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News and Information for BC/BE Neonatologists and Perinatologists

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IN THIS ISSUE

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Case Resolved in the Virtual NICU at 99nicu.org

By Stefan Johansson, MD, PhD and Yuriy Korzhynskyy, MD

A 25-day old female infant was admitted from home to the Neonatal Intensive Care Unit, due to generalized edema, breathing difficulties, low urine output, irritability and elevated body temperature (38,2 ˚C).

The infant was the first child to healthy parents. The pregnancy had been normal and she was delivered by a Caesarean section at 42 gestational weeks due to a abnormal presentation (transverse position). The infant was born small-for-gestational-age (birth weight 2300 g, birth length 44 cm, head circumference 34 cm) of unclear etiology. Apgar scores were 8-9-9. The perinatal period was uneventful and the infant was discharged fully breast fed from the maternity unit on the 6th postnatal day.

The female infant had been well until the day before admission, when she became "anxious" and "swollen." History revealed preceding symptoms, no infections in the family and no hereditary diseases.

On clinical examination, the infant was irritable and tachycardic (190/min), and with generalized edema. Breathing frequence was elevated (62/min) and breathing was heavy. The abdomen was distended and the liver was palpable 2 cm below the costal margin. No other clinical signs were found.

On admission, blood tests showed anemia, neutropenia, and hyponatremia (Table 1).

Table 1. Blood and Urine Analyses During Admission

Day of hospitalization	1	10	15	21	47
Hemoglobin (g/l)	103	91		79	90
White blood cells (10^9/l)	6.5	8	4.3	4.3	5.6
- neutrophils (%)	26	2	4	5	4
- lymphocytes (%)	70	92	82	88	87
Trombocyte count (10^9/l)	128			195	
Sedimentation rate (mm/h)	23	24	22	41	10
S-sodium	126				146
S-potassium	4.1	4			
S-urea	3.9		2.7		
Total serum protein (g/l)	45	55.9	45.3	55.4	50.8
Urine protein (g/l)	0.099	3.3	3.3	0.66	0.165

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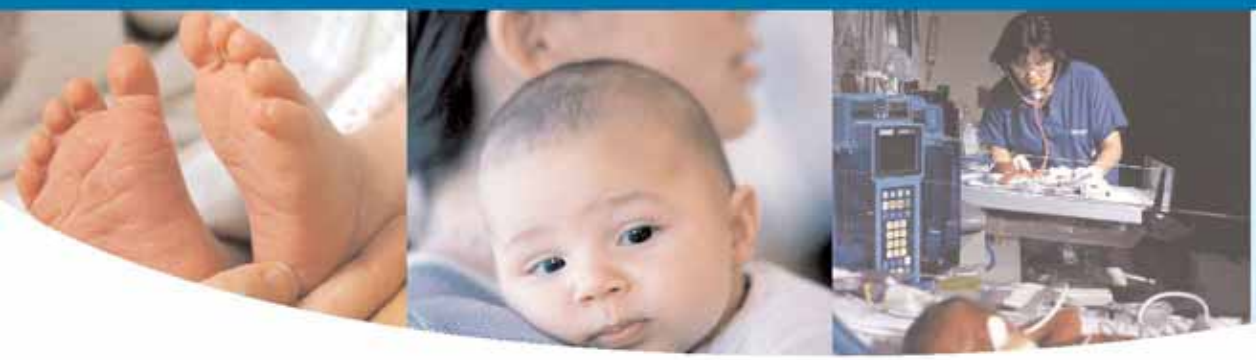

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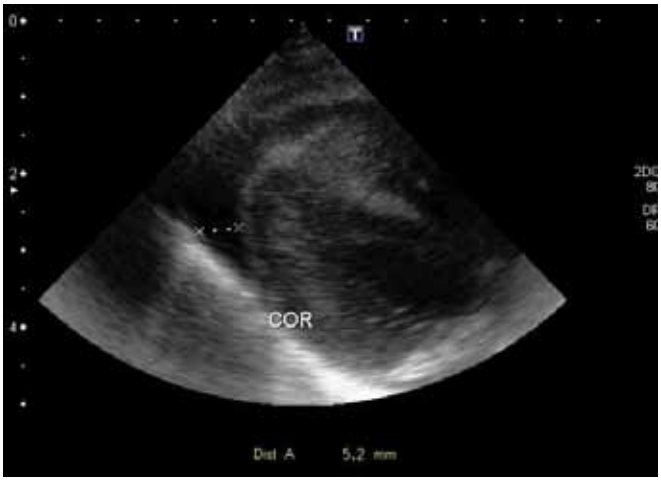

Infant with fascial edema and pericardical effusion.

99nicu.org

The Internet community for professionals in Neonatal Medicine

The Internet is at its best when it comes to making people meet and talk. I and colleagues thought that neonatal staff should have their own web community. In May 2006, we officially opened 99nicu*. Today, there are more than 1800 international members.

The main features of 99nicu are the Discussion Forums, the Image Library, the Message Board, and the Scientific Library with a collection of neonatal abstracts. There's also a virtual NICU, where members can "admit" unresolved cases, and get help from other members. The Ukrainian case presented in this article was diagnosed in the Virtual NICU.

Membership is needed for full access to all features. Registration is free.

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** "99nicu" means that our community is almost, but not entirely devoted to Neonatal Medicine (i.e. 99%). Only members have access to the Lounge.*

Urine analyses was positive for proteinuria. The infant was extensively investigated. Chest x-ray showed cardiomegaly, a pericardial effusion was found on echocardiography, and renal ultrasound revealed bilateral hydronephrosis. Blood culture was negative, as were serologies for hepatitis B and C, syphilis, toxoplasmosis and CMV. The infant had a normal karyotype, 46 XX.

