintains STmin even when exposed to plasma proteins and oxidants found in the alveolar fluid of diseased lung, while the STmin of animal-derived surfactants increases significantly[8]. These observations suggest that Surfaxin resists inactivation to a greater extent, compared with animal derived products, although the clinical implications of these findings have not been determined.

In animal models of surfactant deficiency, Surfaxin significantly improves lung compliance[9]. Interestingly, data from in vitro and in vivo experiments suggest that Surfaxin may modulate the inflammatory response of the lung to hyperoxia. In one study, airway cells exposed to high levels of oxygen produced significantly less IL-6 and IL-8 when treated with Surfaxin compared with airway cells treated with saline or Survanta[10]. In another study, mice placed in a hyperoxic environment developed high levels of alveolar polymorphonuclear leukocytes (PMNs) that was not attenuated by intranasal Survanta. In contrast, mice treated with intranasal Surfaxin had almost no alveolar PMNs[11]. The clinical implications of these findings have not been determined.

Surfaxin was evaluated in the Safety and Effectiveness of Lucinactant Versus Exosurf in a Clinical Trial of RDS in Premature Infants (SELECT) study[12]. In this multi-center, multi-national, masked randomized trial, 1294 preterm infants less than 32 weeks, weighing 600 to 1250 grams, were randomized to receive Surfaxin, Exosurf, or Survanta in a 2:2:1 ratio, with Exosurf serving as the primary comparator and Survanta serving as a reference arm. Surfaxin demonstrated superiority over Exosurf by significantly reducing both co-primary outcome endpoints, RDS at 24 hours and RDS-related mortality through 14 days after birth, in infants at risk for severe RDS. Comparisons between infants treated with Surfaxin and Survanta were not designated prospectively. However, RDS-related mortality was significantly lower in infants treated with Surfaxin compared with infants treated with Survanta (Figure 2).

In the SELECT trial, BPD (defined by the use of supplemental oxygen at 36 weeks

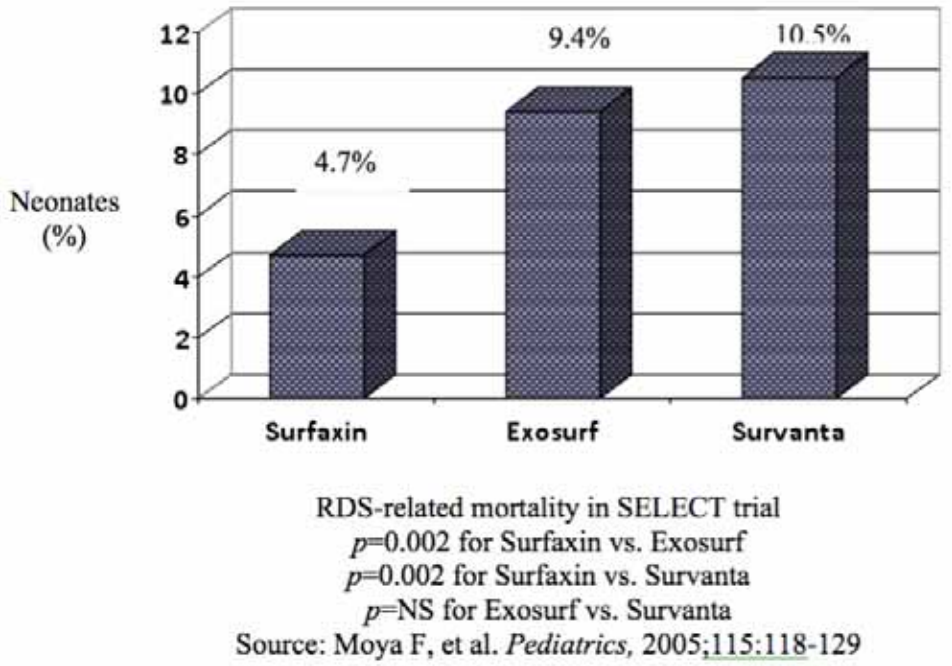

Figure 2.

post conception) was significantly reduced in infants treated with Surfaxin compared with infants treated with Exosurf. There were no differences in the incidence of other complications of prematurity between the three treatment groups. The overall incidence of adverse reactions during dosing was lower in infants treated with Exosurf, but there was no difference in this observation between infants in the Surfaxin and Survanta treatment groups.

