



# 2007 PAS Annual Meeting

As you plan your meeting itinerary, be sure to include these late-breaking abstract presentations, selected for their high-quality and news-breaking research.

## Late-Breaker Abstract Presentations

Saturday, May 5

8:00am–10:00am

### 5130 Late Breakers I:

#### Clinical Trials in Neonatology

PAS Platform Session ~ Hall G

**8:00 The International Caffeine for Apnea of Prematurity (CAP) Trial: Preliminary Analyses of Outcomes at a Corrected Age of 18 - 21 Months.** Barbara Schmidt, Robin Roberts, Peter Davis, Lex Doyle, Keith Barrington, Arne Ohlsson, Alfonso Solimano, Win Tin, The CAP Investigators.  
*Publication 5130.1*

**8:15\* Higher Indomethacin Doses Do NOT Increase the Rate of PDA Closure but DO Increase the Rate of Threshold ROP.** P. Jegatheesan, V. Ianus, B. Buchh, G. Yoon, N. Chorne, A. Ewig, A. Moon-Grady, T. Tacy, J. Milstein, M. Schreiber, J. Padbury, R. Clyman.  
*Publication 5130.2*

**8:30 A 16-Center Randomized Trial of Aggressive vs. Conservative Phototherapy for Extremely Low Birth Weight Infants.** Brenda Morris, the NICHD Neonatal Research Network.  
*Publication 5130.3*

**8:45 One Year Respiratory Outcomes of the Preterm Infants Enrolled in the NO CLD Trial of Inhaled Nitric Oxide (iNO).** A.M. Hibbs, M.C. Walsh, R.J. Martin, W.E. Truog, S.A. Lorch, E. Alessandrini, A. Cnaan, X. Luan, S.R. Wadlinger, C.E. Coburn, P.L. Ballard, R.A. Ballard, The NO CLD Study Group.  
*Publication 5130.4*

**9:00 Prophylactic Surfactant without Mandatory Ventilation in Extremely Premature Infants Treated with Early NCPAP.** M.A. Rojas, J. Lozano, M. Laughon, C. Bose, M.X. Rojas, L. Charry, J. Bastides, L. Perez, C. Rojas, O. Ovalle, A. Celis, J. Harker, M. Rondon.  
*Publication 5130.5*

**9:15 Randomized Trial Comparing the Use of Nasal Continuous Positive Airway Pressure (nCPAP) to Synchronized Nasal Non-Invasive Positive Pressure Support (sNIPP) in Preterm Infants.** Aaron Chiu, Jubara Alallah, John Minski, William Petranick, Ruben Alvaro.  
*Publication 5130.6*

**9:30 Neonatal Dexamethasone but Not Hydrocortisone Treatment Changes Cardiovascular Response, HPA-Axis Reactivity and the Cytokine Balance of Ex-Premature Children at School Age.** Frank van Bel, Rosa Karemaker, Sylvia Veen, Wim Baerts, Janny Samsom, Gerard Visser, Annemieke Kavelaars, Cobi Heijnen.  
*Publication 5130.7*

**9:45\* A Randomized Controlled Trial of a Post Discharge Neurobehavioral Early Intervention Program in VLBW Infants: Six Months' Neurodevelopmental Outcome.** K. Koldewijn, M.-J. Wolf, A.G. van Wassenaer, D. Meijssen, L. van Sonderen, A. Beelen, A. van Baar, F. Nollet, J.H. Kok.  
*Publication 5130.8*

1:00pm–3:00pm

### 5570 Late Breakers II

PAS Platform Session ~ Room 716A

**1:00 Virtual Disappearance of Pneumococcal Vaccine Strains from Massachusetts Communities.** Susan S. Huang, Virginia L. Hinrichsen, Abbie E. Stevenson, Sheryl L. Rifas-Shiman, Stephen I. Pelton, William P. Hanage, Jonathan A. Finkelstein.  
*Publication 5570.1*

**1:15\* Implementation of Rotavirus Vaccine in Philadelphia Reveals Off-Label Use by Age.** Irimi Daskalaki, C. Victor Spain, Brian Jorgage, Sarah S. Long, Barbara Watson.  
*Publication 5570.2*

**1:30 Pertussis Resurgence in Toronto, 2007: The View from the Lab.** David N. Fisman, Patrick Tang, Steve Drews, Susan Richardson, Frances Jamieson.  
*Publication 5570.3*

**1:45 Naso-Pharyngeal Carriage of Common and Emerging Respiratory Viruses in Health Care Workers.** A. Gundlapalli, R. Greenberg, M. Poritz, L. Meyers, K. Korkenski, J. Daly, A. Pavia, M. Samore, C. Byington.  
*Publication 5570.4*

**2:00 A Randomized Controlled Trial Evaluating the Safety of a Quadrivalent HPV (6, 11, 16, 18) L1 VLP Vaccine in Adolescents.** Keith S. Reisinger, Stan L. Block, Eduardo Lazcano-Ponce, Rudiwilai Samakoses, Katherine E. Giacoletti, Sara Kerin, Frances Alvarez, Heather L. Sings, Eliav Barr.  
*Publication 5570.5*

**2:15 Feasibility of Elementary School Children's Use of Hand Gel and Face Masks during Influenza Season.** M.A. Allison, G. Guest-Warnick, P.H. Gesteland, R. Srivastava, D. Nelson, A.T. Pavia, R.T. Rolfs, L. Calame, C. Byington.  
*Publication 5570.6*

**2:30 Apparent-Life Threatening Events (ALTE) Are a Significant Risk for Child Abuse and Chronic Epilepsy.** Josh Bonkowsky, Elisabeth Guenther, Rajendu Srivastava, Francis Filloux.  
*Publication 5570.7*

**2:45 Impact of Vitamin E and Omega 3 Supplementation in Children with Verbal Apraxia.** Claudia R. Morris, Marilyn C. Agin.  
*Publication 5570.8*

**3:00\* Prenatal Care and Delivery Room Staff Attitudes towards Research and the National Children's Study.** L.M. Mudd, V. Skorokhod, S. Nechuta, M.R. Elliott, J.M. Lepkowski, N. Paneth, MANCS Coalition.  
*Publication 5570.9*

4:00pm–7:30pm

### 5912 Late Breakers I Poster Session

Exhibit Hall E

**552 Feasibility and Efficacy Trial of Automated Regulation of Inspired Oxygen in Mechanically Ventilated Preterm Infants.** Nelson Claire, Carmen D'Ugard, Eduardo Bancalari.  
*Publication 5912.1*

**553 Effects of Early Aggressive Nutrition in Infants with Birth Weight (BW) <1250g: A Randomized Controlled Trial.** Sudha Kashyap, Kirsten Abildskov, Stephen F. Holleran, Rajashekhar Ramakrishnan, Helen M. Towers, Rakesh Sahni.  
*Publication 5912.2*

**554\* Many Conclusive Neonatal Meta-Analyses Are Inconclusive - An Audit of Neonatal Meta-Analyses with Trial Sequential Analyses.** Jesper Brok, Kristian Thorlund, Jørn Wetterslev, Christian Gluud.  
*Publication 5912.3*

**555 Parenteral Nutrition-Associated Liver Disease and Omega-3 Lipid Emulsions: Preliminary Findings on Safety and Efficacy.** Kathleen M. Gura, Sang Lee, Christopher Duggan, Mark Puder.  
*Publication 5912.4*

**556 Quantitative EEG in Babies at Risk for Hypoxic Ischemic Encephalopathy after Perinatal Asphyxia.** Manan Hathi, Neil Rothman, Lisa Korst, Tom Pantano, Terrie Inder, Ananth Natarajan.  
*Publication 5912.5*

**557 Fluconazole Prophylaxis and Candidemia: Case-Control Analysis of a Multicenter Study Database.** David Kaufman, Amy Morris, Barry Kapik, Seth Hetherington.  
*Publication 5912.6*

**558 The Global Network's FIRST BREATH Study: Testing the Impact of World Health Organization Essential Newborn Care Training on Neonatal and Perinatal Mortality.** Waldemar A. Carlo.  
*Publication 5912.7*

\* Indicates First Author is a Trainee (Student, Fellow, House Officer)



# 2007 PAS Annual Meeting

## Late-Breaker Abstract Presentations

Monday, May 7

3:00pm–6:45pm

### 7937 Late Breakers II Poster Session

Exhibit Hall E

- 546 Single Versus Double Umbilical Cord Blood Transplantation (UCBT): Higher Risk of Acute Graft-Versus-Host Disease (GVHD) but Lower Transplant Related Mortality (TRM) in Recipients of Double UCBT.** Margaret L. MacMillan, Claudio R. Brunstein, Todd E. DeFor, Qing Cao, Bruce R. Blazar, Daniel J. Weisdorf. *Publication 7937.1*
- 547 Thymic Shielding (TS) in Recipients of Total Body Irradiation (TBI) and Alternative Donor Hematopoietic Stem Cell Transplant (AD-HSCT): Reduced Risk of Opportunistic Infection in Patients with Fanconi Anemia (FA).** Margaret L. MacMillan, Bruce R. Blazar, Todd D. DeFor, Kathryn R. Dusenbery, John E. Wagner, Daniel J. Weisdorf. *Publication 7937.2*
- 548 Phase 1 Safety, Pharmacokinetic, and Exploratory Biomarker Study of IV Temsirolimus in Children with Advanced Solid Tumors.** S.L. Spunt, S. Grupp, T. Vik, V. Santana, D. Greenblatt, R. Gilbertson, B. Hewes, J. Boni, B. Esteves, L. Speicher. *Publication 7937.3*
- 549 The Safety of High Concentration Nitrous Oxide for Procedural Sedation and Analgesia in Children.** Franz E. Babl, Cameron Seaman, Ed Oakley, Peter Barnett. *Publication 7937.4*
- 550 WITHDRAWN**
- 551 Body Mass Index in Adolescence Predicts Diabetes and Coronary Artery Disease in Adulthood: A 20-Year Follow up.** Gal Dubnov-Raz, Irit Tirosh, Tzipora Shochat, Amir Tirosh. *Publication 7937.6*
- 552 The Effects of a Dance Dance Revolution Exercise Program in Obese Adolescents: A Randomized Controlled Trial.** Casey Hester, Laura Chalmers, Aditi Sule, Sara Vesely, Andrew Gardner, David Fields, Kenneth Copeland, Terrence Stull. *Publication 7937.7*
- 553 A National Survey of Pediatricians: Attitudes and Practices towards Influenza Vaccination.** Maureen S. Kolasa, Abigail Shefer, Karen G. O'Connor, David L. Wood, Allison Kempe, Denia Varrasso, Thomas Olivia. *Publication 7937.8*
- 554 Adolescent Risk Reduction in Developing Countries: An HIV Prevention Intervention with and without a Parental Monitoring Component Targeting Sixth Grade Students in the Bahamas.** Sharon P. Marshall, Lynette Deveaux, Bonita Stanton, Sonya Lunn, Leslie Cotrell, Shuli Yu, Nanika Brathwaite, Xiaoming Li, Hong Jie, Carol Harris. *Publication 7937.9*
- 555 Increasing Involvement of Pediatric Residents in Community Activities: 2002 to 2006.** Cynthia Minkovitz, Cassie Althausser, Jennifer Mettrick, Barry Solomon, Holly Grason. *Publication 7937.10*
- 556 Hematopoietic Stem Cell Transplant for Osteopetrosis.** Paul J. Orchard, Mary Eapen, Jakub Tolar, Edwin Horwitz, Paul Veys, Anders Fasth. *Publication 7937.11*
- 557 A Needs Assessment of Pediatric Medical School Faculty: Comparing Academic Ranks and Tracks.** Charles B. Pelshaw, Ronald L. Thomas, Bonnie Stanton, Ambika Mathur, Deepak Kamat, Edward R. Dabrowski. *Publication 7937.12*
- 558 Impact of Hospital Disaster Exercises on Emergency Department Patient Flow.** Nathan L. Timm, Stephanie S. Kennebeck. *Publication 7937.13*
- 559 Infant Mortality Rate (IMR) Reaches Single Digit in a District in South India, Can It Be Sustained?** Shantharam B. Baliga. *Publication 7937.14*
- 560 Pain Ease® Vapocoolant Spray Versus Placebo in Reducing Pain Associated with Intravenous Insertion in Children: RCT.** Ken J. Farion, William M. Splinter, Karen Splinter, Kym Newhook, Isabelle Gaboury. *Publication 7937.15*
- 561 CT Scan with IV Contrast Alone for Evaluation of Pediatric Appendicitis.** Madelyn Garcia, George T. Drugas, Lynn Babcock-Cimpello, Luann Teschmacher. *Publication 7937.16*
- 562 Predicting Imminent Menarche from Salivary Steroid Hormones and Body Mass Index: A Pilot Study.** Susan H. Gray, Lauren K. Ebe, Henry A. Feldman, S. Jean Emans, Marc R. Laufer. *Publication 7937.17*
- 563 Therapy Intensification Improves Outcome in Multisystem Langerhans Cell Histiocytosis: Results of the Histiocyte Society LCH-II Trial.** Stephan Ladisch, Nicole Grois, Ulrike Pötschger, Milan Minkov, Maurizio Aricò, Jorge Braier, Valerie Broadbent, Jean Donadieu, Jan-Inge Henter, Robert McCarter, Helmut Gadner. *Publication 7937.18*
- 564\* Procalcitonin To Predict Vesico-Ureteral Reflux in Children with Acute Pyelonephritis: A European Study.** S. Leroy, A. Galetto-Lacour, C. Romanello, A. Fernandez-Lopez, D. Tuerlinckx, V. Smolkin, A. Gervaix, M. Contardo, C.L. Cubells, T. Vander Borgh, R. Halevy, D. Gendrel, G. Breart, M. Chalumeau. *Publication 7937.19*
- 565\* Utility of the Quantiferon-Gold In-Tube in the Diagnosis of TB in Children.** Jennifer Lighter, Mona Rigaud, Thomas Miyoshi, Ed Fryer, Chia-Hui Peng, Henry Pollack. *Publication 7937.20*
- 566 Prospective Multicenter Study of the Viral Etiology of Bronchiolitis in the Emergency Department.** Jonathan M. Mansbach, Alexander J. McAdam, Sunday Clark, Carlos A. Camargo. *Publication 7937.21*
- 567 Oral Versus High Dose Pulse Corticosteroids in Problematic Infantile Hemangiomas: A Randomized Controlled Trial.** Elena Pope, Bernice R. Krafchik, Colin Macarthur, Diana Stempak, Derek Stephens, Miriam Weinstein, Nhung Ho, Sylvain Baruchel. *Publication 7937.22*
- 568 Impact of Fundoplication Versus Gastrojejunal Feeding Tubes on Mortality and in Preventing Aspiration Pneumonia in Young Children with Neurological Impairment Who Have Gastroesophageal Reflux Disease.** Rajendu Srivastava, Earl C. Downey, Molly O'Gorman, Peter G. Feloa, Richard Holubkov, Michael Mundorff, Peter Rosenbaum, Paul C. Young, Jonathan M. Dean. *Publication 7937.23*
- 569\* The Role of Lymphocytes in Pulmonary Inflammation in a Mouse Model of Sickle Cell Disease.** Kori Wallace, Joel Linden. *Publication 7937.24*
- 570 Study of Brain Function Compensation of Children with Cerebral Palsy treated by Acupuncture and Nerve Growth Factor.** Zhenhuan Liu. *Publication 7937.25*
- 571 C-Reactive Protein Velocity - A New Inflammatory Marker.** Moran Lavie, Shlomo Berliner, Tali Taxir, Ori Rogowski, Shimon Reif. *Publication 7937.26*