The preliminary clinical diagnosis was Nephrotic Syndrome, and supportive treatment was initiated with albumin, enalapril and digoxin.

Since the etiology of the Nephrotic Syndrome was unclear, the infant was "admitted" to the virtual NICU at 99nicu.org, a large international Internet community for health professionals in Neonatal Medicine. Advice from one member suggested that infection with cytomegalovirus (CMV) may explain the combination of clinical signs and symptoms. This member also pointed out that a negative serology for CMV does not exclude a perinatal infection at this age. Re-testing for CMV was performed with PCR, and the patient was found to positive for CMV in blood. The final diagnosis was therefore, considered to be Congenital Nephrotic Syndrome secondary to perinatal CMV infection.

With supportive treatment, the infant got better. Proteinuria decreased, water balance stabilized, lung function improved and hydronephrosis disappeared. She started to breastfeed, and gained weight normally after three weeks. She was discharged seven weeks after admission,

and is now being followed in the outpatient clinic. Clinically, the infant is doing very well, but a low-grade proteinuria is still present. Therefore, she is still treated with enalapril.

URL to review the case on 99nicu.org: http://www.99nicu.org/forum/showthread.php?t=9334

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MEETINGS & SYMPOSIA

8th National Neonatal Nurses Meeting
Washington, DC USA
October 9-11, 2008
www.neonatalnetwork.com

AAP National Conference & Exposition
October 11-14, 2008
Boston, MA USA
www.aap.org/nce

24th Annual Fetus and Newborn Conference State-of-the-Art Care
October 22-25, 2008
La Jolla, CA USA
www.contemporaryforums.com/brochure.asp

Management of Congenital Heart Disease in the Fetus and Neonate
October 25, 2008
Washington, DC USA
www.childrensnational.org

Contemporary Management of Neonatal Pulmonary Disorders Conference
October 30-31, 2008
Tempe, AZ USA
www.nalweb.com/cmnpdconference

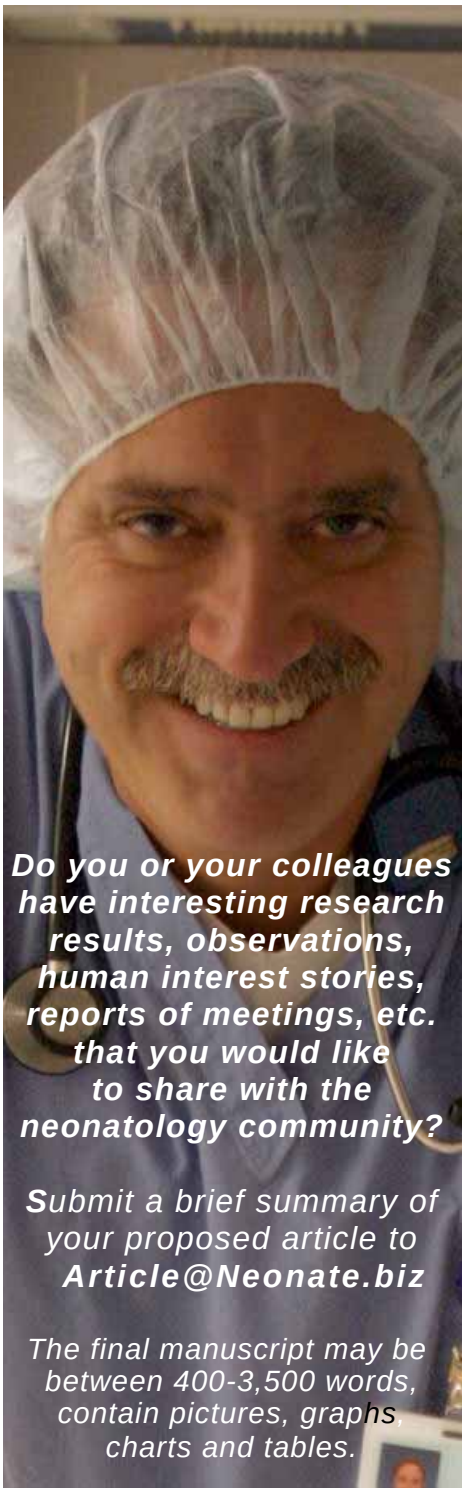
1st International Congress of UENPS (Union of European Neonatal and Perinatal Societies)- Global Neonatology & Perinatology
November 17-19, 2008
Rome, Italy
www.uenps2008.eu

Jeddah Neo 2008
November 17-19, 2008
Jeddah, Saudi Arabia
www.ngha.med.sa

Neonatology Update 2008 - *The Science of Newborn Care*
November 24-28, 2008
London, UK
www.symposia.org.uk/neonatal/

Hot Topics in Neonatology Conference
December 7-9, 2008
Washington, DC USA
www.hottopics.org

The Conference for Neonatology
February 26 - March 1, 2009
Lake Buena Vista, FL USA
www.neoconference.com



Neonatology Today's First Annual Salary Survey: How Do You Stack-up?

A Salary Survey Questionnaire was published in the February through April issues of *Neonatology Today*. This was the first in a series of annual surveys on salaries in neonatology. Those who wished to participate were instructed to fax back their completed questionnaires.

One hundred and thirty-five viable surveys were used in the tabulation of the results. The returned surveys came from across the US. While the number of responses is not sufficient to make scientific projections to the total universe of US or International neonatologists, or to break down by geographic regions, still, the results anecdotally reveal information about the ranges of salaries, bonuses, number of vacation weeks, etc., Furthermore, the results can be used as a guide for current salary levels, and act as a benchmark for future studies. Next year, *Neonatology Today* will make the survey available on the web, for ease-of-use use by all its readers.