Surfaxin is an investigational drug product and is currently under review by the Food and Drug Administration (FDA). Meanwhile, new formulations are being developed. Through lyophilization, lucinactant is converted to a dry powder that can be reconstituted by adding sterile water. While currently available surfactants require refrigeration during storage and subsequent warming before administration, this formulation is intended for storage at room temperature and reconstituted and used rapidly. Additionally, lyophilization reduces lucinactant viscosity, and a lower viscosity product may reduce the incidence of adverse events during dosing, as was observed in Exosurf, a lyophilized product, in the SELECT study. Reduced viscosity may also facilitate intrapulmonary spreading of the surfactant, thereby improving distribution in the lung.

A major limitation of SRT is the requirement for endotracheal intubation to enable administration. Current aerosol technologies do not allow for the practical, safe, or effective means of administration of surfactant via aerosol inhalation. However, Aerosurf® (lucinactant for inhalation), an investigational drug-device combination, is being developed to address this unmet need. Aerosurf has been tested in vitro and has been shown to produce a consistent and sustained high aerosol output of lucinactant. Moreover, the aerosolization process does not affect the chemical or physical properties of lucinactant. Aerosolized lucinactant has also been tested in established animal models of RDS[13] and acute lung injury[14] with delivery to spontaneously breathing animals receiving continuous positive airway pressure (CPAP). In these in vivo experiments, animals that received aerosolized lucinactant demonstrated improved pulmonary function, preserved lung architecture, and decreased levels of inflammatory mediators compared with animals receiving CPAP alone. Initial clinical trials in preterm infants are anticipated in early 2010.

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NICU Cuddler Program: Golisano Children's Hospital at the University of Rochester Medical Center, Rochester, New York

By Rhonda Rusinko, RN, BSN and Chris Tryon, BS, CCLS

The Beginning: Our unit is a 54 bed Level III/IV NICU regional center covering a 13 county region in Upstate NY. Many factors including distance, transportation difficulties and the need to return to work make it difficult for parents to spend the entire hospitalization with their infant. Seeing a need for additional support that volunteers holding babies would help fulfill to meet the social/emotional and developmental needs of the patients, one of the authors (RR), a NICU staff nurse, had an interest in establishing a volunteer program. The idea for the program came from a NICU where she had worked previously. She discussed the idea with the Clinical Nurse Specialist, Lynne Slat, and some of her peers to determine if they were willing to start a program in the unit.

The Research: NICUs all over the country have developed cuddler programs since studies of babies born prematurely--born before being in the womb for at least 37 weeks--show that the human touch can enhance a premature infant's growth, improve their health and help them develop trusting relationships later in life, Fritsch-deBruyn, Capalbo, Rea&Siano, (1990). Cuddler programs provide soothing answers. Neonatal Network, 8(6), 45-49. The work group networked with other hospitals across the country to learn about how other successful volunteer programs were implemented and maintained in NICUs of comparable level and size. Simultaneously, the nursing staff was surveyed to assess their willingness to incorporate a volunteer program into daily patient care. Staff response was positive, and with information compiled through networking, a multidisciplinary task force was formed to create the first volunteer program for our NICU.

Program Development: A multi-disciplinary task force was formed which included representation from: nursing, medicine, child life, social work, hospital volunteer department and a NICU parent. Based on research from other NICU volunteer programs, the task force created a job description (including a one year commitment for community volunteers and a two semester commitment for college student volunteers), volunteer selection criteria (including a minimum age of 18), and an orientation process to ensure that the patient privacy and health and safety needs of the infants and staff would be met. Interested volunteers were screened by the hospital volunteer department and selected to become the first group of Cuddlers.

Orientation and Training: The first orientation class took place in July 2003 with twelve eager volunteers. Three members of the multi-disciplinary group formed the teaching triad which became the model for all subsequent orientation classes. Information about preterm infant growth and development, medical equipment and terminology, parents' emotional journey, infection control and confidentiality was shared. Participants were also given a tour of the unit to help them understand the environment in which they would soon be volunteering.