## Late Breakers I:

## Neonatal Clinical Trials Platform Session

Saturday, May 5

8:00am-10:00am

Hall G, TCC

5130.1

Presentation Time 8:00 AM

**The International Caffeine for Apnea of Prematurity (CAP) Trial:****Preliminary Analyses of Outcomes at a Corrected Age of 18 - 21 Months**

Barbara Schmidt, Robin Roberts, Peter Davis, Lex Doyle, Keith Barrington, Arne Ohlsson, Alfonso Solimano, Win Tin, The CAP Investigators, McMaster University, Hamilton, Canada; University of Melbourne, Australia; McGill University, Montreal, Canada; University of Toronto, Canada; University of British Columbia, Vancouver, Canada; James Cook University, Middlesbrough, United Kingdom.

**BACKGROUND:** The Caffeine for Apnea of Prematurity trial was conducted to study the short- and long-term efficacy and safety of methylxanthine therapy in very low birth weight (VLBW) infants. We previously reported the short-term outcomes of the study infants before their first discharge home (N Engl J Med 2006;354:2112-21). The effects of caffeine and other methylxanthines on long-term neurodevelopment and growth remain uncertain.

**OBJECTIVE:** To determine the effects of caffeine on survival without neurodevelopmental disability in infants weighing 500-1250 g at birth.

**DESIGN/METHODS:** This randomized placebo-controlled trial of caffeine enrolled 2006 VLBW infants from 35 centers during the first 10 days of life. The primary outcome at a corrected age of 18-21 months was a composite of death, cerebral palsy, cognitive delay (MDI < 85 on the Bayley Scales of Infant Development II), deafness requiring amplification and bilateral blindness.

**RESULTS:** Of the 2006 infants randomized, 1867 children (93%) had adequate data for this preliminary analysis of the composite 18-month outcome. The rates of death or disability were 40% with caffeine and 46% with placebo; OR 0.77, 95% CI 0.63 to 0.93, p=0.006. Caffeine reduced the incidence of cerebral palsy and of cognitive delay. Cerebral palsy rates were 4.4% after caffeine and 7.3% after placebo; OR 0.58, 95% CI 0.39 to 0.87, p=0.009. In the caffeine group, 34% of children had an MDI < 85, compared with 38% in the placebo group; OR 0.80, 95% CI 0.65 to 0.98, p=0.035. The rates of death before 18 months, severe deafness, bilateral blindness, and the mean percentiles for height, weight and head circumference at follow up were similar in both groups.

**CONCLUSIONS:** Caffeine therapy for apnea of prematurity improves the rate of survival without neurodevelopmental disability in VLBW infants at a corrected age of 18-21 months. Supported by the Canadian Institutes of Health Research. NHMRC Australia was a study sponsor in Australia. ClinicalTrials.gov NCT00182312.

5130.2

Presentation Time 8:15 AM

**Fellow in Training****Higher Indomethacin Doses Do NOT Increase the Rate of PDA Closure but DO Increase the Rate of Threshold ROP**

P. Jegatheesan, V. Ianus, B. Buchh, G. Yoon, N. Chorne, A. Ewig, A. Moon-Grady, T. Tacy, J. Milstein, M. Schreiber, J. Padbury, R. Clyman, Pediatrics, UCSF, CA; Brown, RI; U Chicago, IL; UC Davis, CA.

**BACKGROUND:** Preterm infants (<28 wks), who fail to close their patent ductus arteriosus (PDA) with 3 doses of prophylactic indomethacin (begun within 24 h of birth), have a high rate of developing PDA-related symptoms. Even if the initial 3-dose course is extended with 3 additional doses of indomethacin (0.1 mg/kg/day), about half the infants will still develop a symptomatic PDA (sPDA). Recent uncontrolled studies have recommended higher indomethacin doses to improve the rate of PDA closure. We conducted a multicenter, randomized, blinded, controlled trial to see if higher doses of indomethacin would improve the rate of PDA closure.

**DESIGN/METHODS:** Infants (<28 wks) were eligible if they still had a PDA on echo, just prior to the 3rd dose of prophylactic indomethacin. Enrolled infants (n=105) received an extended treatment course with 3 additional days of either LOW dose (0.1 mg/kg/day) or HIGH dose indomethacin. For infants 26-27 wk, the HIGH dose was 0.2 mg/kg/day; for 24-25 wk the HIGH dose was either 0.2 or 0.5 mg/kg/day. An echo was performed 24 h after the last dose of study drug. Further treatment decisions were left to the attending physician.

**RESULTS:** In the LOW dose group, serum indomethacin levels, measured 12 h after the last dose of study drug, were similar to those measured just before starting the study (pre: 0.71 microgm/ml, post:0.73 microgm/ml). In the HIGH dose group, indomethacin levels increased 2.8-fold during the study (pre: 0.63 microgm/ml, post:1.74 microgm/ml). The rates of ductus closure on echo (51%), of symptoms related to the sPDA (47%), and of ligation (34%) were not affected by either the dose given or the levels of indomethacin at the end of the study. Nor were the rates of NEC or BPD. In contrast, a significant increase in Retinopathy of Prematurity (>stage 2-plus) was seen in the HIGH dose group (OR=3.07, CI=1.13-8.38) and with increasing indomethacin levels (OR=1.8, CI=1.14-2.72) (even after adjusting for gestational age and study site).

**CONCLUSIONS:** Higher doses of indomethacin did not improve the rate of PDA closure compared to commonly used lower doses; however, the rate of threshold Retinopathy of Prematurity was significantly increased by higher indomethacin doses.

5130.3

Presentation Time 8:30 AM

**A 16-Center Randomized Trial of Aggressive vs. Conservative Phototherapy for Extremely Low Birth Weight Infants**

Brenda Morris, the NICHD Neonatal Research Network, Pediatrics, UTHSC, Houston, TX; Bethesda, MD.

**BACKGROUND:** The risks, benefits, and indications for phototherapy (PT) in ELBW infants are unclear and have not been well studied.

**OBJECTIVE:** To compare the incidence of neurodevelopmental impairment (NDI) or death at 18-22 mo corrected age among ELBW infants treated with aggressive (AG) or conservative (CON) PT.

**DESIGN/METHODS:** Between 9/2002 - 4/2005, 1,974 ELBW infants were randomized at 12-36 h age to AG or CON for the 1st 14d. AG was started at enrollment. CON was started at total serum bilirubin (TSB; mg/dl)  $\geq 8$  for 501-750g BW and  $\geq 10$  for 751-1000g BW. PT (15-40 $\mu$ W/cm<sup>2</sup>/nm) was given for  $\geq 24$ h, stopped at TSB: AG- <5; CON 501-751g- <8 or 751-1000g- <10, and restarted if TSB was  $\geq$  these levels. Uniform indications were used for exchange transfusions (ET). Masked evaluators assessed NDI (Bayley mental or psychomotor index <70, cerebral palsy (CP), or bilateral blindness or deafness). Death was analyzed as a competing outcome. Relative risks (RR) are adjusted for center and BW (stratifying variables), and race, gender, and inborn.

**RESULTS:** AG (n=990) and CON (n=984) cohorts had a mean BW of 777 vs. 777g and GA of 25.9 vs. 26.0 wks, respectively. 216 (22%) CON infants never received PT. 2 in AG and 3 in CON had an ET. Primary outcome at 18-22 mo has been determined for 1,770 (90%); follow up of final 37 infants is expected by PAS meeting.

	AG	CON	Absolute $\Delta$ (95% CI)
TSB at start PT <sup>1</sup>	4.8 $\pm$ 1.6	10.0 $\pm$ 1.5	-5.2 (-5.4, -5.1)
Peak TSB <sup>1</sup>	7.0 $\pm$ 1.8	9.8 $\pm$ 2.1	-2.8 (-3.0, -2.7)
Hours of PT <sup>1</sup>	88 $\pm$ 48	35 $\pm$ 31	53 (50, 57)
			<b>RR (95% CI)</b>
Intraventricular hemorrhage 3/4 or death by 28d	30%	30%	1.03(0.90, 1.17)
Bronchopulmonary dysplasia (BPD) at 36wks	41%	48%	0.88(0.79, 0.97)
BPD or death by 36 wks	52%	57%	0.92(0.85, 0.99)
Patent ductus or death by d/c $\geq$ Stage 3 ROP or death by d/c	56%	59%	0.96(0.89, 1.03)
NDI or death (Primary Outcome)	<b>52%</b>	<b>55%</b>	<b>0.96(0.89, 1.05)</b>
NDI <sup>2</sup>	35%	40%	0.89(0.78, 1.02)
Death by 18-22 mos	24%	23%	1.09(0.94, 1.26)
CP <sup>2</sup>	6%	8%	0.77(0.51, 1.15) <sup>3</sup>
CP or death	29%	30%	1.02(0.89, 1.17)
Deaf <sup>2</sup>	1%	4%	0.38(0.18, 0.79) <sup>a</sup>
Deaf or death	26%	27%	1.01(0.88, 1.17)

<sup>1</sup>mean $\pm$ SD <sup>2</sup> % survivors assessed <sup>3</sup>Not adjustable for center <sup>a</sup>Not adjustable for center & race

**CONCLUSIONS:** Except for a few intriguing secondary outcomes, we have found no large differences between AG and CON.

5130.4

Presentation Time 8:45 AM

**One Year Respiratory Outcomes of the Preterm Infants Enrolled in the NO CLD Trial of Inhaled Nitric Oxide (iNO)**

A.M. Hibbs, M.C. Walsh, R.J. Martin, W.E. Truog, S.A. Lorch, E. Alessandrini, A. Cnaan, X. Luan, S.R. Wadlinger, C.E. Coburn, P.L. Ballard, R.A. Ballard, The NO CLD Study Group, Rainbow Babies & Children's Hospital, CWRU, Cleveland;

Children's Mercy Hospital, Kansas City; Children's Hospital of Philadelphia; University of California, San Francisco.

**BACKGROUND:** In the NO CLD trial, iNO increased survival without bronchopulmonary dysplasia (BPD) (NEJM 355:343 2006).

**OBJECTIVE:** We aimed to identify whether iNO therapy also decreased indicators of more long-term pulmonary morbidities after discharge from the NICU.