This article is an executive summary of the Salary Survey results.

Length of Time Since Obtaining Fellowship and Length of Time at Current Employer

The survey found that of those responding, the highest number of years since obtaining a fellowship was thirty years, and the lowest number of years was two. The average among all respondents was just over thirteen years.

Number of Years Since Obtaining Fellowship?		
Average Number of Years Reported	**Most Number of Years Reported**	**Least Number of Years Reported**
13.4	30	2

The average number of years at the current employer was higher than expected (8.7 years), with the longest length of stay reported at 30 years. The shortest length of time was one year.

Number of Years at Current Place of Employment		
Average Number of Years Reported	**Most Number of Years Reported**	**Least Number of Years Reported**
8.7	30	1

Board Certification Status

In this survey, over 80% of the respondents were Board Certified, while slightly over 15% practicing in the field, were not. Just over 2% were in the processing of obtaining their certification.

Board Certified in Neonatology		
Yes %	**No %**	**In the Process of Getting Certified %**
82.2%	15.6%	2.2%

Compensation and Retirement

Salaries reported ran the gamut, and were based on number of years in the field. The highest salary reported was $700.000, while the lowest was $35,000. It should be noted, however, that the doctor reporting the $35,000 salary has a total compensation package (salary and bonus) of $110,000. The average salary for a neonatologist in this survey was just under $259,000.

Compensation, Base Salary		
Average Salary $	**Highest Reported $**	**Lowest Reported $**
$258,818	$700,000	$35,000

Most physicians have a bonus plan as part of their compensation package, in addition to a salary. Like salaries, there was a wide range reported, with the highest reported bonus of $120,000, and the lowest at $5,000. The average bonus was just over $38,500.

Compensation, Bonus		
Average $	**Highest Reported $**	**Lowest Reported $**
$38,571	$120,000	$5,000

When salary and bonus were included, the total compensation for Neonatologists was $110,000 at the low end, and $750,000 at the high end of the spectrum, with an average compensation package of slightly over $285,000.

Total Compensation		
Average $	**Highest Reported $**	**Lowest Reported $**
$285,263	$750,000	$110,000

Places of employment offered a variety of retirement plans, most plans (62.2%) offered were 401Ks. The survey did not go into questions such as, if the employer did any type of matching. However, there was a substantial number of respondents, almost a third, who checked off, "Other." In this survey, "Other" was not defined. In future surveys, the questions on retirement programs will be expanded.

Types of Retirement Plan Through Place of Employment			
401K %	**403B %**	**Other (not defined) %**	**None %**
62.2%	6.7%	28.9%	2.2%

Clinical vs. Academic

As expected most of those responding to the survey were employed in a clinical setting (80%), with almost 16% in an academic environment. Just over 4% did not report their affiliation.

Positions Held		
Academic %	**Clinical %**	**No Response %**
15.6%	80.0%	4.4%

Benefits: Healthcare and Vacation

When it came to the number of vacation weeks, the average neonatologist reported receiving 6.6 weeks of vacation. On careful scrutiny, this was dependent on how long a doctor had been at his place of employment. Those physicians just starting, received as low as two weeks, while some of the more senior neonatologists had as many as eight weeks vacation time.

Number of Vacation Weeks / Year			
Average Number of Weeks Reported	**High Number of Weeks Reported**	**Low Number of Weeks Reported**	**No Response %**
6.6	8.0	2.0	2.2%

All physicians reported receiving healthcare, and some sort of dental care insurance benefits, and over 90% reported also receiving vision care through their employer.

In this day-and-age, it was surprising to see that almost two-thirds of the respondents reported that their healthcare insurance benefits were fully-paid by their employers. Slightly more than a third of those responding to this survey, reported that their employer partially paid for healthcare benefits. It will be interesting to see if in future surveys, there is a trend for employers to move more of the medical insurance cost to the employee.

Type of Healthcare Benefits Received		
Healthcare %	**Dental %**	**Vision %**
100%	100%	93.3%

Healthcare	
Fully Paid by Employer %	**Partially Paid by Employer %**
64.4%	35.6%

CME Allowance

All those responding had a CME allowance from their employers, although the amount varied greatly. On the low end, CME allotment was $1,500, while on the higher end of the scale, the allotment was $10,000. The average was $3,690.

Of Those Getting a CME Allowance - How Much $		
Average CME Allowance Reported $	**High CME Allowance Reported $**	**Low CME Allowance Reported $**
$3,690	$10,000	$1,500

Summary

While the results of the survey are not projectable to the entire universe, it does, as noted in the beginning of this article, offer a look into compensation and benefits in the field. Through future surveys, Neonatology Today hopes to provide solid information to its readers. Watch for the 2009 Annual Salary Survey early next year.

"...the total compensation for Neonatologists was $110,000 at the low end, and $750,000 at the high end of the spectrum, with an average compensation package of $285,263."

What types of questions would you like to see added to the 2009 survey? Send your comments and suggestions to Survey2009@Neonate.biz.

Research Department
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NT

Medical News, Products and Information

Researcher Helping to Pioneer Medical Therapy for Fragile X Syndrome Presented Latest Findings at 11th International Fragile X Conference

(CHICAGO) - Neurological experts from across the US and other countries, including a nationally renowned researcher from Rush University Medical Center, discussed the latest findings in basic and clinical research for Fragile X at the 11th International Fragile X Conference, that was held July 23-27 in St. Louis, MO. Families with children who were diagnosed with Fragile X also attended the conference.

Fragile X, an X-chromosome-linked condition, is the most common inherited cause of mental retardation, and the most common known cause of autism or autistic-like behaviors.