Program Introduction: The Cuddler Program was launched one month later in August, 2003. Initially doctors, nurses and the child life specialist recommended patients for the program and parent permission was required for an infant to participate in the program. To clearly identify themselves to staff and families, Cuddlers were required to, and still do, wear a volunteer jacket and a name tag. Permission for cuddling was documented by parent signature and kept in the bedside chart. Cuddlers are not allowed to change diapers, give medicine, feed, bathe or even kiss the infants, but they can hold and rock them. Cuddlers do not walk with the babies for safety reasons, but they can talk, sing, or read quietly to them. Strollers are available for babies allowed by the medical team to leave their bedside and go for a

"NICUs all over the country have developed cuddler programs since studies of babies born prematurely--born before being in the womb for at least 37 weeks--show that the human touch can enhance preemies' growth, improve their health and help them develop trusting relationships later in life, Fritsch-deBruyn, Capalbo, Rea&Siano, (1990)."

walk in the stroller within the NICU. Cuddlers are encouraged to leave a note for the family explaining what occurred during their interaction with the infant. Over the first year, mutual trust and confidence between the health care providers, families and Cuddlers grew. This relationship contributed to the program becoming a standard service provided by the NICU for all eligible infants. As a result of the success of the program, the requirement for parental permission was eliminated, although parents maintain the right to decline the service.

Initially, Cuddler shifts were 2-3 hours in length, between the hours of 9:00 am and 8:45 pm. These hours coincide with hospital's volunteer department hours of operation. In the beginning, Cuddlers weren't scheduled during nursing evening change of shift (7:00 pm-7:30 pm). Because Cuddlers proved to be such a crucial support for babies, however, this soon changed. After surveying staff and families, Cuddlers were allowed to remain on the unit during shift change. This pleased many families. It comforted them to know that their infant had someone available to hold him or her if needed while the nurses were giving bedside report.

Basic Operations: At the beginning of their shift, volunteers sign in at the hospital volunteer office and get their jacket and name tag. Once on the unit, Cuddlers sign in a log book that tracks their hours and identifies the patients they have spent time with. This tracking system was put in place to monitor Cuddler hours and the number of infants/families served and the process also became important during a situation when we experienced an infection control issue. A list identifying patients eligible for Cuddling is maintained by nursing and child life staff and is kept on a clipboard near the sign in log. Most Cuddlers refer to this list before rounding in the unit. Nurses, however, have the final say about whether or not an infant can be held based on current eligibility criteria (Box 1) or the patient's medical condition.

Box 1

NICU INFANT CRITERIA FOR CUDDLING
- No infants on vents, CPAP, art lines (UAL or peripheral), chest tubes
- No infant deemed "unstable" by the nurse
- Any infant 34 weeks gestational age and older
- Any babies with trachs (not vented) are OK to be held
- Infants in isolation can be cuddled using appropriate isolation criteria

NICU INFANT CRITERIA FOR ADVANCED TRAINED CUDDLERS
- Infants with stable trachs, vented and non-vented and CPAP
- No infants with arterial lines (UAL or peripheral) or chest tubes
- Any infant deemed "unstable" by nursing
- Any infant 34 weeks gestational age and older
- Infants in isolation can be cuddled using appropriate isolation criteria

Early on in the program, we discovered that Cuddler's may not have an infant to hold right after they arrive on the unit. Understanding that the volunteer's time is valuable, a "down time" activity list was created to keep them active while they wait for a patient to hold. Activities included making rounds throughout the NICU and NICU annex/Newborn Nursery every 20 minutes, folding linen, checking batteries in infant mobiles/music boxes/swings/bouncy chairs, straightening books in the family waiting area, making sibling activity bags and offering parents and nurses ice water.

Program Growth: As the program evolved, families and staff, as well as the Cuddlers, were pleased and satisfied with the program's progress, which has led to longevity among the Cuddler volunteers. As a result, the frequency of the orientation program was decreased to twice a year, provided there are openings to be filled – there is always an ongoing waiting list! Once Cuddlers complete the hospital volunteer orientation and the two hour unit-specific orientation, they are paired with an experienced Cuddler for at least one shift to get a feel for the role and develop a level of comfort when holding these special infants.

In 2005, the NICU care providers were approached about expanding the Cuddler role to include holding infants with stable trachs (on or off the ventilator) and infants on nasal CPAP (Box 1). An advanced training program for selected Cuddlers was developed to meet the needs of these special patients. Also in 2005, the NICU introduced the philosophy of Developmental/Family-Centered Care. One of the first initiatives was to use two people for painful or stressful procedures: one person to perform the procedure and one to comfort the infant during and after the procedure. The health care team determined that Cuddlers could assume the role of comforter if a parent wasn't present. This entailed offering a pacifier and providing comfort holding throughout and after the procedure. Cuddlers are not allowed in any way to restrain the infant during the procedure.