**DESIGN/METHODS:** As previously reported, the NO CLD trial enrolled preterm infants (<1250g) who were ventilated at 7-21 days of age and at high risk for BPD. Follow-up occurred at 12  $\pm$  3 mo adjusted age; parents were asked about their children's health in structured blinded interviews. Two yr neurodevelopmental follow-up is ongoing.

**RESULTS:** 456 infants (84%) were seen at 1 yr. Compared to control infants, infants randomized to iNO received significantly less bronchodilators, inhaled steroids, systemic steroids, diuretics, and oxygen after discharge from the NICU (see table). There were no significant differences between parental report of wheezing or whistling in the chest or re-hospitalizations.

**CONCLUSIONS:** Infants treated with iNO required fewer respiratory medications than the control group, suggesting persistent clinically significant pulmonary benefit from therapy. However, iNO should not be routinely used to prevent lung disease until the 24 month neurodevelopmental outcomes are known.

Pulmonary Symptoms and Treatments in 1st Year

	iNO(%)	Control(%)	RR* (95%CI)	NNT** (95% CI)
<b>Wheezing or whistling in the chest</b>	49.6	56.4	0.88 (0.74-1.05)	---
<b>Bronchodilator Use</b>	39.9	54	0.74 (0.61-0.91)	7.1 (4.3-19.9)
<b>Inhaled Steroid Use</b>	19.7	32.4	0.61 (0.44-0.85)	7.9 (4.8-21.7)
<b>Systemic Steroid Use</b>	11.0	17.7	0.62 (0.39-0.99)	14.8 (7.6-347.0)
<b>Diuretic Use</b>	18.5	28.4	0.65 (0.46-0.92)	10.1 (5.6-47.5)
<b>Hospitalization -- Respiratory Hospitalization--Any</b>	22.5	21.8	1.03 (0.72-1.45)	---
<b>Home Oxygen Use</b>	46.5	50.4	0.92 (0.76-1.11)	---
<b>Persistent Oxygen Use at 1 yr</b>	39.0	50.0	0.79 (0.64-0.97)	9.4 (5.1-66.0)
	3.4	9.4	0.37 (0.17-0.81)	16.9 (9.6-69.2)

\*Relative risk. \*\*Number needed to treat.

5130.5

Presentation Time 9:00 AM

**Prophylactic Surfactant without Mandatory Ventilation in Extremely Premature Infants Treated with Early NCPAP**

M. A. Rojas, J. Lozano, M. Laughon, C. Bose, M. X. Rojas, L. Charry, J. Bastides, L. Perez, C. Rojas, O. Ovalle, A. Celis, J. Harker, M. Rondon. Pediatrics, Vanderbilt, Nashville, TN; Epidemiology, Javeriana, Bogota, Colombia; Pediatrics, UNC, Chapel Hill, NC; Pediatrics, Los Farallones, Cali, Colombia; Pediatrics, Hospital Santander, Bucaramanga, Colombia; Pediatrics, Policlinico Olaya, Bogota, Colombia; Pediatrics, Saludcoop, Bogota, Colombia; Pediatrics, Simon Bolivar, Bogota, Colombia; Pediatrics, Clinica San Luis, Bucaramanga, Colombia. BACKGROUND: Prophylactic surfactant therapy (PST) improves the short-term respiratory status of extremely premature infants, but its use is limited to infants intubated immediately after birth. The early application of NCPAP has been used in these infants as a strategy for avoiding intubation and mechanical ventilation (MV). The addition of PST to this strategy, during a brief period of intubation, may further decrease the need for MV. OBJECTIVE: To determine whether PST without mandatory ventilation decreases the need for MV when used in extremely premature infants treated with NCPAP immediately after birth. DESIGN/METHODS: Six centers in Colombia participated in this randomized controlled trial. Infants between 27 and 31 weeks gestation with evidence of respiratory distress treated with supplemental oxygen in the delivery room were stratified by gestational age and randomized within the first hour of life to intubation, PST, extubation, and NCPAP (treatment group) or NCPAP alone (control group). The primary outcome was the need for subsequent MV (predefined criteria). RESULTS: From January 1, 2004 to December 2, 2006, 278 infants were randomized, 141 to the treatment group and 137 to the control group. The need for MV was lower in the treatment group (26%) than in the control group (39%), relative risk (RR) 0.69 (95% CI: 0.49 - 0.97). Pneumothorax occurred less frequently in the treatment group (2%) versus the control group (9%), RR 0.24 (95% CI: 0.07 - 0.85). The incidence of CLD (oxygen at 36 weeks PMA) was 45% in the treatment group versus 53% in the control group, RR 0.86 (95% CI: 0.68 - 1.08). All other outcomes, including mortality, subglottic stenosis, IVH, and PVL, were similar between groups. CONCLUSIONS: In extremely premature infants treated with NCPAP immediately after birth, PST without mandatory ventilation decreases the need for subsequent MV and decreases the incidence of pneumothorax.

5130.6

Presentation Time 9:15 AM

**Randomized Trial Comparing the Use of Nasal Continuous Positive Airway Pressure (nCPAP) to Synchronized Nasal Non-Invasive Positive Pressure Support (sNIPP) in Preterm Infants**

Aaron Chiu, Jubara Alallah, John Minski, William Petranick, Ruben Alvaro. Pediatrics, University of Manitoba, Winnipeg, MB, Canada; Medical Rehabilitation, University of Manitoba, Winnipeg, MB, Canada; Respiratory Medicine, St Boniface Hospital, Winnipeg, MB, Canada. BACKGROUND: sNIPP may be conceptually better than nCPAP. It is uncertain if its use can simultaneously decrease the need for methylxanthine therapy and prevent reintubation in preterm infants. OBJECTIVE: To compare sNIPP (Triggered Pressure Assist) to nCPAP, both using Infant Flow Advance®, in preventing reintubation and methylxanthine therapy in preterm infants undergoing initial extubation. DESIGN/METHODS: Methylxanthine naive preterm infants (birth weight 500-1250 gms) were stratified into 3 weight groups and randomized at first extubation to either sNIPP or nCPAP. Cross-over was not allowed. Protocol for escalation and weaning of study treatment and criteria for reintubation and methylxanthine treatment were utilized. Study success was

avoidance of reintubation and methylxanthine therapy during first 7 days after extubation. RESULTS: 45 infants were enrolled (22 sNIPP, 23 nCPAP). Maternal age, antenatal steroids, chorioamnionitis, route of delivery, gestational age, SNAP-II PE, birth weight, and Apgar scores were similar in both groups. A greater number of female infants were present in the nCPAP group (73.9% versus 36.4%, p=0.01). At extubation, groups were similar in oxygen requirement, PEEP and MAP. Mean age at extubation was 3.59±3.02 days in sNIPP group and 4.3±4.94 days in nCPAP group (p=0.56). Both groups were similar in avoiding reintubation and methylxanthine treatment during the first 7 days (sNIPP 40.9%, nCPAP 52.6%, p=0.45). Although not statistically significant, the sNIPP group was reintubated earlier (120.1 versus 133.8 hours, p=0.49) but required methylxanthine treatment later (137.4 versus 111.2 hours, p=0.12). The sNIPP group showed a trend for fewer days of methylxanthine therapy during hospitalization (23.9 versus 36.5 days, p=0.07). There was no difference in feeding intolerance during study period. 2 infants developed NEC after the 7 day study period (one in each group). Both groups were similar in incidence of BPD (36 weeks), ROP, severe IVH, and death. CONCLUSIONS: sNIPP was not superior to nCPAP in preventing reintubation and methylxanthine treatment in preterm infants during the first 7 days after initial extubation.

5130.7

Presentation Time 9:30 AM

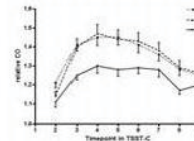
**Neonatal Dexamethasone but Not Hydrocortisone Treatment Changes Cardiovascular Response, HPA-Axis Reactivity and the Cytokine Balance of Ex-Premature Children at School Age**

Frank van Bel, Rosa Karemaker, Sylvia Veen, Wim Baerts, Janny Samsom, Gerard Visser, Annemieke Kavelaars, Cobi Heijnen. Neonatology, University Medical Center, Utrecht, Netherlands; Neonatology, University Medical Center, Leiden, Netherlands; Neonatology, Isala Clinics, Zwolle, Netherlands; Neonatology, Free University Medical Center, Amsterdam, Netherlands; Obstetrics, University Medical Center, Utrecht, Netherlands; Psychoneuroimmunology, University Medical Center, Utrecht, Netherlands.

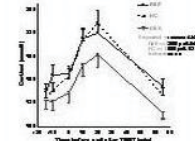
BACKGROUND: Prematurely born children who neonatally received DEX to prevent chronic lung disease were compared to a group of children neonatally treated with the clinically equally effective drug hydrocortisone (HC) and an untreated reference group (REF) in a retrospectively matched cohort study at school age.

OBJECTIVE: To observe long term effects of neonatal treatment with DEX and HC. DESIGN/METHODS: The groups were matched for gestational age, birth weight and year, gender, severity of respiratory distress syndrome and neurological complications. From 141 children (DEX, n=46; HC, n=52; REF, n=43) we tested the cardiovascular response and HPA-axis function in a response to the Trier Social Stress test. In addition, the capacity to produce pro- and anti-inflammatory cytokines was determined. RESULTS: In response to the laboratory stressor, we observed a decreased cardiovascular and nor-adrenergic response. Also the HPA axis of the DEX-treated children showed a hyporesponsivity to the Trier Stress Test. Moreover, the cytokine TH1/Th2 balance of DEX-treated children was increased compared to the REF group. CONCLUSIONS: We conclude that neonatal treatment with DEX but not HC programs the cardiovascular response, HPA-axis and immune system. We also suggest that HC is a safe alternative for DEX for the neonatal treatment of CLD.

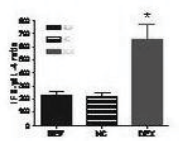
**CARDIOVASCULAR SYSTEM**  
Stress-induced change CO



**HPA-AXIS**  
Stress-induced cortisol



**IMMUNE RESPONSE**  
Th1/Th2 balance



5130.8

Presentation Time 9:45 AM

**Ph.D. Student A Randomized Controlled Trial of a Post Discharge Neurobehavioral Early Intervention Program in VLBW Infants: Six Months' Neurodevelopmental Outcome**

K. Koldewijn, M.-J. Wolf, A.G. van Wassenaer, D. Meijssen, L. van Sonderen, A. Beelen, A. van Baar, F. Nollet, J.H. Kok. Rehabilitation, Academic Medical Center, Amsterdam, Netherlands; Neonatology, Emma Children's Hospital AMC, Amsterdam, Netherlands; Pediatric Psychology, University of Tilburg, Tilburg, Netherlands. BACKGROUND: The impact of prematurity and perinatal insult leads to an increased developmental vulnerability. This may be mediated by socio-environmental factors and parental stress. Until now, developmental care programs (e.g. NIDCAP) were applied during the NICU phase. The Infant Behavioral Assessment and Intervention Program (IBAIP) is based on the same theory as NIDCAP, but is developed as a neurobehavioral home based intervention in the first six months post-term. This is the first RCT to study its effects. OBJECTIVE: To study the effects of the IBAIP on behavioral and developmental outcome in VLBW infants at the corrected age of 6 months. DESIGN/METHODS: VLBW infants were enrolled in the RCT when they were alive at

## Late Breakers II: Platform Session

34 weeks corrected age. The intervention group (I) received one intervention shortly before discharge and 6-8 home interventions until the age of 6 months. The control infants (C) received standard care. Based upon the infant's behavior, facilitation strategies and/or co-regulatory support were offered to the infant with focus on positive parent-child interaction. After completion of the intervention phase, the Bayley Scales (BSID-II) were administered by an investigator, masked for trial assignment.

RESULTS: Mean birth weight in group I was 1242 g, in group C 1306 g, mean gestation was 29.6 weeks in group I and 30 weeks in group C. The groups were well balanced except for more infants on oxygen at 28 days and more septic episodes in group I.

BSID-II scores at six months corrected age.							
	intervention infants (n=86)		control infants (n=83)		intervention effect*		
	mean	(SD)	mean	(SD)	beta	(SE)	P-value
Motor index scores	97	(16)	94	(16)	6.1	(2.4)	0.01
Mental index scores	105	(20)	100	(20)	7.3	(3.1)	0.02
Behavioral Perc. score	52.5	(31.3)	40	(27.3)	18.3	(4.6)	0.001

\* adjusted for baseline differences

CONCLUSIONS: Infants receiving IBAIP performed better at 6 months on the Mental, Motor and Behavioral Scales of the BSID-II compared to control infants. We are now evaluating whether these positive effects sustain.