Rush's Dr. Elizabeth Berry-Kravis, led a number of discussions at the conference, including a plenary session on promising new treatments and clinical sessions on stem cell research, seizures and psychopharmacology. In addition, she presented research on the use of lithium to target the underlying defect in Fragile X Syndrome.

Dr. Berry-Kravis runs the only Fragile X clinic in Chicago, and one of the few in the Midwest. Her research program also includes studies of Fragile X-associated Tremor/Ataxia Syndrome (FXTAS), a degenerative neurological condition which occurs in Fragile X mutation carriers. She presented research on development of new methods for evaluating risk for FXTAS using a state-of-the-art imaging technique called diffusion tensor imaging.

Some of the scientific sessions led by Dr. Berry-Kravis included:

- New Treatments on the Near Horizon,
- Seizure Disorders
- Five Current Topics of Interest in Psychopharmacology of FXS
- FXTAS (Fragile X-Associated Tremor/Ataxia Syndrome)
- Diffusion Tensor Imaging in Male FMR1 Premutation Carriers With and Without FXTAS
- Fragile X Syndrome (FXS)
- Vocabulary Comprehension in FXS
- ERK Activation Kinetics as a Biomarker for Metabolic Status in FXS
- A Conversation with the Experts: Drug Trials and Adults with Developmental Disabilities - Ethical Issues and Informed Consent
- Stem Cell Research and Its Implications for Fragile X Research and Treatment,
- Plus others….

The Fragile X clinic at Rush was started in 1991 to serve the unique needs of the Fragile X population. The clinic maintains affiliations with specialists in pediatrics, neurology, genetics, optometry, child psychology, special education/education psychology, speech and language, occupational therapy and dentistry who have experience working with individuals with Fragile X Syndrome.

Prenatal Drinking, Environmental Enrichment: Effects on Neurotrophins are Independent of Each Other

Prenatal alcohol exposure may be particularly destructive for neurotrophins, a family of peptides that influence the growth, development and functional plasticity of the fetal brain. A new rodent study of alcohol's effects on three key neurotrophins has found that, even though environmental enrichment may be able to improve some fetal-alcohol effects, those benefits do not appear to be mediated by neurotrophins.

Results will be published in the October issue of *Alcoholism: Clinical & Experimental Research,* and are currently available at Early View.

"Neurotrophins are produced in the nervous system, and are critical for normal development of the brain," explained Robert F. Berman, a Professor in the Department of Neurological Surgery and at the Center for Neuroscience at the University of California – Davis, as well as corresponding author for the study.

"Neurotrophins also play important roles in learning and memory, and contribute to the repair of the brain following injury or stress. We chose to examine three – nerve growth factor (NGF), neurotrophin-3 (NT-3), and brain-derived neurotrophic factor (BDNF) – because previous research had shown that prenatal alcohol exposure alters their levels in the brain, and that treatment of other types of brain injury with NGF or BDNF can be beneficial."

Researchers divided 22 pregnant Sprague-Dawley rats into four groups: Zero (receiving 0 g of alcohol), Low (4 g/kg/day), High (6 g/kg/day) and Naïve (untreated pregnant rats). The two alcohol groups were given alcohol on gestational days eight to 20. After weaning on postnatal day 21, the 228 offspring were housed for six weeks in one of three conditions: Isolated, Social or Enriched. Levels of NGF, NT-3 and BDNF were then measured in the offsprings' frontal cortex, occipital cortex, hippocampus, and cerebellar vermis.

"We found that prenatal alcohol exposure generally increased brain neurotrophin levels in adult rats," said Berman. "This suggests that neurotrophin levels increased as compensation for damage to the developing brain from prenatal alcohol exposure. Results also demonstrated that the effects of prenatal alcohol exposure can be enduring and last into adulthood."

Previous rodent research, conducted by Berman, had shown that rearing rats in an enriched environment following prenatal alcohol exposure improved their motor function, as well as learning and memory. "In this study, we found that being raised in an enriched environment, with ample opportunities for motor and sensory stimulation, and social interactions, unexpectedly resulted in reduced levels of neurotrophins in some areas of the cortex, but not in other areas which are well-known to be affected by prenatal alcohol exposure," he said.

When both sets of findings are considered together, he added, they indicate that the effects of prenatal alcohol exposure and environmental rearing conditions on neurotrophin levels are largely independent, with

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little evidence that one directly influenced the other's effects on neurotrophin levels. "In other words," he said, "our results did not support our hypothesis that the beneficial effects of early environmental enrichment in rats exposed prenatally to alcohol were mediated directly by the three neurotrophins we examined in four specific brain areas."

This means that the molecular and cellular mechanisms underlying environmental enrichment effects after prenatal alcohol exposure are still not understood, said Berman. "While the importance of the postnatal rearing environment for brain development is clear, we need additional research to aid in devising rational treatment strategies for Fetal Alcohol Spectrum Disorders, including Fetal Alcohol Syndrome," he said.

Alcoholism: Clinical & Experimental Research (ACER) is the official journal of the Research Society on Alcoholism and the International Society for Biomedical Research on Alcoholism. Co-authors of the ACER paper, "Environmental Enrichment Alters Neurotrophin Levels after Fetal Alcohol Exposure in Rats," were: Elizabeth A. Parks of the Neuroscience Program and Department of Neurological Surgery at the University of California - Davis; and Andrew P. McMechan and John H. Hannigan of the Department of Obstetrics & Gynecology and the C.S. Mott Center for Human Growth and Development in the School of Medicine, and the Department of Psychology at Wayne State University. The study was funded by the National Institutes of Health/ National Institute on Alcohol Abuse and Alcoholism.