Because of the location of our Newborn Nursery and NICU Annex being within the same physical space (down the hallway from the NICU), the need to train Newborn volunteers to cross-cover NICU Annex patients became apparent. In October 2007, Newborn Nursery volunteers with an interest in cross-covering were required to participate in the semi-annual Cuddler orientation. This also allowed them to be utilized as backups in the main NICU when a Cuddler was not available for a shift. As demand for Cuddler services grew, a mechanism for finding a Cuddler quickly within the NICU was needed and the Cuddler

Wireless Phone was implemented in 2007. This provided quick access to a Cuddler and eliminated the need for the staff to leave their Pod (room) or the unit.

"The Cuddler volunteer program has proven to be an asset to the NICU and the Cuddlers are regarded as integral members of the NICU team."

With the introduction of Developmental/ Family-Centered Care, we introduced the use of developmental positioning aids and Halo (Back to Sleep) sleepers in 2005. Initially, laundering of these products was done by the parents, but was quickly transitioned to the main hospital linen service to assure these products were cleaned according to infection control standards, and to allow for their use by all NICU patients. However, the turnaround time was slow, the quality of the products deteriorated rapidly and along with an increasing number of items being lost, we decided to embark on getting our own unit laundry. Cuddlers were surveyed to see if they would be willing to incorporate laundering of developmental care products into their duties. They all responded positively and because of that, this new initiative of laundering unit items was moved forward. Cuddlers and staff collaborated to create a daily routine for laundering developmental positioning aids, incubator, swing and bouncy chair covers, Back to Sleep products and donated items. The transition to laundering unit items has been fairly smooth. We have already noticed an increase in the quality and availability of the developmental products.

The Cuddler volunteer program has proven to be an asset to the NICU and the Cuddlers are regarded as integral members of the NICU team. We now have 43 volunteers who fulfill this role. To-date, the volunteers have logged over 7,500 hours of service. Since the inception of the Cuddler program, their role has continued to evolve, and we have been able to implement many initiatives that have improved the quality of care provided to patients and families. As we look to the future, a new direction for Cuddlers may be after hours (overnight) cuddling (9 pm-7 am) to further meet the needs of our NICU patients, families and staff.

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Medical News, Products and Information

Somanetics announces OxyAlert NIRSensors

Clinicians now have a helping hand in the early detection of risks during and after surgery on neonatal and infant patients with cerebral and somatic oximetry. Somanetics announces that its OxyAlert NIRSensors™, used in conjunction with its INVOS System cerebral and somatic oximeter, enables noninvasive, around-the-clock monitoring, assuring the brain and body are receiving adequate blood oxygenation while undergoing surgery and in recovery.

The infant-friendly sensors feature a gentle, medical-grade hydrocolloid adhesive and a flexible sensor pad that conforms to tight curvatures and small areas, like the forehead of tiny neonates. OxyAlert NIRSensors can be placed in up to four site-specific areas of the brain and body to reveal continuous, real-time perfusion data on tissues beneath the sensors.

The INVOS System can “speak” for these young patients by alerting surgical and care teams in real time when oxygen dips to threatening levels associated with kidney failure, brain damage, shock, neurologic damage, low cardiac output and seizures. When regional oxygen saturation (rSO_2) values drop, clinicians can intervene to lessen or prevent potentially life-changing or life ischemic complications.

While most traditional vital signs, lab draws and subjective assessments reflect systemic status or may be time-delayed, the clinically-proven INVOS System immediately detects site-specific changes in blood oxygenation in real time. In fact, INVOS System monitoring has been shown to be a better indicator of regional oxygenation issues than systemic vital signs.

The INVOS system technology has now been embraced at more than 700 US hospitals, including 80% of those centers performing pediatric cardiac surgeries to help keep the most fragile patients safe. I’m happy to provide you with more information on how the INVOS system technology is used (including images) or arrange a time for you to speak with doctors, who developed and beta tested the technology, as well as those who can discuss how the technology provides a greater level of control when operating on infants and neonates.

For more information, visit the website: www.Somanetics.com.

Discovery Labs Receives Notice of Allowance for Patent to Treat Infants at Risk of Developing Bronchopulmonary Dysplasia

(GLOBE NEWSWIRE) Discovery Laboratories, Inc. (Nasdaq:DSCO) announced that it has received a Notice of Allowance from the US Patent and Trademark Office (USPTO) for its US Patent Application Number 11/326,885 titled "Surfactant Treatment Regiment." The Notice of Allowance is the USPTO's official communication that the examination of the patent application has been successfully completed and that a patent will be issued. Once issued, the patent will provide broad coverage for methods of using pulmonary surfactant to treat infants at risk of developing bronchopulmonary dysplasia (BPD).