## Late Breakers II: Platform Session

Saturday, May 5

1:00pm-3:00pm

Room 716A, TCC

### 5570.1

Presentation Time 1:00 PM

#### Virtual Disappearance of Pneumococcal Vaccine Strains from Massachusetts Communities

Susan S. Huang, Virginia L. Hinrichsen, Abbie E. Stevenson, Sheryl L. Rifas-Shiman, Stephen I. Pelton, William P. Hanage, Jonathan A. Finkelstein.

Department of Ambulatory Care and Prevention, Harvard Medical School and Harvard Pilgrim Health Care, Boston, MA; Channing Laboratory and Division of Infectious Diseases, Brigham & Women's Hospital, Boston, MA; Department of Pediatrics, Boston University School of Medicine, Boston, MA; Department of Infectious Disease Epidemiology, Imperial College, London, United Kingdom; Children's Hospital, Boston.

BACKGROUND: Introduction of pneumococcal conjugate vaccine (PCV7) resulted in selective pressure for replacement with non-vaccine *S. pneumoniae* (SP) serotypes in both invasive disease and asymptomatic carriage. Analysis of colonizing serotypes among healthy children in communities provides critical data on changes in serotype distribution and antimicrobial susceptibility, particularly of emerging non-vaccine strains.

OBJECTIVE: To assess changes in colonizing serotypes among healthy children in the community with particular attention to emergence of non-vaccine serotypes (NVT), and evolution of antimicrobial resistance.

DESIGN/METHODS: Nasopharyngeal specimens were obtained from children <7 years old during well-child or sick visits in primary care practices in 8 Massachusetts communities during the winters of 2001, 2004, 2007. Antimicrobial susceptibility testing and serotyping were performed on *S. pneumoniae* (SP) isolates.

RESULTS: We collected 357, 588, and 610 specimens, and identified 89, 141, and 182 SP isolates during the winters of 2001, 2004, and 2007, respectively. Although SP colonization overall was relatively stable (25%, 24%, 30%), PCV7 serotypes decreased from 43% in 2001, to 18% in 2004, and to 4% in 2007 ( $p<.001$ ). This dramatic decrease was countered by an increase in NVT (from 35% to 52% to 60%,  $p<.01$ ) and potentially cross-reactive serotypes (from 22% to 31% to 35%,  $p=.06$ ) during the same periods. Of individual serotypes, most notable is the increase of serotype 19A (from 2% to 9% to 17%,  $p<.001$ ). Overall penicillin non-susceptibility was relatively stable (33% to 30% to 40%), but has substantially increased among NVT (14% to 15% to 31%,  $p<.05$ ).

CONCLUSIONS: SP serotypes colonizing children in Massachusetts have changed dramatically over the 6 years following PCV7 introduction, with virtual disappearance of vaccine-included strains from the community. The emergence of 19A as a frequent colonizer is of particular concern, given its invasive potential.

### 5570.2

Presentation Time 1:13 PM

#### Fellow in Training

#### Implementation of Rotavirus Vaccine in Philadelphia Reveals Off-Label Use by Age

Irina Daskalaki, C. Victor Spain, Brian Jorgage, Sarah S. Long, Barbara Watson.

Pediatrics, St Christopher's Hospital for Children, Philadelphia, PA; Drexel University College of Medicine, Philadelphia, PA; Division for Disease Control,

Philadelphia Department of Public Health, Philadelphia, PA.

BACKGROUND: The first licensed rotavirus vaccine was withdrawn from the market after association with intussusception. Some data suggested increased relative risk with age at vaccination. The licensure of the new pentavalent human-bovine rotavirus vaccine (PRV) was executed after extensive safety trials and with recommendation for use only within strictly defined ages, i.e. age  $\leq 84$ d for series initiation,  $\leq 224$ d for series completion. The Centers for Disease Control and Prevention recently issued a notification to encourage reporting of intussusception cases in an effort to elucidate potential association with PRV.

OBJECTIVE: To examine whether and to what extent PRV is used in Philadelphia infants outside of the recommended age limits (off-label).

DESIGN/METHODS: The Philadelphia Department of Public Health, through the Division of Disease Control, operates a computerized population-based children's immunization registry (KIDS), which captures data on immunizations given to all city residents <6 years old. We analyzed demographics and age at immunization with 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> PRV for children born and living in Philadelphia since the time of vaccine availability (August 1<sup>st</sup> 2006 to January 31<sup>st</sup> 2007).

RESULTS: During the 6-month period, data from 3,967 PRV doses were recorded in KIDS: 2,956 were reported as 1<sup>st</sup>, 858 as 2<sup>nd</sup> and 153 as 3<sup>rd</sup> doses. Of 2,956 children who received at least one PRV dose, 591 (20%) received 1<sup>st</sup> dose after age 84 days and 27 (1%) received a PRV dose after 224 days. Of the 2,956 recipients of 1<sup>st</sup> PRV, 42 (1%) will be ineligible for 2<sup>nd</sup> dose and 110 (4%) for 3<sup>rd</sup>, if age limits and minimum dose intervals are observed. Similarly, 36 (4%) of 858 recipients of 2<sup>nd</sup> dose will be ineligible for 3<sup>rd</sup> PRV.

CONCLUSIONS: Increased awareness is required for following the age recommendations for PRV administration. The narrowly defined age limits result in high levels of vaccine ineligibility, potentially precluding protection through herd effect. The substantial proportion of off-label PRV use underscores the importance of surveillance for intussusception cases.

### 5570.3

Presentation Time 1:26 PM

#### Pertussis Resurgence in Toronto, 2007: The View from the Lab

David N. Fisman, Patrick Tang, Steve Drews, Susan Richardson, Frances

Jamieson. Ontario Central Public Health Laboratory, Toronto, ON, Canada;

Hospital for Sick Children, Toronto, ON, Canada.

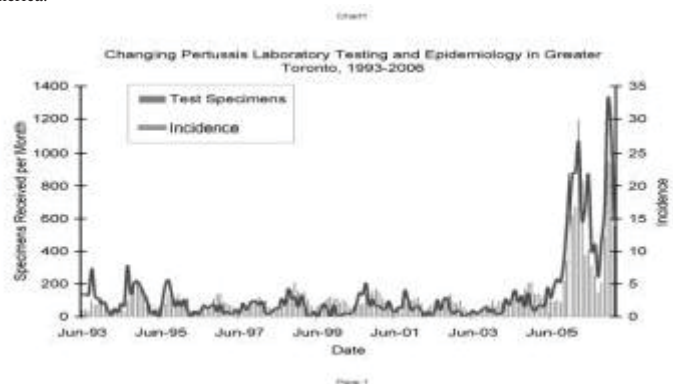
BACKGROUND: Pertussis was a leading cause of death in children prior to the introduction of vaccination in the 1940s. Disease incidence has been increasing since the early 1990s in North America, and has increased markedly in Toronto, Canada, since 2005. More sensitive laboratory testing methods may have contributed to this increase.

OBJECTIVE: Our objective was to describe the epidemiology of pertussis in Toronto, and to determine whether disease trends are likely to be due to changes in laboratory test utilization or techniques.

DESIGN/METHODS: We estimated pertussis trends, and the relative contributions to disease incidence of culture and PCR, using Poisson regression models that controlled for seasonal variation in disease occurrence and specimen submission numbers.

RESULTS: From 1993 to 2006, 21,789 specimens were submitted to for laboratory testing, of which 2,351 (10.8%) were positive. The annual incidence of pertussis was stable at 1-2 per 100,000 population from 1994 to 2004 but increased to 18 per 100,000 in 2006. Test specimen submission increased six-fold during the same period. In regression models, the incidence rate ratio (IRR) for pertussis in Toronto was 8.9 (7.6 to 10.4) after 2005. However, the IRR decreased to 3.0 (2.5 to 3.5) when increased test numbers were taken into account. The proportion of culture-positive tests declined by 25% (95% CI 23% to 28%) each year after the introduction of pertussis PCR.

CONCLUSIONS: Toronto's current pertussis outbreak appears to reflect a true increase in local disease activity, but the size of the outbreak has likely been magnified by increasing use of pertussis testing by clinicians, and by improved sensitivity of PCR. These findings may be applicable to changes in pertussis epidemiology that have been noted elsewhere in North America.



### 5570.4

Presentation Time 1:39 PM

#### Naso-Pharyngeal Carriage of Common and Emerging Respiratory Viruses in Health Care Workers

A. Gundlapalli, R. Greenberg, M. Poritz, L. Meyers, K. Korkenski, J. Daly, A.

## Late Breakers II: Platform Session

Pavia, M. Samore, C. Byington, Internal Medicine, U of Utah; Pediatrics, U of Utah; Microbiology Laboratory, Primary Children's Medical Center; Pathology, U of Utah; Idaho Technology Inc., Salt Lake City, UT.

**BACKGROUND:** Pediatric emergency department (ED) health care workers (HCW) have increased exposures to patients with respiratory illnesses in the winter season. In this setting, respiratory virus (RV) transmission may occur from patients resulting in carriage of those viruses in HCW.

**OBJECTIVE:** Determine if naso-pharyngeal carriage of RV can be detected in pediatric ED HCW.

**DESIGN/METHODS:** A random sampling of ED HCW from Primary Children's Medical Center answered a short survey and underwent naso-pharyngeal (NP) wash for viral culture and multiplex PCR for 15 respiratory viruses. Patient-HCW interactions were observed. **RESULTS:** 100 samples were obtained from 72 HCW between Jan.18 and Feb 12, 2007, with nurses contributing 52 samples. Overall, 55% of the samples were from asymptomatic HCW. Of the 45 with symptoms, the most common were runny nose (33%) and sore-throat (12%). Testing revealed 16 positive samples (16%). Recovered pathogens included rhinovirus (6, 38%); non-SARS coronavirus 229E (3), adenovirus (2), respiratory syncytial virus, (2), and one each of influenza A and B and non-SARS coronavirus NL63. 22% of samples from symptomatic HCW were positive compared to 11% of samples from asymptomatic HCW (p=0.13). Nasal congestion and sore-throat predicted viral carriage (OR 4.4, p=0.009, 95% CI 1.5 - 13.5; OR 5, p=0.02, 95% CI 1.4 - 18.5, respectively). Five HCW showed viral acquisition by serial sampling and 3 showed a loss. Detection of virus was not associated with children at home or the number of shifts worked in the past week. During 19 hours of observations of multiple HCW interactions with 4 patients with respiratory illness, all patients were symptomatic, all interactions were within the 3 feet cough zone and neither the patients nor HCW routinely wore masks.

**CONCLUSIONS:** This pilot demonstrates that NP sampling of HCW can be performed in a busy ED. A diverse viral carriage was detected in symptomatic and asymptomatic HCW. The use of barrier methods to prevent transmission was low. In the setting of emerging infectious threats, further studies are needed to confirm occupational transmission of viruses from patients to HCW and improve countermeasures to protect both groups.

### 5570.5

Presentation Time 1:52 PM

#### A Randomized Controlled Trial Evaluating the Safety of a Quadrivalent HPV (6, 11, 16, 18) L1 VLP Vaccine in Adolescents

Keith S. Reisinger, Stan L. Block, Eduardo Lazcano-Ponce, Rudiwilai Samakoses, Katherine E. Giacoletti, Sara Kerin, Frances Alvarez, Heather L. Sings, Eliav Barr, Primary Physicians Research, Pittsburgh, PA; Kentucky Pediatric Research, Inc, Bardstow, KY; National Institute of Public Health, Cuernavaca, Morelos, Mexico; Phramongkutklao Hospital, Bangkok, Thailand; Merck and Co., Inc., West Point, PA.

**BACKGROUND:** A quadrivalent HPV vaccine has been licensed in over 50 countries for prevention of cervical cancer, genital warts, and vulvo/vaginal pre-cancerous lesions. The U.S. Advisory Committee for Immunization Practices and the American Academy of Pediatrics recommend routine vaccination of 11-12 year old girls with catch-up vaccination of 13-26 year females.

**OBJECTIVE:** We evaluated the tolerability of quadrivalent vaccine in boys and girls aged 9-15 years through 2 years post-vaccination.

**DESIGN/METHODS:** In this ongoing randomized, double-blind trial, 1781 sexually-naïve children were assigned (2:1) to vaccine or saline placebo at day 1, months 2 and 6. Subjects were observed for at least 30 minutes post-vaccination for any immediate reaction, with particular attention to allergic phenomena. Any systemic, injection-site, or serious adverse experience (SAE) was recorded on a diary card day 1-15 post-vaccination. Vaccine-related SAEs, deaths and new medical conditions were collected throughout the study.

**RESULTS:** A higher proportion of vaccine recipients than placebo recipients reported an injection-site AE following any vaccination. Over 2 years, six SAEs were reported, with one considered possibly vaccine-related (a 13 year old female was hospitalized for severe ulcerative colitis 389 days after receiving Dose 3). The cumulative incidences of autoimmune diagnoses were 0.32% among vaccine and 0.83% among placebo recipients. Overall 61.0% of subjects in the vaccine group and 60.7% of subjects in the placebo group reported new medical conditions during the entire follow-up period. Most common conditions reported were pharyngitis, upper respiratory infections, and influenza.