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Large Study Identifies Most Costly Adverse Events in Children's Hospitals May Help Set Priority Targets for Patient Safety Efforts

A large study of health records from 38 American children's hospitals has measured adverse events that most increase length of stay and overall cost. The researchers say their findings provide useful targets for hospital programs aimed at preventing harm to young patients.

"Our study offers a framework for physicians, researchers and administrators to think about pediatric-specific adverse events that are potentially preventable," said study leader Samir S. Shah, MD, an Infectious Diseases Specialist at The Children's Hospital of Philadelphia. "Among the areas in which children's hospitals can address quality improvement, it is important to set priorities. This study provides some guidance."

In a study in the June issue of *Pediatrics,* the researchers analyzed information from more than 430,000 discharges from 38 pediatric hospitals in the United States that participated in the Pediatric Health Information Systems database in 2006. They searched the database for 12 different adverse patient safety events, designated pediatric-specific quality indicators (PDIs) by the federal Agency for Healthcare Research and Quality (AHRQ). The adverse events included infections and other complications that occurred as unintended consequences of treatment and hospitalization.

"Our study was the first to use this pediatric-specific tool to screen for adverse events," said co-author Matthew Kronman, MD, a hospital-based specialist in infectious diseases at Children's Hospital.

"AHRQ had previously developed patient-safety indicators for adult patients, but some of those adverse events in adults, such as hip fractures after a fall in the hospital, were uncommon in children. Our findings suggest that the pediatric safety indicators reflect a better understanding of the situation of children."

The total number of adverse events was 6,656, or approximately 1.5% of the sample. Overall, the most frequent adverse events in hospitalized children were infection due to medical care, respiratory failure following surgery and postoperative sepsis (an infection in the bloodstream).

The excess length of hospital stay from PDI events ranged from 2.8 days for accidental puncture and laceration to 23.5 days for postoperative sepsis. Excess overall charges ranged from $34,884 for accidental puncture and laceration to $337,226 for in-hospital mortality after pediatric heart surgery. Among excess charges, the largest were for laboratory, room and nursing charges. The researchers adjusted charges to reflect geographical differences in prices and wages.

"Our findings may help guide physicians and hospital administrators toward changes in practices where even modest improvements could have a high impact in patient safety and in more efficient, less costly health care," said Shah. "For instance, focusing quality improvement efforts on reducing postoperative sepsis and infection due to medical care could create large cost savings and reduction in length of hospitalization. Additional studies should focus on determining specific safety measures and practices that pediatric hospitals can implement in the most appropriate areas."

Shah added that such quality improvement programs are all the more important in light of a recent decision by the federal Centers for Medicare and Medicaid Services to begin denying payments to hospitals for patients who develop preventable complications during hospitalization.

Shah's and Kronman's co-authors were Anthony D. Slonim, MD, PhD, of Carilion Clinic Children's Hospital, Roanoke, VA; and Matthew Hall, PhD, of the Child Health Corporation of America, Shawnee Mission, KS.

NIH Study Reveals Factors That Influence Premature Infant Survival and Disability

Based on observations of more than 4,000 infants, researchers in an NIH newborn research network have identified several factors that influence an extremely low birth weight infant's chances for survival and disability. The findings offer new information to physicians and families considering the most appropriate treatment options for this category of infants.

The study authors referred to the issue of providing intensive care for extremely low birth weight infants. For example, physicians and family members may be reluctant to expose an infant to painful life support procedures if the infant is unlikely to survive. In such cases, they may opt for "comfort care," which provides for an infant's basic needs, but foregoes painful medical procedures. In deciding the kind of care to provide, specialists at intensive care facilities traditionally have relied heavily on an infant's gestational age—the week of pregnancy a premature infant is born. Gestational age is known to play a large role in the infant's survival. For this reason, in many facilities, intensive care is likely to be routinely given to infants born in the 25th week of pregnancy, whereas infants born in the 22nd week may be more likely to receive comfort care.

The study authors noted, however, that it is often difficult to assess gestational age. Moreover, an estimate that is inaccurate by only a week could result in an infant receiving care that was not appropriate for his or her individual case. To identify other factors that influenced survival and disability risk, the study authors observed more than 4,000 extremely low birth weight infants in their network.

The researchers published their findings in the April 17 *New England Journal of Medicine*. In addition to gestational age, factors influencing survival and risk of disability consisted of: whether the baby is male or female (sex); birthweight; whether the baby was a single baby, or one of two or more infants born; and whether the baby's mother was given medication during pregnancy to prompt the development of the baby's lungs. Known as antenatal steroids, these drugs

are typically given to women in premature labor, or who are at known risk for giving birth prematurely.

Physicians may access an online tool that generates statistics, based on the factors the researchers listed in their article, at www.nichd.nih.gov/about/org/cdbpm/pp/prog_epbo/. By specifying the baby's sex, weight, and information related to each of the variables listed above, physicians and family members can generate composite statistics on infant outcomes, based on the experiences of extremely low birthweight infants in the NICHD Neonatal Research Network study. The Web tool is not a substitute for a physician's careful assessment, but physicians and families may find the statistics it generates useful when considering the most appropriate care to provide an infant.

"Every individual is different, and no single tool can precisely predict a given baby's chances of survival or disability," said Duane Alexander, MD, Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the NIH Institute that supports the Neonatal Research Network. "However, the researchers' findings, and the tool they developed, provide important information that physicians and family members can consult to help them make the most informed treatment decisions possible."

The researchers were led by Jon E. Tyson, MD, of the University of Texas Medical School at Houston. Other authors of the study were Nehal A. Parikh, DO, and Charles Green, PhD., also of the University of Texas Medical School at Houston; John Langer, MS, of the Research Triangle Institute, Research Triangle Park, NC, and Rosemary Higgins, MD, the Program Scientist for the NICHD Neonatal Research Network.