Robert Segal, MD, FACP, Senior Vice President and Chief Medical Officer of Discovery Labs and one of the inventors, commented, "We are very pleased with the USPTO's decision to grant the patent for-treatment of infants at risk of developing BPD. This patent provides additional intellectual property protection to our KL4 surfactant technology. We plan to continue strengthening our patent portfolio around KL4 surfactant to include treatment of a wide range of respiratory disorders."

Surfactants are produced naturally in the lungs and are essential for breathing. Discovery Labs' novel proprietary KL4 surfactant technology produces a synthetic, peptide-containing surfactant that is structurally similar to pulmonary surfactant and is being developed in liquid, aerosol or lyophilized formulations.

About BPD and Discovery Labs' Development Programs: BPD, also known as Chronic Lung Disease, affects premature infants and is associated with surfactant deficiency and the prolonged use of mechanical ventilation and oxygen supplementation. There are presently no approved drugs for the treatment of BPD. Infants diagnosed with BPD suffer from abnormal lung development and typically have a need for respiratory assistance, often for many months, as well as comprehensive continuing care potentially spanning years. It is estimated that the cost of treating an infant with BPD in the United States can approach $250,000 during the initial inpatient stay alone. Discovery Labs

estimates that approximately 100,000 infants are at risk for BPD in the United States and Europe each year.

BPD is diagnosed when premature infants require mechanical ventilation or supplemental oxygen at 36 weeks post-menstrual age. Premature babies are often born with a lack of natural lung surfactant and are unable to absorb sufficient oxygen, resulting in Respiratory Distress Syndrome (RDS). These infants often require endotracheal intubation to administer surfactant (usually within the first hours of birth), and to provide respiratory support via mechanical ventilation. Unfortunately, many infants relapse following initial therapy and require reintubation and prolonged mechanical ventilation as well as supplemental oxygen, which increase their risk of developing BPD.

Discovery Labs believes that treatment with KL4 surfactant after the initial RDS treatment (on day one or two of life) may prevent BPD and improve the clinical outcome of these infants. Discovery Labs conducted a Phase 2 clinical trial for Surfaxin(r) (its lead product from its KL4 surfactant pipeline in liquid instillate formulation) for the prevention and treatment of BPD. The results from the trial suggest that Surfaxin may potentially represent a novel therapeutic option for infants at risk for BPD. These results were published in Pediatrics in January 2009. Discovery Labs plans further development of KL4 surfactant for the prevention of BPD with Surfaxin LS(tm) (lyophilized formulation of KL4 surfactant) or Aerosurf(r) (aerosolized formulation of KL4 surfactant). For more information, visit the website at www.Discoverylabs.com.

Evidence Grows That Maternal Immune Response to Fetal Brain During Pregnancy a Key Factor in Some Autism

Newswise — New studies in pregnant mice using antibodies against fetal brains made by the mothers of autistic children show that immune cells can cross the placenta and trigger neurobehavioral changes similar to autism in the mouse pups.

A report on the research from investigators at the Johns Hopkins Children's Center published online in the *Journal of Neuroimmunology* expands on a 2008 report from the same team showing that mothers of autistic children tested positive for fetal brain antibodies. Antibodies are proteins the body naturally makes to attack foreign tissues, viruses or bacteria. Because a growing fetus is not "rejected" by the mother's immune system even though some of its DNA is "foreign" (from the father), scientists have long suspected that some combination of maternal and fetal biological protection is at work. The new research from Hopkins, however, suggests that the protective system is not perfect and that antibodies are not only made but are re-circulated back to the fetus through the placenta, possibly triggering inflammation in the brain and leading to a cascade of neurological changes resulting in neurodevelopmental disorders, such as autism.

Despite this new evidence, the researchers warn against over-interpreting the results, saying prenatal exposure to maternal antibodies is likely only one of several factors implicated in autism.

"Autism is a complex disorder and it would be naïve to assume there's a single mechanism that can cause it," says Harvey Singer, MD, Director of Pediatric Neurology at Hopkins Children's. "It's most likely the cumulative result of several factors, including genes, metabolism and environment. We believe we have identified one of these factors."