**CONCLUSIONS:** Administration of quadrivalent vaccine to healthy adolescent girls and boys was generally well tolerated over a two year observation period. These results support the implementation of universal HPV vaccination programs in adolescents to reduce the burden of clinical HPV disease, particularly cervical cancer.

### 5570.6

Presentation Time 2:05 PM

#### Feasibility of Elementary School Children's Use of Hand Gel and Face Masks during Influenza Season

M. A. Allison, G. Guest-Warnick, P. H. Gesteland, R. Srivastava, D. Nelson, A. T. Pavia, R. T. Rolfs, L. Calame, C. Byington, Dept. of Pediatrics, Univ. of UT, SLC, UT; UT Dept. of Health, SLC, UT; SLC Public Schools, SLC, UT.

**BACKGROUND:** School-age children are key vectors for influenza transmission in the community. Use of hand gel and face masks in schools could decrease the number of infected children and reduce influenza's spread, but the feasibility of this approach has not been

demonstrated.

**OBJECTIVE:** Conduct a feasibility study of an elementary school-based influenza prevention intervention by determining the acceptability of, adherence with, and barriers to use of hand gel and face masks among teachers and students.

**DESIGN/METHODS:** *Intervention:* Between 1/22/07 and 2/16/07, hand gel and face masks were provided to 20 teachers and their students at 2 elementary schools in SLC, UT. Gel use (4x/day) was promoted for 2 weeks then mask use (except during recess & lunch) was promoted for 2 weeks. *Outcomes:* Acceptability (disruptiveness and willingness to use again by Likert scale), adherence (4 categories), and barriers (open-ended) were measured by teachers' responses on weekly surveys. Observation of the proportion of students wearing masks was also used to measure adherence. Descriptive statistics were used to describe acceptability and adherence. Themes were identified for barriers.

**RESULTS:** The response rate for weekly surveys was 70 to 95%. 90% of respondents thought gel use was not/mildly disruptive, 97% would use gel next winter, and 97% would use gel in a pandemic. 39% thought mask use was not/mildly disruptive, 23% would use masks next winter, and 97% would use masks in a pandemic. For both weeks of gel use, 75% of teachers estimated that students used gel  $\geq$  4x/day. Mask use declined over time with 63% of teachers reporting regular mask use ( $\geq$  50% of students wearing) in week 1 and 29% in week 2. 11 to 95% of students were wearing masks in 42% (5/12) of observed classrooms in week 1, and 24 to 60% were wearing masks in 21% (3/14) of classrooms in week 2. Barriers to gel use were limited. Barriers to mask use were inability to see facial expressions and discomfort.

**CONCLUSIONS:** Frequent use of hand gel is a feasible prevention strategy in elementary schools. While overall adherence with face masks was low, some classrooms consistently used masks for 2 weeks and most teachers agree that they would use masks in their classroom in a pandemic.

### 5570.7

Presentation Time 2:18 PM

#### Apparent-Life Threatening Events (ALTE) Are a Significant Risk for Child Abuse and Chronic Epilepsy

Josh Bonkowsky, Elisabeth Guenther, Rajendu Srivastava, Francis Filloux,

Pediatrics, University of Utah, SLC, UT.

**BACKGROUND:** Short and long-term outcomes following apparent life-threatening events (ALTEs) are poorly characterized. An ALTE may be a risk factor for serious outcomes such as sudden infant death syndrome, non-accidental trauma (NAT), or abnormal neurological sequelae.

**OBJECTIVE:** To characterize the risks for death, child abuse, and abnormal neurological sequelae (including chronic epilepsy and developmental delay) following hospitalization for an ALTE, and to identify clinical characteristics that may predict these outcomes.

**DESIGN/METHODS:** Retrospective study of infants 0-12 months, admitted from 1999-2003 to a children's hospital for an ALTE. Patients were followed to 9/1/06. Inclusion criteria included breathing irregularity, color change, altered muscle tone, abnormal movements, or altered mental status. Exclusion criteria were known pre-existing condition or diagnosis apparent at the emergency room presentation. To determine outcomes the ALTE cohort was cross-referenced with the records of the state vital statistics and health departments, and for any inpatient or outpatient visit within the vertically-integrated health care system (20 hospitals and 100 clinics).

**RESULTS:** 446 patients met criteria for an ALTE. Median follow-up was 5.1 years. 56 patients (13%) had subsequent child abuse, including 14 (3.1%) with physical and/or sexual abuse. Only 2 patients were identified with NAT during initial hospitalization. 2 children died (0.44%); both deaths were related to their chronic epilepsy. No ALTE patient had SIDS. 21 patients developed abnormal neurological sequelae (4.9%). EEG and CNS imaging had sensitivities of only 7.6% and 7.1% for predicting the development of chronic epilepsy. Family history of seizures, male gender, neurology consultation, and anti-epileptic drug use had significant odds ratios for predicting chronic epilepsy (OR 5.3, 4.8, 5.6, and 5.6, respectively).

**CONCLUSIONS:** This study reports the short- and long-term outcomes of the largest cohort of patients admitted with an ALTE, with the greatest duration of follow-up, in the medical literature. Death is a rare event, occurring only after development of abnormal neurological sequelae. We found that 1 in 8 children admitted with an ALTE will have child abuse and 1 in 20 children will develop abnormal neurological sequelae. Current inpatient evaluation is of low yield to detect these outcomes.

### 5570.8

Presentation Time 2:31 PM

#### Impact of Vitamin E and Omega 3 Supplementation in Children with Verbal Apraxia

Claudia R. Morris, Marilyn C. Agin, Emergency Medicine, Children's Hospital & Research Center Oakland, Oakland, CA.

**BACKGROUND:** Verbal apraxia (VA) is a neurologically-based motor planning disorder of unknown etiology common in autism spectrum disorders (ASD) that anecdotally responds to omega 3 polyunsaturated fatty acid (PUFA) supplementation. Vitamin (vit) E deficiency causes symptoms that overlap those of VA. PUFAs in the cell membrane are vulnerable to lipid peroxidation & early destruction if vit E is not readily available, potentially leading to neurological sequelae. Inflammation of the gastrointestinal tract and gluten sensitivity may contribute to malabsorption of nutrients such as vit E and carnitine, contributing to fatty acid metabolism dysfunction and neurological abnormalities.

**OBJECTIVE:** Determine efficacy of vit E and PUFA supplementation in children with VA. **DESIGN/METHODS:** 50 children diagnosed with VA were treated with vit E + PUFA. 10 of these children were known to have ASD. A celiac panel, fat soluble vitamins, & carnitine

## Late Breakers I Poster Session

level was obtained in patients having blood analyzed.

**RESULTS:** Age ranged from 2-13 years, (majority < 5 yrs), & 38/50 were boys. A history of gastrointestinal symptoms, sensory integration dysfunction, low muscle tone & coordination difficulties (dyspraxia) was commonly reported. 48 families (96%) anecdotally reported dramatic improvements in a number of areas including speech, imitation, coordination, eye contact, behavior, sensory issues & the development of pain sensation. 2 children experienced new tearful or aggressive behavior within 3 days of initiating vit E (400 IU/d) without apparent benefits in speech, & therapy was withdrawn within a week. No other adverse effects were reported. Plasma alpha tocopherol levels varied in children tested (low in 2, high in 4 and normal in 4), however pre-treatment levels did not reflect clinical response. Low plasma carnitine was identified in 13/14 (93%) children. Antigliadin IgG antibodies were high in 9/11 (82%) children tested. 2 children reported vit D deficiency & early signs of rickets.

**CONCLUSIONS:** We describe a new disease paradigm of abnormal vit E & fatty acid metabolism causing neurological dysfunction in VA that responds to a safe nutritional intervention. The association of carnitine deficiency & gluten sensitivity with VA is a novel observation, suggesting that these children deserve a more comprehensive metabolic work-up than what is current standard practice. Larger controlled trials in apraxia & autism are warranted.

### 5570.9

Presentation Time 2:44 PM

Ph.D. Student

#### Prenatal Care and Delivery Room Staff Attitudes towards Research and the National Children's Study

L. M. Mudd, V. Skorokhod, S. Nechuta, M. R. Elliott, J. M. Lepkowski, N. Paneth, MANCS Coalition, Michigan State University, E. Lansing, MI; University of Michigan, Ann Arbor, MI.

**BACKGROUND:** The cooperation of healthcare personnel will be essential for implementing protocols of the upcoming National Children's Study (NCS).

**OBJECTIVE:** To assess attitudes of prenatal care and delivery room (DR) staff to recruitment and data collection for the NCS and towards research incentives.

**DESIGN/METHODS:** Staff from seven prenatal clinics (N = 82) in Kent County, MI and all three county delivery rooms (N = 167) completed an anonymous survey assessing willingness to participate in recruiting efforts (clinic staff) or data collection procedures (DR staff) for the NCS, as well as the amount of desired incentive, barriers to research, research experience, and demographics.

**RESULTS:** Clinic staff included 34 office workers, 28 nurses, 11 medical assistants and 6 physicians/physician assistants. DR staff included 127 nurses, 19 support staff, 11 physicians and 10 technicians. Clinic (92%) and DR staff (94%) felt that medical research was "very important". Clinic staff agreed to display or personally hand out brochures (72%), and verbally describe the NCS (65%) to eligible women, but only 44% wanted NCS staff to recruit patients in their clinic. DR staff were open to collecting placentas (84%) and cord blood (77%) or allowing NCS staff to collect these items (82%, 78%); however, when given the choice, DR staff preferred to self-collect specimens. Past research experience, race, age, and years of work experience did not influence willingness to recruit or collect data. Most clinic staff did not require incentive to display or hand out brochures (68%) or verbally describe the study to patients (60%). To obtain a placental sample, 16% of DR staff specified ≤ \$10 and 45% felt no incentive was needed. To collect cord blood 15% specified ≤ \$10 and 51% felt no incentive was needed. Lack of time was the most common barrier to research in both prenatal care (57%) and DR (82%). Clinic staff reported patient flow (46%), and DR staff lack of space (38%) as barriers.

**CONCLUSIONS:** Prenatal clinic and DR staff had positive attitudes towards research and were willing to participate in recruitment or data collection efforts for the NCS, but were aware of barriers to research in their clinical settings. Bringing in NCS study personnel to conduct research was unpopular in both prenatal clinics and delivery rooms.

## Late Breakers I Poster Session

Saturday, May 5

4:00pm-7:30pm

Exhibit Hall E, TCC

### 5912.1

Poster Board 552

#### Feasibility and Efficacy Trial of Automated Regulation of Inspired Oxygen in Mechanically Ventilated Preterm Infants

Nelson Claire, Carmen D'Ugard, Eduardo Bancalari, Division of Neonatology, Department of Pediatrics, University of Miami Miller School of Medicine, Miami, FL.

**BACKGROUND:** Most mechanically ventilated preterm infants present with spontaneous fluctuations in oxygen saturation and episodes of hypoxemia. Manual adjustment of the fraction of inspired oxygen (FiO<sub>2</sub>) is labor intensive and inconsistent. As a result, most infants spend considerable time with oxygen saturation (SpO<sub>2</sub>) above or below the intended range.

**OBJECTIVE:** To assess the safety and efficacy of a new neonatal ventilator system capable of automated FiO<sub>2</sub> regulation in a group of preterm infants with frequent episodes of hypoxemia.

**DESIGN/METHODS:** The study consisted of two consecutive 4-hr periods of routine and automated FiO<sub>2</sub> regulation in random sequence with an intended SpO<sub>2</sub> range of 88-95%. Data were analyzed for the entire 4-hr periods as intention to treat. Within-subject comparisons were done by Paired t-test.

**RESULTS:** Preliminary data from 6 infants (BW 608±134 g, GA 25.2±1.3 w, postnatal age 30±9 d, SIMV 19±7 b/m, PIP 19±2 cmH<sub>2</sub>O, PEEP 5.2±0.4 cmH<sub>2</sub>O, PSV 7±1 cmH<sub>2</sub>O) indicates

an increase in time spent within and a reduction in time spent above the intended range of SpO<sub>2</sub> during automated periods compared to routine care. The duration of hypoxemia did not differ. Median FiO<sub>2</sub> during 4 hrs of automated regulation was lower than during routine care while median SpO<sub>2</sub> did not differ.

	ROUTINE	AUTOMATED	p
%time SpO <sub>2</sub> > 95%	28.2 ± 7.8	13.1 ± 13.9	0.003
%time SpO <sub>2</sub> 88-95%	38.4 ± 7.0	49.9 ± 10.1	0.023
%time SpO <sub>2</sub> < 88%	32.3 ± 6.5	36.9 ± 8.3	0.197
%time SpO <sub>2</sub> < 75%	8.4 ± 6.8	6.6 ± 2.9	0.407
4-hr median FiO <sub>2</sub> (%)	34.8 ± 6.2	29.5 ± 4.1	0.013

**CONCLUSIONS:** These data suggest a reduction in hyperoxemia and inspired oxygen concentration with automated FiO<sub>2</sub> regulation leading to more time within the intended range of oxygenation compared to routine care in preterm infants with frequent episodes of hypoxemia. (Supported by Viiasys Healthcare).