The study involved only infants born at level III neonatal intensive care facilities. For this reason, the study findings may not apply to infants born at level I and II facilities.

To conduct their analysis, researchers in the NICHD Neonatal Research Network observed 4,446 infants born at 22-25 weeks' gestational age at hospitals around the United States, explained the NICHD co-author of the study, Rosemary Higgins, MD. Dr. Higgins said that extremely low birthweight infants (those weighing less than 1,000 grams, or 2.2 pounds) make up about 1% of babies born in the US each year, or roughly 40,000 babies a year.

Using standardized measures of mental development, vision, and hearing, the researchers assessed the health status of surviving infants when the infants were from 18 to 22 months corrected age—the age they would have been, had they been born full term. Dr. Higgins said that 49% of the infants in the study had died, 21% lived and did not have a disability, while the remainder experienced some degree of disability.

After conducting mathematical analyses of all the infants' cases, the researchers determined that infants were more likely to survive—and more likely to survive without disability—if they were of older gestational age, their mothers had been given corticosteroids, if they were female, were single born rather than part of a multiple birth, and been of a higher birthweight.

"Many neonatal intensive care units base treatment decisions mainly on gestational age," said Dr. Higgins. "We found that it's much more accurate if the assessment is based on the combination of 5 factors, rather than just on gestational age."

Dr. Higgins added that it is often difficult to accurately estimate gestational age, and a preterm infant may be as much as a week or two younger, or older, than believed.

She noted that the researchers found that race appeared to play no role in subsequent survival or chances of disability.

She stressed that the study data could not be used to predict with certainty the outcome of individual cases.

"A lot of medicine is a judgment call," Dr. Higgins said. "We provided our data in the hope that it would be helpful for making the best judgments for a particular situation."

A video interview with Dr. Higgins in which she provides additional information about the study and the online tool, is available at www.nichd.nih.gov/news/resources/links/neonatal/.

Clinical Trials

The neonatal clinical trials presented here were taken from ClinicalTrials.gov, a service of the US National Institutes of Health. ClinicalTrials.gov offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions.

For up-to-date and additional information on the trials presented here, and others, please visit: ClinicalTrials.gov

ClinicalTrials.gov currently contains 60,492 trials sponsored by the National Institutes of Health, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 States and in 157 countries.

ClinicalTrials.gov receives over 40 million page views per month 50,000 visitors daily.

Genomics, Single Nucleotide Polymorphisms (SNPs) and Clinical Neonatology

Currently recruiting participants.

Sponsors and Collaborators: Children's Mercy Hospital, Kansas City, University of Kansas

Purpose: This research seeks to establish a neonatal DNA Tissue Bank to find out if differences in small segments of DNA predispose babies to Chronic Lung Disease (CLD), Periventricular Brain Injury (PVI), Necrotizing Enterocolitis (NEC), or Hypoxic Respiratory Failure (HRF).

Condition: Lung Disease; Brain Injury;Necrotizing Enterocolitis; Respiratory Failure

Study Type: Observational

Study Design: Case Control, Prospective

Estimated Enrollment: 450

Study Start Date: April 2006

Estimated Study Completion Date: April 2009

Detailed Description: This genetic predisposition study does not involve investigational drugs, devices, or treatments. Our broad goal is to identify genomic factors, which contribute to the development or exacerbation of common and critical illnesses that affect preterm and near-term infants. We seek to accomplish this goal in the following ways:

- First: to test candidate gene DNA variations and link already identified single nucleotide polymorphisms (SNPs) producing functional alterations to the risk of clinically important disorders.
- Second: to utilize a whole-genomic approach to identify SNPs not previously linked to the risk of development or progression of neonatal disorders.

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Sampling Method: Non-Probability Sample

Study Population: Intensive Care Nursery

Inclusion Criteria: Less than 34 weeks gestation and less than 1500 grams at birth; Greater than or equal to 36 weeks gestation and either with hypoxic respiratory failure or with mild respiratory distress never requiring assisted ventilation

Exclusion Criteria: Life-threatening anomalies of any organ system (e.g., cardiac, thoracic, lethal, or non-lethal chromosomal abnormalities)

Contacts and Locations:
Children's Mercy Hospitals and Clinics, Kansas City, MO, USA 64108; Contacts: William E Truog, MD (Principal Investigator); 816-234-3592; wtruog@cmh.edu; Michael Norberg, BS, MDiv 816-235-1981; mnorberg@cmh.edu

Study ID Numbers: 01.3965
First Received: April 14, 2006
Last Updated: April 9, 2008
ClinicalTrials.gov Identifier: NCT00315263
Health Authority: United States: Institutional Review Board

Face Anthropometric Pattern Recognition Technology for Computer Aided Diagnosis of Human Genetic Disorders

Currently recruiting participants.

Sponsors and Collaborators: Carmel Medical Center; Soroka University Medical Center; Technion, Israel Institute of Technology
Purpose: The hypothesis to be tested: After the construction of a database of anthropometric measurements, the system would extract important features of a given facial surface and be able to match it with existing morphometric figures. A given combination of normal and abnormal measurements will open a "probable diagno-

sis" and a list of "differential diagnosis" that will be expressed as percent of matching in a descendent order to the examiner.

Condition: Genetic Disorders

Study Type: Observational

Study Design: Cohort, Prospective

Primary Outcome Measures: To create the bases for a "normal patterns" database [Time Frame: unknown] [Designated as safety issue: No]

Estimated Enrollment: 800

Study Start Date: November 2007

Estimated Study Completion Date: November 2010

Estimated Primary Completion Date: November 2008 (Final data collection date for primary outcome measure)

Groups/Cohorts: 1 - Normal Male; 2 - Normal Female

Ages Eligible for Study: up to 2 Weeks

Genders Eligible for Study: Both

Accepts Healthy Volunteers: Yes

Sampling Method: Non-Probability Sample

Study Population: Newborn infants born at Carmel Medical Center or at Soroka Medical Center

Inclusion Criteria: all newborn infants born at the Carmel Medical Center following parental consent, and at Soroka Medical Center.