For the new study, Singer and colleagues injected antibodies from mothers of autistic children into pregnant mice and used several standard neurobehavioral tests to identify neurobehavioral changes in the pups. As control groups, they used offspring of mice injected with antibodies from mothers of nonautistic children and the offspring of mice who received no injections.

"Comparing mice to humans is tricky, and we should be cautious anytime we do so, but our findings strongly suggest that the behaviors we observed in the offspring of mice injected with fetal brain antibodies from human mothers did behave in a manner that mimics some behaviors seen in people with autism," Singer says.

Following the mice throughout adolescence (four to six weeks) and adulthood (four to six months), the Hopkins team measured novelty-seeking (or willingness to explore unfamiliar open spaces), response to loud noise, sociability and anxiety-like behavior.

Overall, mice exposed prenatally to antibodies from mothers of autistic children behaved more anxiously, spent less time in open spaces when placed in an elevated maze, and were overall more hyperactive, fretting back and forth between open and closed spaces in the maze and in an open field environment, both behaviors that in humans would equal abnormal activity.

Again, compared to control mice, the mice exposed to antibodies from mothers of autistic children were also more easily startled by loud noises and were less social, choosing to spend more time visiting an empty cage rather than one with a live mouse in it.

The differences among groups were less pronounced in the adolescent mice, but as the mice aged, researchers observed an increase in autism-like symptoms, a finding consistent with neurodevelopmental disorders in humans, who tend to develop new or more pronounced symptoms over time, investigators point out.

Comparing brain tissues from all groups of mice, researchers observed markedly more activation of microglia -- immune cells in the central nervous system activated during inflammation – in the brain tissues of the group injected prenatally with antibodies from mothers of autistic children.

In further studies, the Hopkins scientists hope to identify which specific brain proteins the antibodies affect and to correlate changes in brain anatomy and function to changes in behavior.

Ultimately, researchers hope to develop ways to detect and analyze culprit antibodies in pregnant women and prevent them from binding to fetal brain proteins.

The causes of autism, a disorder manifesting itself with a range of brain problems, impaired social interactions, communication disorders and repetitive behaviors, remain unknown for an estimated 90% of children diagnosed with it. Genetic, metabolic and environmental factors have been implicated in various studies of autism, which affects an estimated 1 in 150 US children, according to the Centers for Disease Control and Prevention.

Co-authors: Mikhail Pletnikov, MD, PhD, Christina Morris, Colin Gause, Matthew Pollard, all of Hopkins; and Andrew W. Zimmerman, MD, of the Center for Autism and Related Disorders at the Kennedy Krieger Institute.

The study was funded by the Hussman Foundation.

Iodine Deficient Prenatal Vitamins Put Infants At-Risk

Newswise — The American Thyroid Association has recommended that all pregnant and breastfeeding women in the US should take daily supplements containing 150 mcg iodine. However, a study conducted by researchers at Boston University Medical Center has found that only 51% of US prenatal multivitamins contain iodine.

"Normal thyroid function in fetuses and breast-fed infants, which is dependent on sufficient intake of iodine, is crucial for a child's normal neurocognitive development," said Elizabeth N. Pearce, MD, Assistant Professor of Medicine, in a research letter appearing in the February 26 issue of the *New England Journal of Medicine* (Vol. 360, No. 9).

According to the researchers, iodine deficiency affects more than 2.2 billion people worldwide and is the leading cause of preventable mental retardation. Over the last three decades, the iodine intake of U.S. women of childbearing age has decreased by more than half, and a subset of U.S. women of childbearing age may have mild iodine deficiency.

"Even mild iodine deficiency may have adverse effects on the cognitive function of children," said Dr. Pearce. "The measured iodine content of multivitamins with kelp as the iodine source was extremely variable, and often did not match labeled values," said Dr. Pearce. "Prenatal multivitamins containing potassium iodine were a more reliable source."

The iodine content of prenatal vitamins is not mandated in the US, noted the researchers, who suggest that manufacturers of prenatal vitamins in the U.S. should be encouraged to ensure that their products contain the amount of iodine recommended by the American Thyroid Association and to use only potassium iodine - which contains 76 percent iodine - to maintain consistency in iodine content.

Dr. Pearce discussed "Iodine in Pregnancy: Needs, Impact and Controversy" at the *American Thyroid Association's "Research Summit and Spring Symposium*," held in Washington, DC. April 16-17, 2009.