### 5912.2

Poster Board 553

#### Effects of Early Aggressive Nutrition in Infants with Birth Weight (BW) <1250g: A Randomized Controlled Trial

Sudha Kashyap, Kirsten Abildskov, Stephen F. Holleran, Rajashekhar

Ramakrishnan, Helen M. Towers, Rakesh Sahni, Pediatrics, College of Physicians & Surgeons of Columbia Univ., New York, NY.

**OBJECTIVE:** To determine the effects of early aggressive nutritional regimen providing 18% of energy as protein vs. a conventional regimen providing 12.5% of energy as protein on growth and metabolic response of infants with BW<1250g. This will test the hypothesis that early higher protein intake is tolerated and results in better growth.

**DESIGN/METHODS:** Appropriate for gestational age infants with BW <1250g were prospectively randomized to an early total parenteral nutritional (TPN) regimen providing 18% of energy as protein (Group A) or a conventional TPN regimen providing 12.5% of energy as protein (Group C). Once the targeted protein intakes of 4g/kg.d (Group A) and 3g/kg.d (Group C) were achieved, they were maintained and the energy intake was increased to provide 100-105 kcal/kg.d. TPN was discontinued when 120ml/kg.d of enteral feeding was tolerated. Feeds were then advanced to provide protein intake of 4g/kg.d and energy intake of 132 kcal/kg.d for both groups. Growth and metabolic response were followed weekly. Group comparisons were made for growth at age 28 days and 1800g weight (lowest discharge weight) and for metabolic tolerance as determined by peak BUN concentration (P-BUN) and number of days BUN above 30mg/dl (H-BUN) using unpaired t-test or by ANCOVA with BW as a covariate.

**RESULTS:** There were no differences in weight (W), length (L) and head circumference (HC) at birth, the age TPN or enteral feeds were started, P-BUN, and H-BUN between the two groups. Rest of the data is summarized as group means below:

Group	Re-gain BW (days)	W-28d (g)	L-28d (cm)	HC-28d (cm)	L-1800g (cm)	HC-1800g (cm)	PMA-1800g (wks)
A (n=53)	10.0*		38.4	25.7*	42.1	28.7	33.5*
C (n=48)	12.3	1141	37.6	25.1	41.6	28.8	34.2

\*p<0.05, \*\*p<0.01 for Group A vs. Group C; PMA: post menstrual age

**CONCLUSIONS:** Earlier regain in BW, and greater W and HC at age 28 days were observed in infants randomized to early aggressive nutritional regimen compared to the conventional regimen. No group differences in L and HC at W-1800g were observed, suggesting similar composition of weight gain. The infants in Group A reached 1800g significantly earlier. These data support the hypothesis that early higher protein intake is well tolerated and results in improved growth in infants BW<1250g.

### 5912.3

Poster Board 554

Ph.D. Student

#### Many Conclusive Neonatal Meta-Analyses Are Inconclusive – An Audit of Neonatal Meta-Analyses with Trial Sequential Analyses

Jesper Brok, Kristian Thorlund, Jørn Wetterslev, Christian Gluud, Copenhagen Trial Unit, Center for Clinical Intervention Research, The Cochrane Hepato-Biliary Group, Rigshospitalet, Copenhagen University Hospital, Copenhagen, Denmark.

**BACKGROUND:** Recent research shows that meta-analyses often provide misleading evidence due to random errors. It is recommended that a sample size for a meta-analysis should be at least as large as a single trial. Evaluating meta-analyses before reaching the sample size with trial sequential monitoring boundaries (TSMB) (analogous to interim monitoring boundaries in single trials) adjust for the risk of random errors.

**OBJECTIVE:** To calculate the needed sample size and the adjacent TSMB in conclusive neonatal meta-analyses.

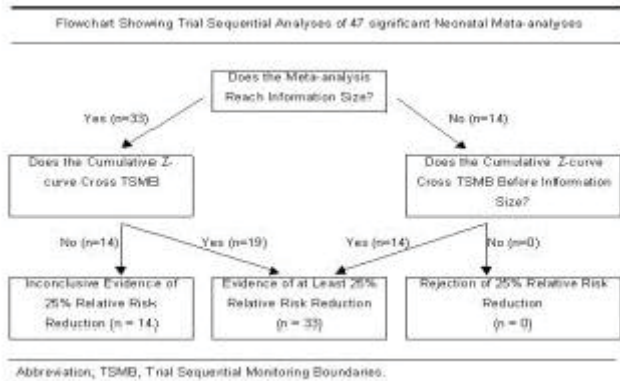
**DESIGN/METHODS:** We selected conclusive (P<0.05) Cochrane neonatal meta-analyses. For each meta-analysis we calculated the needed sample size, the TSMB, and constructed the cumulative Z-curve (ie, Z-statistics after each trial in a cumulative meta-analysis). These were constructed with a pre-specified relative risk reduction of 25% and type I<sub>2</sub> error of 5% and 20%. To obtain reliable significant meta-analytic evidence, the Z-curve should cross TSMB if the sample size is not reached.

**Outcome Measures:** Proportion of meta-analyses that did not reach the needed sample size.

Proportion of these meta-analyses in which the Z-curve did not cross TSMB. The number of participants required to reach the sample size.

RESULTS: Of 47 eligible meta-analyses 33 (70%; 95% CI, 55-88%) did not reach the sample size needed to accept or reject a 25% relative risk reduction. Of these, 14 meta-analyses (42%; 95% CI, 26-61%) were inconclusive as the cumulative Z-curve did not cross the TSMB. In these meta-analyses, the median number of patients required to reach the needed sample size was 1492 participants (range 174-8376).

CONCLUSIONS: Many 'conclusive' neonatal meta-analyses are inconclusive.



## 5912.4

### Poster Board 555

#### Parenteral Nutrition-Associated Liver Disease and Omega-3 Lipid Emulsions: Preliminary Findings on Safety and Efficacy

Kathleen M. Gura, Sang Lee, Christopher Duggan, Mark Puder, Pharmacy, Children's Hospital Boston, Boston, MA; Department of Surgery, Children's Hospital Boston, Boston, MA; The Vascular Biology Program, Children's Hospital Boston, Boston, MA; Department of Gastroenterology, Children's Hospital Boston, Boston, MA.

BACKGROUND: Intravenous fat emulsions (IFE) have been implicated in the development of cholestasis, a common precursor of parenteral nutrition associated liver disease (PNALD) in children.

OBJECTIVE: The purpose of this study was to evaluate the safety and initial efficacy of parenteral fish oil-based omega-3 lipid emulsion in the treatment of PNALD.

DESIGN/METHODS: The setting was a tertiary pediatric hospital. Patient ages ranged from 1-7 months (mean 3.4 ± 1.7). Primary diagnoses included necrotizing enterocolitis, gastrochisis, malrotation/midgut volvulus, intestinal atresia, and perforated small bowel obstruction. Inclusion criteria were PN dependence and cholestasis, confirmed by liver biopsy and/or direct bilirubin (DB) greater than 2 mg/dL. Patients were administered fish oil-based omega-3 emulsions instead of standard soybean-based omega-6 emulsions (n = 18). Dosage began between 0.2-0.5 g/kg/day and advanced to 1 g/kg/day. Treatment duration ranged from 1-25 months (mean 5.1 ± 5.8). Additional non-protein calories were provided via carbohydrates per standard of care and no other parenteral form of fat was administered. Enteral feeds were advanced per standard of care. Monitoring included serum fatty acid profiles and liver function tests. Compassionate use was approved by the IRB and FDA.

RESULTS: Initial DB levels ranged from 2.5-10 mg/dL (mean 5.5 ± 2.5). All patients tolerated the intravenous infusion of omega-3 lipid emulsions without any associated complications. There was no evidence of bleeding or essential fatty acid deficiency. All patients experienced normalization of bilirubin (DB < 2), in the setting of varying degrees of enteral nutrition, with elapsed time ranging from 14.5-91.5 days (mean 56.5 ± 23.4). There were two deaths, secondary to aspiration pneumonia and withdrawal of care.

CONCLUSIONS: We conclude that parenteral omega-3 lipid emulsions may be a safe alternative to standard omega-6 lipid emulsions in the nutritional support of pediatric patients with PN-associated liver disease. Initial results demonstrate resolution of cholestasis, indicating potential reversal of this disease.

## 5912.5

### Poster Board 556

#### Quantitative EEG in Babies at Risk for Hypoxic Ischemic Encephalopathy after Perinatal Asphyxia

Manan Hathi, Neil Rothman, Lisa Korst, Tom Pantano, Terrie Inder, Ananth Natarajan, Infinite Biomedical Technologies, Baltimore, MD; University of Southern California, Los Angeles, CA; Brainz Instruments Ltd, Auckland, New Zealand; Washington University in St. Louis, St. Louis, MO.

BACKGROUND: Perinatal Asphyxia affects 3 per 1,000 live term newborns and is responsible for 19% of neonatal deaths worldwide. Survivors suffer from an encephalopathy associated with cerebral injury from hypoxia ischemia (HIE). Objective recognition of HIE in the term infant remains challenging for neonatal clinicians.

OBJECTIVE: To evaluate a novel EEG based index, the Cerebral Health Index in babies (CHI/b) following perinatal asphyxia.

DESIGN/METHODS: The CHI/b was evaluated in 20 babies with HIE and 20 controls. All infants underwent 2-Channel bedside EEG monitoring. Diagnoses were made on clinical

grounds by the attending physician based on history and examination findings. The stage of encephalopathy was graded for all of the infants with HIE using a modified Sarnat clinical classification with maximum score within 72 hours of admission being noted. The EEGs were read by a trained electroencephalographer blinded to all clinical data. The EEGs were classified as Green (normal), Yellow (mildly abnormal) or Red (severely abnormal).

RESULTS: *Sarnat Score*: Single factor ANOVA (equal variance) of the four groups (Sarnat 1, 2, 3 and controls) showed that the mean CHI/b differed across groups {p=0.002}. A Receiver Operator Characteristic (ROC) curve analysis demonstrated that the CHI/b had an optimal discriminating ability of 90.9% between good outcome (controls and Sarnat 1) and bad outcome (Sarnat 2 and Sarnat 3) (sensitivity: 82.4%; specificity: 88.9%).

*Visual EEG Interpretation*: Statistical analysis of the CHI/b results demonstrated classification ability of CHI/b for the three groups (Single Factor ANOVA, p<8E-7). There were differences in the Green vs. Yellow (p<0.002); Yellow vs. Red (p<0.0002) and Green vs. Red (p<9E-7) groups. An ROC analysis demonstrated that the optimal ability of CHI/b to discriminate poor outcome (Red EEG) was 97.1% (sensitivity: 80.0%; specificity: 89.3%).

CONCLUSIONS: CHI/b was found to be associated with the Sarnat Score and visual EEG grading. These results suggest its potential use as an objective indicator of neurological injury and recovery in term infants with HIE.

## 5912.6

### Poster Board 557

#### Fluconazole Prophylaxis and Candidemia: Case-Control Analysis of a Multicenter Study Database

David Kaufman, Amy Morris, Barry Kapik, Seth Hetherington, Pediatrics, University of Virginia Children's Hospital, Charlottesville, VA; Inhibitex, Atlanta, GA.

BACKGROUND: Invasive *Candida* infections are associated with high mortality and morbidity in preterm infants. Studies of fluconazole prophylaxis has demonstrated efficacy and further studies are needed to evaluate safety.

OBJECTIVE: Evaluate the incidence of candidemia and fluconazole prophylaxis on outcomes from a multicenter database.

DESIGN/METHODS: We used the database of the Veronate 006 Phase III study to analyze the impact of the use of antifungals on candidemia. In the parent study, infants with BW between 500 and 1250 g were enrolled and randomized to receive Veronate or saline placebo. Patients had data collected over 70 days or until discharge, transfer to another institution or death. The use of antifungals for prophylaxis was specifically designated on the case report form by the investigator, but the decision to use antifungals was at the discretion of the investigator.

We conducted a case-control analysis. For each infant receiving antifungal prophylaxis (case), 3 infants not receiving antifungal (controls) were matched by BW (±50 g), and when possible, by gestational age (±1 week), gender, and study site. Differences between these two groups of infants on rates of infection and morbidities were performed using a Cochran-Mantel-Haenszel Chi-squared test, controlling for birth weight group. Adverse events and serious adverse events were analyzed.

RESULTS: The 125 patients receiving fluconazole prophylaxis had a mean BW of 754 g and the 399 control patients had a mean BW of 756 g. Maternal use of antibiotics within 24 hours of delivery and Apgar scores were higher among the prophylaxis group, but otherwise there were no demographic differences from the control group.