Exclusion Criteria: No parental consent; Facial deformation not related to chromosomal or genetic anomalies; babies transferred to the neonatal intensive care unit that need ventilatory support.

Contacts and Locations:
Israel - Dept. of Neonatology, Carmel Medical Center Recruiting; Haifa, Israel; Contact: Dan Waisman, MD (principal investigator) +972506265525; dwaisman@netvision.net.il; Contact: Tali Ben Ari, MsN; +972523653302; tali.ibclc@gmail.com;

Irena Kessel, MD (Sub-Investigator); Dept of Neonatology, Soroka Univ. Medical Center; Beer Sheva, Israel; Daniela Landau, MD (principal investigator); +972544874910; danielala@clalit.org.il

Study ID Numbers: DW6/2007
First Received: June 19, 2008
Last Updated: June 24, 2008
ClinicalTrials.gov Identifier: NCT00705055
Health Authority: Israel: Ministry of Health

Continuous Monitoring of the Lungs Ventilation Dynamics During Mechanical Ventilation

Currently recruiting participants.

Sponsors and Collaborators: Carmel Medical Center
Technion, Israel Institute of Technology

Purpose: Patients that suffer from respiratory failure and need mechanical ventilation are at risk of further life threatening deterioration following the development of mechanical problems related to airway management, development of lung barotrauma or displacement of the endotracheal tube. Therefore there is a need to improve the safety of mechanical ventilation by earlier detection of deterioration and by prevention of complications. This will decrease morbidity, mortality, duration of hospitalization and the huge cost.

A technology for improving the safety of ventilation is required for patients in Adult and Pediatric intensive care units, in emergency medicine, during prolonged surgery, and for chronic ventilated patients in Chronic Respiratory Care Units and Intermediate Care Units.

Condition: Mechanical Ventilation

Study Type: Observational

Study Design: Case Control, Prospective

Primary Outcome Measures: Feasibility study to create a databank for assessing the changes in lung dynamics at various clinical settings by the chest motion sensors. [Time Frame: unknown] [Designated as safety issue: No]

Secondary Outcome Measures: Detection of changes in lung ventilation. [Time Frame: unknown] [Designated as safety issue: No]

Estimated Enrollment: 100

Study Start Date: December 2007

Estimated Study Completion Date: November 2010

Estimated Primary Completion Date: November 2008 (Final data collection date for primary outcome measure)

Groups/Cohorts: 1 - Premature and term newborn infants (male/female)

Ages Eligible for Study: up to 3 Months

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Sampling Method: Probability Sample

Study Population: Premature ventilated babies from the day after birth, born after 27 weeks and over 750 grams.

Inclusion Criteria: Ventilated babies from the day after birth

Exclusion Criteria: Parental refusal to be included in the study; Premature babies under 750 grams birth weight; Prematurity below 27 weeks gestation; Severe edematous babies (Hydrops fetalis); Severe Hypoxic Ischemic Encephalopathy, initial brain injury or severe intracranial bleeding or major congenital anomalies

Contacts and Locations:
Israel - Dept. of Neonatology, Carmel Medical Center; Haifa, Israel; Contact: Dan Waisman, MD (Principal Investigator); 972-5-0626-5525; dwaisman@netvision.net.il; Irena Kessel, MD

(Sub-Investigator); Avi Rothchild, MD (Sub-Investigator); Carmit Levy, PhD (Sub-Investigator); Amir Landesberg, MD, DSc (Sub-Investigator)

Study ID Numbers: Neo- 01/2006
First Received: June 19, 2008
Last Updated: June 19, 2008
ClinicalTrials.gov Identifier: NCT00702169
Health Authority: Israel: Ministry of Health

Preterm Infants' Weight Gain Following Massage Therapy

Currently recruiting participants.

Sponsored by: National Center for Complementary and Alternative Medicine (NCCAM)

Purpose: The specific aims of this study are: 1) to replicate the data that following ten days of massage therapy, preterm infants show greater daily weight gain and are discharged from the hospital earlier than the controls, thus demonstrating the cost-effectiveness of the intervention; 2) to test a model on two potential underlying mechanisms for weight gain including a) enhanced vagal activity leading to greater gastric motility, higher levels of insulin, IGF-1, and oxytocin and lower cortisol levels in the massage versus the control infants at the end of the study; and/or b) increased physical activity and its associated increase in heart rate oxygen consumption and temperature leading to greater weight gain. These pathways (vagal activity and physical activity) will be tested by path analyses. Determining underlying mechanisms for the massage therapy/weight gain relationship is a critical process required by the neonatology community for massage therapy to be adopted as a standard neonatal intensive care unit.