The American Thyroid Association (ATA) is the lead organization in promoting thyroid health and understanding thyroid biology. The ATA values scientific inquiry, clinical excellence, public service, education, collaboration, and collegiality. ATA members are physicians and scientists who work to enhance the understanding of thyroid physiology and pathophysiology, improve diagnosis and treatment of thyroid diseases, and promote the education of physicians, patients, and the public about thyroid cancer. Thyroid diseases are the most common disorders of the endocrine system, affecting almost 13 million Americans.

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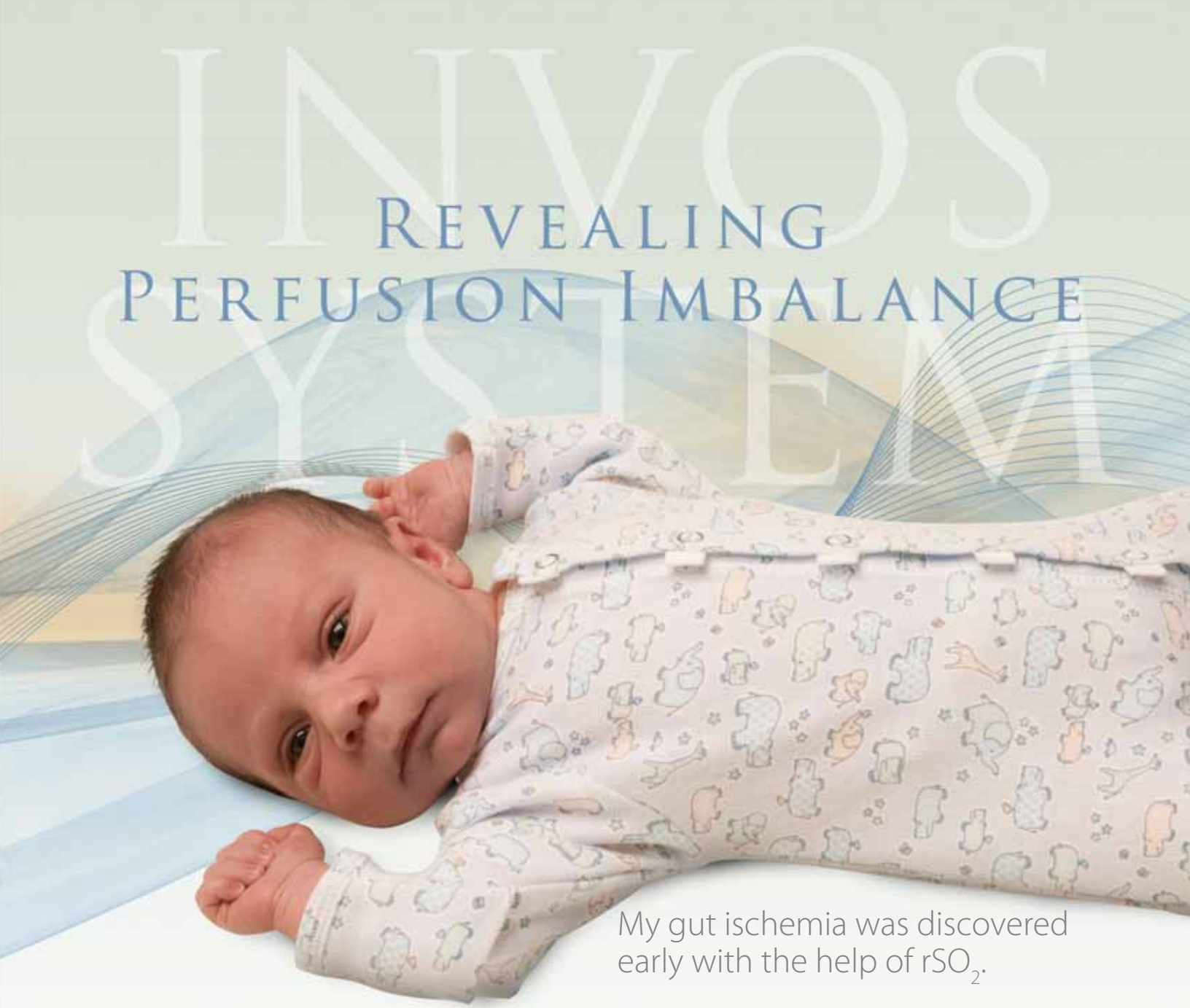

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