One (0.8%) of 126 infants in the prophylaxis group compared to 22 of 399 matched controls (5.5%) developed candidemia (p=0.019). There were no differences in late-onset sepsis due to gram-positive or gram-negative organisms or necrotizing enterocolitis. Cholestasis and urodexoycholic acid use was similar between both groups. Information of fungal susceptibilities was not available. There was also no difference in overall mortality between cases and controls.

CONCLUSIONS: Use of fluconazole prophylaxis was associated with a reduced rate of candidemia. This multicenter data adds to the efficacy and safety data in preterm infants <1000 g.

## 5912.7

### Poster Board 558

#### The Global Network's FIRST BREATH Study: Testing the Impact of World Health Organization Essential Newborn Care Training on Neonatal and Perinatal Mortality

Waldemar A. Carlo, the FIRST BREATH Study Group.

BACKGROUND: 99% of the 4 million neonatal deaths and 3 million stillbirths per year occur in developing countries. The World Health Organization (WHO) Essential Newborn Care (ENC) course is an educational program that sets minimum training standards for neonatal care providers, including routine care, resuscitation, thermoregulation, breastfeeding, kangaroo care, and small baby care.

OBJECTIVE: To determine if ENC training reduces all-cause early (7-day) neonatal and perinatal (stillbirth plus all-cause 7-day) mortality in a multicenter population-based study.

DESIGN/METHODS: 3,676 birth attendants from 95 communities (clusters) in 6 countries (Argentina, DR Congo, Guatemala, India, Pakistan, Zambia) were certified in data collection and ENC using a train-the-trainer model and local trainers. Active baseline data collection was done on infants 1500 grams for 6±1 months before and for 8±2 months after ENC training (duration based on the births/community to establish baseline early neonatal mortality rates). To test the difference in the rates of pre and post ENC periods, the variance was adjusted for the cluster design.

RESULTS: Consent was obtained on 99.7% of births. Births (n=55,593) occurred at home (66%) or hospital/clinic (34%) and were attended by traditional birth attendants (51%), nurses (27%), physicians (16%), or family members (6%). 7-day follow-up rate was 99.5%. Perinatal mortality decreased from 45.8 to 37.8/1000 after ENC training (p<0.05, a relative

## Late Breakers II Poster Session

risk reduction of 17%). Rates of stillbirth decreased (due to a reduction in fresh stillbirths) but all-cause 7-day mortality remained the same.

	Pre-ENC N=22,771	Post-ENC N=32,822	p-value
Perinatal mortality rate	45.8/1000	37.8/1000	<0.05
Stillbirth rate	22.8/1000	14.8/1000	<0.001
All cause 7-d mortality rate	23.0/1000	23.0/1000	NS

**CONCLUSIONS:** WHO ENC training of birth attendants reduced perinatal mortality by 8/1000 due to a decrease in fresh stillbirths. Training in resuscitation and in differentiating stillbirth from early neonatal death may explain the type of death averted. To assure generalizability, further research is needed to determine if ENC training can markedly reduce perinatal mortality worldwide.

Funded by the NICHD Global Network for Women's and Children's Health Research and the Bill and Melinda Gates Foundation.

## Late Breakers II Poster Session

Monday, May 7

3:00pm-6:45pm

Exhibit Hall E, TCC

8455.1

Poster Board 546

### Single Versus Double Umbilical Cord Blood Transplantation (UCBT): Higher Risk of Acute Graft-Versus-Host Disease (GVHD) but Lower Transplant Related Mortality (TRM) in Recipients of Double UCBT

Margaret L. MacMillan, Claudio R. Brunstein, Todd E. DeFor, Qing Cao, Bruce R. Blazar, Daniel J. Weisdorf, Pediatric Blood and Marrow Transplant Program, University of Minnesota, Minneapolis, MN.

**BACKGROUND:** Transplantation of 2 partially HLA matched UCB units has been shown to be a safe and effective means to overcome the cell-dose barrier in adolescents and adults. In addition, preliminary data suggest that double UCBT is associated with a greater graft-versus-leukemia effect (Blood 2005;106:93a).

**OBJECTIVE:** To conduct a comparative analysis on the risk of acute GVHD in single vs double UCB recipients.

**DESIGN/METHODS:** Transplant outcomes were compared between 210 single and 169 double UCBT consecutive transplant recipients at the University of Minnesota.

**RESULTS:** Incidences of grades II-IV and III-IV acute GVHD were higher in recipients of double than single UCBT recipients (60% vs 33%, p.01) and (21% vs 11%, p=.01), respectively. Adjusting for differences between groups, two factors were associated with the development of grade II-IV acute GVHD in Cox regression: use of 2 UCB units (RR 2.0 vs 1.0 [95% CI, 1.3-3.2, p.01]) and absence of ATG in the preparative regimen (RR 1.0 vs 0.5 [95% CI, 0.3-0.8, p.01]). Other factors that were tested in the model but not determined to be significantly associated with acute GVHD were recipient age, gender, weight, diagnosis, time from diagnosis to UCBT, HLA disparity, total and CD3 cell dose, CMV serostatus, conditioning regimen, and GVHD prophylaxis. Despite increased risk of acute GVHD, TRM 1 year was significantly lower in recipients of double UCBT (17%, 95% CI, 5-29%) as compared to recipients of a single UCBT (47%, 95% CI, 26-68%; p=.02) among those that developed grade III-IV acute GVHD. Survival at 1 year among those with grade III-IV acute GVHD was significantly higher after double UCBT (67%, 95% CI, 51-83%) than after single UCBT (41%, 95% CI 21-61%; p=.04).

**CONCLUSIONS:** In conclusion, risk of acute GVHD is significantly higher in recipients of two partially HLA matched UCB units, yet it does not appear to adversely effect TRM or survival. ATG in the preparative therapy, however, does not appear to reduce TRM despite its favorable association with reduced GVHD. Impact of GVHD on immune recovery and infection risk in recipients of single and double UCBT is under investigation.

8455.2

Poster Board 547

### Thymic Shielding (TS) in Recipients of Total Body Irradiation (TBI) and Alternative Donor Hematopoietic Stem Cell Transplant (AD-HSCT): Reduced Risk of Opportunistic Infection in Patients with Fanconi Anemia (FA)

Margaret L. MacMillan, Bruce R. Blazar, Todd D. DeFor, Kathryn R. Dusenbery, John E. Wagner, Daniel J. Weisdorf, Pediatric Blood and Marrow Transplant Program, University of Minnesota, Minneapolis, MN.

**BACKGROUND:** Delayed immune reconstitution and consequent opportunistic infections remain major obstacles to successful HSCT, particularly in older patients, those with HLA mismatched donors and in selected diseases such as FA.

**OBJECTIVE:** Based on preclinical work suggesting that TS may improve immune reconstitution in recipients of TBI and allogeneic HSCT (J Immunol 1987;139:358), we evaluated the safety and potential efficacy of TS in FA patients.

**DESIGN/METHODS:** After CT localization of the thymus, blocks were fabricated to shield the thymus. Otherwise all patients received the standard regimen of fludarabine 175 mg/m<sup>2</sup>, cyclophosphamide 40 mg/kg, single fraction TBI 450 cGy, and ATG, with CSA and methylprednisolone as GVHD prophylaxis. In order to assess the potential risks and benefits of

TS, we compared outcomes of these FA patients who received TS to FA patients treated with the exact same preparative regimen without TS.

**RESULTS:** Between April 1999-June 2006, 59 FA patients underwent AD-HSCT at the University of Minnesota; 16 patients had TBI with TS and 43 had TBI without TS. While excess graft failure was considered the principal toxicity risk in recipients of TS, incidence of engraftment was similar in those with and without TS. Importantly, TS was associated with a significantly lower risk of opportunistic infection after HSCT (table).

Pre-parative Regimen	Impact of TS on HSCT Outcomes					
	Probability of Neutrophil Engraftment (95% CI)	Probability of Survival at 1 Year (95% CI)	Total # Infections	# Bacterial Infections	# Viral Infections	# Fungal Infections
TBI with TS (n=16 patients)	94 (82-100)	67 (23-91)	9	4	3	2
Without TS (n=43 patients)	97 (92-100)	53 (38-68)	126	68	37	21
P value	NS	NS	<.01	<.01	<.01	<.01

**CONCLUSIONS:** In conclusion, TS in TBI recipients is associated with significantly lower risk of opportunistic infections without any deleterious effect on hematopoietic recovery.

While these results indicate that TS reduces the infection rate and potentially improves survival in patients with FA, they also suggests that TS should be considered for other high risk populations (e.g. adults) and in those with other non malignant disorders.

8455.3

Poster Board 548

### Phase 1 Safety, Pharmacokinetic, and Exploratory Biomarker Study of IV Temsirolimus in Children with Advanced Solid Tumors

S. L. Spunt, S. Grupp, T. Vik, V. Santana, D. Greenblatt, R. Gilbertson, B. Hewes, J. Boni, B. Esteves, L. Speicher, St Jude Childrens Research Hospital, Memphis, TN; Childrens Hospital of Philadelphia, PA; James Whitcomb Riley Hospital for Children, Indianapolis, IN; Tufts University School of Medicine, Boston, MA; Wyeth Research, Cambridge, MA; Colledgeville, PA.

**BACKGROUND:** The mTOR inhibitor temsirolimus shows antitumor activity in various adult cancers, improved overall survival in renal cell carcinoma, is generally well tolerated. To date, no clinical studies examined temsirolimus in children.

**OBJECTIVE:** Assess safety, identify maximum tolerated dose (MTD) of temsirolimus in children; determine pharmacokinetics, pharmacodynamics, and preliminary antitumor activity.

**DESIGN/METHODS:** Open-label study of once weekly IV temsirolimus administered to patients (pt) 1-21 yr with relapsed/refractory advanced solid and central nervous system tumors. Sequential cohorts of 3-6 pts given 10, 25, 75, and 150 mg/m<sup>2</sup>.

**RESULTS:** 19 pts (11 male, 69% white, median age 11 yr [range 4-21 yr]) enrolled. Common primary diagnoses: osteosarcoma/rhabdomyosarcoma (3 pts each), medulloblastoma/neuroblastoma (2 pts each). Dose escalation halted at 150 mg/m<sup>2</sup> due to gr 3 anorexia (1 pt), gr 4 thrombocytopenia (1 pt, duration <7 days). Most common AEs: leukopenia, thrombocytopenia, anemia, hyperlipemia, increased AST, neutropenia, anorexia, hypercholesteremia, hypokalemia, hypoproteinemia, rash, vomiting, diarrhea, mucositis, asthenia, fever, hyperglycemia, nausea. 7 pts had ≥gr 3 treatment-related AEs: neutropenia, leukopenia, anemia, anorexia, thrombocytopenia, increased ALT. 1 pt (stage 4 neuroblastoma) had complete response (treated 253 days); 4 stable disease (treated 77-379 days), incl 1 pt with posterior fossa ependymoma (treated 379 days). C<sub>max</sub> comparable to adults; temsirolimus AUC higher in children. Greater exposure to parent drug appeared balanced by shorter t<sub>1/2</sub>, lower AUC of sirolimus metabolite. Analysis of pS6, Akt proteins in peripheral blood mononuclear cells confirmed temsirolimus 75 mg/m<sup>2</sup> significantly inhibited Akt pathway signaling.

**CONCLUSIONS:** IV temsirolimus generally well tolerated in children with advanced solid tumors; preliminary data suggest Akt pathway inhibition, antitumor activity. Additional children with neuroblastoma, rhabdomyosarcoma, or high-grade glioma are receiving 75 mg/m<sup>2</sup> weekly to verify safety and further evaluate antitumor activity.

8455.4

Poster Board 549

### The Safety of High Concentration Nitrous Oxide for Procedural Sedation and Analgesia in Children

Franz E. Babl, Cameron Seaman, Ed Oakley, Peter Barnett, Emergency Department, Royal Children's Hospital, Melbourne, Victoria, Australia.

**BACKGROUND:** Nitrous oxide (N<sub>2</sub>O) is an attractive agent for procedural sedation and analgesia (PSA) in the emergency department (ED). However, safety data for high concentration continuous flow N<sub>2</sub>O (50% to 70%), the most useful form in children, are limited. We set out to determine the adverse events profile in the ED setting.