Condition: Premature Birth

Intervention: Procedure: massage

Procedure: Sham massage

Phase: Phase III

Study Type: Interventional

Study Design: Treatment, Randomized, Single Blind (Subject), Placebo Control, Factorial Assignment, Efficacy Study

Primary Outcome Measures: weight gain [Time Frame: post-massage] [Designated as safety issue: No]

Estimated Enrollment: 120

Study Start Date: April 2003

Estimated Study Completion Date: March 2010

Estimated Primary Completion Date: March 2010 (Final data collection date for primary outcome measure)

Detailed Description: A number of studies have documented an average of 47% greater weight gain in preterm neonates following massage therapy. Our currently funded study suggests that massage therapy increases vagal activity, oxytocin, and IGF-1. In the proposed continuation of this study preemies would be provided daily massages three times a day for 10 days, as in our previously successful protocol. To determine potential mechanisms that may underlie the massage therapy/weight gain relationship we will continue to assess vagal activity and assay insulin, oxytocin, IGF-1 and cortisol as well as gastric motility. We have added an alternative potential pathway for the massage therapy/weight gain relationship. In this expanded model, activity level and the related measures of heart rate, oxygen consumption (based on a formula calculated from heart rate) and temperature mediate the effects of massage therapy on weight gain. A larger sample will be recruited so that we can have the power needed to test our model of the potential mechanisms underlying the weight gain from preterm infant massage.

For the current application, 120 preterm infants with common medical complications of prematurity, who are medically stable and residing in the intermediate care ("grower") nursery, will be assigned to groups based on a random stratification on the following variables: gender, gestational age, birthweight, days in the NICU, and study entry weight. One hundred twenty infants will be randomly assigned to one of two groups: 1) ten days of massage therapy (n=60), or 2) standard treatment (n=60). Within-subjects and between-groups analyses will focus on physiological (heart rate, vagal tone, gastric motility, and temperature), biochemical (insulin, oxytocin, IGF-1 and cortisol) and behavioral variables (activity level).

Ages Eligible for Study: 28 Weeks to 32 Weeks

Genders Eligible for Study: Both

Accepts Healthy Volunteers: No

Inclusion Criteria: Gestational age between 28 and 32 weeks; Birthweight between 800 and 1,400 grams; Birthweight, length, and head circumference appropriate for gestational age; Scores on the Obstetric/Postnatal Complications scales are each below 80; NICU stay between 15 - 60 days; Current weight between 1,000 - 1,500 grams; Current daily intake is between 120 - 160 calories

Exclusion Criteria: Genetic anomalies, congenital heart malformations, and/or central nervous system dysfunction; HIV infection; History of maternal alcohol or illicit drug use; Syphilis; Hepatitis B; Require surgery

Contacts and Locations:
Univ. of Miami School of Medicine, Miami, FL, USA 33136; Contact: Maria Hernandez-Reif, PhD (Principal Investigator); 305-243-6781; mhernan4@med.miami.edu; Tiffany Field, Ph.D (Sub-Investigator).

Study ID Numbers: R01 AT000370-01, R01 AT000370
First Received: January 9, 2002
Last Updated: August 12, 2008
ClinicalTrials.gov Identifier: NCT00029198
Health Authority: United States: Federal Government

Childhood Autism Risks From Genetics and the Environment (The CHARGE Study)

Currently recruiting participants.

Sponsors and Collaborators: National Institute of Environmental Health Sciences (NIEHS); Univ. of California, Davis; Univ. of California, Los Angeles

Purpose: The purpose of this study is to understand how genes, environment, and the interplay between the two, influence the development of autism and other neurodevelopmental disorders.

Condition: Autism; Developmental Disabilities

Study Type: Observational

Study Design: Screening, Cross-Sectional, Case Control, Retrospective/ Prospective Study

Estimated Enrollment: 2000

Study Start Date: September 2001

Estimated Study Completion Date: September 2006

Detailed Description: The causes and contributing factors for autism are poorly understood. Evidence suggests that incidence is increasing, but diagnostic changes and improvements may be playing a role. Both genetic and environmental factors appear to play a role. Autopsy studies demonstrate structural changes in the brain and clinical investigations reveal neurophysiologic differences in information processing in autistic versus normal children. Members of our team recently demonstrated altered levels of certain neuropeptides at birth in children who later developed autism. This case-control study is the first large-scale epidemiologic investigation of underlying causes for autism and triggers of regression. This study capitalizes on the strengths of the case-control design, which is well suited to examine a broad array of factors for rare conditions that are thought to be multifactorial. Comparisons will be made with both general population controls and mentally retarded children.

The aims are to assess the influence of exogenous exposures, the role of susceptibility factors, and the interplay between these two in the etiology of autism and its phenotypic variation. Chemicals with known or suspected neurodevelopmental toxicity, such as PCB's, certain pesticides, and metals, are being investigated. This study pursues several hypotheses that have recently gained attention, including the combined measles, mumps, rubella vaccine and mercury present in vaccines given during infancy and early childhood. Additionally, biochemical susceptibility is examined through characterization of metabolic, immunologic, and neuronal gene expression profiles and genetic polymorphisms.

Ages Eligible for Study: 24 Months to 60 Months

Genders Eligible for Study: Both

Accepts Healthy Volunteers: Yes

Inclusion Criteria: Children between 2 and 5 years old; Born in California; Parents must speak either English or Spanish; children must be living with at least one biologic parent

Exclusion Criteria: Children not meeting eligibility criteria listed above; Children not residing in selected geographical areas (please contact for more information about specific study locations)

Contacts and Locations:
Univ. of California; Davis, CA, USA, 95616; Contact: Melissa Rose, B.Sci; 530-754-8157; mbrose@ucdavis.edu
Principal Investigator: Irva Hertz-Picciotto, MPH, PhD; Univ. of California, Davis

Study ID Numbers: 11269-CP-001, 200210574-4
First Received: March 28, 2005
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ClinicalTrials.gov Identifier: NCT00106652
Health Authority: United States: Federal Government

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ICD-9 00.12

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- ICD-9 00.12 may reduce claims-processing delays associated with miscellaneous HCPCS[a] or CPT[b] codes
- ICD-9 00.12 may trigger contractual payment mechanisms

[a] HCPCS, Healthcare Common Procedure Coding System.
[b] CPT, current procedural terminology.

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Next Steps…

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