**OBJECTIVE:** To evaluate the safety of high concentration continuous flow N<sub>2</sub>O. **DESIGN/METHODS:** Prospective observational study of N<sub>2</sub>O use for PSA at a tertiary children's hospital ED. PSA administration is part of a comprehensive sedation education and quality assurance program. N<sub>2</sub>O concentration, adverse events and sedation depth were recorded. Adverse events were categorized as mild or serious. Sedation depth was recorded on a 0 to 6 sedation scale (0=unresponsive to painful stimuli, 6=anxious, agitated or in pain). **RESULTS:** 772 patients received N<sub>2</sub>O during the study period. Mean age was 6.9 years (SD

## Late Breakers II Poster Session

4.0), 60% were male. 550 (71%) received N<sub>2</sub>O 70%, 101 (13%) received N<sub>2</sub>O 50%. Procedures under sedation were mainly orthopaedic (39%) and laceration repair (29%). Deep sedation with scores of 2 or less (2=arouses slowly to consciousness with sustained painful stimuli) occurred in 1% (95% CI 0.3%-6%) of N<sub>2</sub>O 50% and 3% (95% CI 2%-5%) of N<sub>2</sub>O 70% (p=0.157). 66 (8.5%, 95% CI 6.7%-10.7%) patients had 84 mild and self resolving adverse events mostly vomiting (6%). 2 (0.3%, 95% CI 0.03%-0.9%) patients had serious adverse events (1 chest pain, 1 desaturation with admission for observation) though no patient suffered a clinically apparent pulmonary aspiration, laryngospasm or required advanced airway support. There was no significant difference in adverse events rates between N<sub>2</sub>O 50% and 70% (p=0.5).

CONCLUSIONS: In this large prospective ED series, high concentration continuous flow N<sub>2</sub>O was found to be a safe agent for PSA when embedded in a comprehensive sedation program.

### Poster Board 550

WITHDRAWN

## 8455.6

Poster Board 551

### Body Mass Index in Adolescence Predicts Diabetes and Coronary Artery Disease in Adulthood: A 20-Year Follow up

Gal Dubnov-Raz, Irit Tirosh, Tzipora Shochat, Amir Tirosh, Pediatrics, Mt. Scopus, Hadassah-Hebrew University Medical Center, Jerusalem, Israel; Pediatrics B, Schneider Children's Medical Center, Petah Tikva, Israel; Medical Corps Headquarters, Israel Defense Forces Medical Corps, Israel; Internal Medicine A+C, Sheba Medical Center, Tel-Hashomer, Israel.

BACKGROUND: The prevalence of pediatric and adolescent obesity is continuingly increasing worldwide. The relationship between body-mass-index (BMI) in youth and adult morbidities are not clear.

OBJECTIVE: The aim of this study was to examine the association between BMI in adolescents and future incidence of coronary-artery-disease(CAD) and diabetes.

DESIGN/METHODS: We used data from the Israeli Defense Forces Personnel cohort, in which measured weight and height were recorded for 11,891 male adolescents (mean age 17.2±0.3 yrs) before recruitment for military service, and their incidence of CAD and diabetes 20 years later.

RESULTS: 11,891 adolescents were divided into quintiles (Q1-5) according to BMI (mean ± SD: 17.89±0.79, 19.56±0.36, 20.78±0.35, 22.23±0.51 and 25.63±2.48 kg/m<sup>2</sup> for Q1-Q5, respectively). There were 127 cases of CAD and 252 cases of diabetes, during 233,302 person-years of follow-up.

In a multivariate model adjusted for age, family history of heart diseases, blood-pressure, smoking, physical activity, total cholesterol/HDL-c ratio and LDL cholesterol, the incidence of CAD at the mean age of 37 years was independently associated with BMI at the age of 17 years: this risk increased linearly across BMI quintiles reaching a hazard-ratio of 2.23(1.03-4.86) and 4.09(1.95-8.58) for Q4 and Q5, respectively. Similarly, the risk of diabetes at adulthood was directly associated with BMI at adolescence, reaching a hazard-ratio of 2.98(2.08-4.26) for Q5 as compared with Q1.

CONCLUSIONS: At the age of 17 years, BMI greater than 21.5 and 23.2 kg/m<sup>2</sup> are independently associated with increased risk for adulthood CAD and diabetes, respectively. These values represent the 50th and 75th percentiles of the CDC BMI-for-age growth chart, suggesting an alarming elevated risk for adulthood disease even within the normal range of BMI in youth.

## 8455.7

Poster Board 552

### The Effects of a Dance Revolution Exercise Program in Obese

#### Adolescents: A Randomized Controlled Trial

Casey Hester, Laura Chalmers, Aditi Sule, Sara Vesely, Andrew Gardner, David Fields, Kenneth Copeland, Terrence Stull, Pediatrics, University of Oklahoma Health Sciences Center, Oklahoma City, OK.

BACKGROUND: Obesity is epidemic in adolescents. Exercise is one tool in the battle against obesity; however, obese children are less likely to participate in traditional exercise than their normal weight peers. Recently, physically interactive video games incorporating fun into exercise, such as Dance Dance Revolution (DDR), have become available for use with home gaming systems. No studies have yet evaluated DDR's efficacy as an exercise regimen, particularly with respect to the known health risks of obesity.

OBJECTIVE: To determine the effects of a 10-week program of DDR on body composition, arterial elasticity, fasting lipids, and insulin sensitivity in obese adolescents.

DESIGN/METHODS: 41 obese adolescents (mean age 14 yrs, SD±2; mean BMI 33.5, SD±5.2) were recruited and randomized to either a supervised 3 hour per week, 10 week program of DDR or to a non-exercising control group. Heart rates were maintained during each DDR session at 75% maximum. Body composition (BodPod and Tanita Bioelectrical Impedance), arterial elasticity (Hypertension Diagnostics, Inc. CR-2000), fasting lipids, glucose and insulin were obtained in all subjects within one week pre-intervention and within 2 days post-intervention. Independent t-tests were performed to compare the change scores of each variable between the two groups. All measurements were adjusted for gender.

RESULTS: 20 of 21 DDR subjects and 20 of 20 control subjects completed the study; completion for DDR subjects was defined as full attendance at ≥28 of 30 total sessions. Total cholesterol lowered an average of 13.2 points more in the DDR group than in the control group

(p=.034), while LDL lowered an average of 12.5 points more (p=.048). The change scores of the remaining measures were similar (p>.05) between the two groups.

CONCLUSIONS: In this pilot study, a ten week, 3 hour per week supervised trial of DDR performed at 75% heart rate maximum intensity decreased total cholesterol and LDL in obese adolescents. Furthermore, adherence to the DDR exercise regimen was remarkably high in this sedentary population. Larger studies using DDR for a longer duration, and in combination with dietary and behavioral components, may be necessary to demonstrate efficacy for changes in other outcome variables in obese adolescents.

## 8455.8

Poster Board 553

### A National Survey of Pediatricians: Attitudes and Practices towards Influenza Vaccination

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BACKGROUND: In 2004, influenza vaccination recommendations were expanded to include all children 6-24 months, and, in 2006 all children 6-59 months.

OBJECTIVE: Examine pediatricians' attitudes and reported practices toward influenza vaccination.

DESIGN/METHODS: A national random sample, mailed Periodic Survey of American Academy of Pediatrics U.S. members, in 2006 (N=1620; response=53%). Questions assessed systems to identify target children and factors to consider in recommending influenza vaccination for all children. Analysis was limited to 629 pediatricians who offer immunizations.

RESULTS: Most (96%) pediatricians offer influenza vaccination to patients ≥24 months at high risk for influenza-related complications. The majority report no systematic method of identifying these patients, although nearly 40% use a list of children with eligible conditions. About half of pediatricians usually or occasionally offer influenza vaccination to parent's of at-risk children. Factors that > two-thirds of pediatricians believe should strong or very strong considerations in recommending universal influenza vaccination of all children include risk of influenza-related complications, vaccine supply, availability of VFC vaccine, and feasibility for practices to implement recommendations. Most pediatricians thought there should be a universal recommendation for influenza vaccination of all children ≥24 months (65%) or were unsure (21%).

CONCLUSIONS: While almost all responding pediatricians offer annual influenza vaccination to patients ≥24 months at high risk for influenza-related complications, the majority report no systematic method of identifying these patients. In addition, almost half do not offer influenza vaccination to parent's of at-risk children. Pediatricians feel positive regarding universal vaccination of all children ≥24 months.

## 8455.9

Poster Board 554

### Adolescent Risk Reduction in Developing Countries: An HIV Prevention Intervention with and without a Parental Monitoring Component Targeting Sixth Grade Students in the Bahamas

Sharon P. Marshall, Lynette Deveaux, Bonita Stanton, Sonya Lunn, Leslie Cotrell, Shuli Yu, Nanika Brathwaite, Xiaoming Li, Hong Jie, Carol Harris, The Carman and Ann Adams Department of Pediatrics, Wayne State University School of Medicine, Detroit, MI; Office of AIDS, Bahamas Ministry of Health, Nassau, Bahamas; Health Research Center, West Virginia University, Morgantown, WV. BACKGROUND: The global burden of HIV/AIDS overwhelmingly affects developing countries.

OBJECTIVE: This study was undertaken in one developing country (The Bahamas) to address the six month efficacy of a youth HIV prevention intervention delivered with and without a parental monitoring intervention.

DESIGN/METHODS: Randomized controlled, three-cell trial delivered to 1282 Bahamian sixth grade students (and 1175 parents) in 15 schools. Youth and parents were randomized at the level of the school to receive a) Focus on Youth in the Caribbean (FOYC) plus Caribbean Informed Parents and Youth Together (CImPACT); b)FOYC plus an attention control for the parents [Goal for It (GFI)]; c) an attention control for the youth [Wonderous Wetlands (WW) plus GFI. The 10-session FOYC or WW curriculum was delivered as part of the elementary school curriculum. GFI or CImPACT was delivered to parents in the evening/weekends.

Baseline and six month follow-up questionnaires were administered to parents and youth to assess risk and protective knowledge, concom-use skills, perceptions, interventions and self-reported behaviors.

RESULTS: FOYC compared to WW significantly increased knowledge, condom use skills, protective perceptions, and intentions to engage in safer behaviors. Among youth, there were no differences in knowledge or condom-use skills based on parent intervention; among parents, those receiving CImPACT demonstrated superior condom-use skills post intervention.

CONCLUSIONS: Protective knowledge, skills, perceptions and intentions of youth from one developing country can be significantly improved by a youth intervention delivered through the schools. Longer follow-up is needed to determine if risk behaviors will be reduced and how

long protective results will be sustained.

**Key words:** Developing countries; HIV prevention; Adolescents, risk behavior, parenting.

## 8455.10

Poster Board 555

### Increasing Involvement of Pediatric Residents in Community Activities: 2002 to 2006

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**BACKGROUND:** Although residency programs are required to offer structured community experiences, implementation of work hours restrictions and core competencies may limit opportunities for community involvement.

**OBJECTIVE:** To assess changes in pediatric residents' perspectives and involvement in community activities from 2002 to 2006.

**DESIGN/METHODS:** National mailed surveys of pediatric residents in 2002 and 2006, drawn from the AMA Masterfile. Residents reported perceived importance of training in 10 community settings and 6 additional activities in residency (1- none to 4- very), participation in these settings and activities in residency (1- none to 4- 30+ days), 7 benefits of community involvement, and mentoring related to community involvement. We dichotomized responses for perceived importance (none/limited vs. moderate/very) and participation in residency (any vs. none). Chi square statistics compared perspectives and involvement over time.

**RESULTS:** 700 residents (43%) in 2002 and 652 (40%) in 2006 responded. Over time, more respondents were female (67% in 2002 vs. 76% in 2006) with no change in mean age, having debt, or having a source of guidance and advice regarding community pediatrics.

Over time, residents reported increased importance of training in 7 settings (Head Start, juvenile justice, shelter, community health center, health dept, home visiting, international health, all  $p < .05$ ), the same importance for 2 settings (schools, day care), and less importance for 1 setting (special needs camp, all  $p < .05$ ). Residents identified greater importance of committee membership (39.3% vs. 47.6%), community-based research (42.0% vs. 53.6%), longitudinal community projects (41.9% vs. 53.5%), and child health advocacy (81.1% vs. 87.5%, all  $p < .05$ ). In 2006, more residents had training in juvenile justice, international health, community-based research, longitudinal projects, and advocacy (all  $p < .05$ ). Perceived importance was associated with more involvement in all settings ( $p < .01$ ); involvement was associated with having a mentor for most activities. In 2006, residents reported more benefits of community activities.

**CONCLUSIONS:** Residents report increased importance of and exposure to community activities during training. Studies are needed to assess whether this heightened emphasis leads to enhanced involvement as careers develop.

## 8455.11

Poster Board 556

### Hematopoietic Stem Cell Transplant for Osteopetrosis

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**BACKGROUND:** Autosomal recessive osteopetrosis (arOP) is generally lethal in the first decade of life without allogeneic hematopoietic stem cell transplantation (HCT).

**OBJECTIVE:** To evaluate the outcomes of patients undergoing transplantation, we examined the long-term survival after HCT in 124 children with arOP reported to the Center for International Blood and Marrow Transplant.

**DESIGN/METHODS:** The data reflects outcomes of transplantation for patients with arOP from 1978-1999. The median age at HCT was 8 months, and median time from diagnosis to transplantation 4 months. Forty percent of allografts were from HLA-matched siblings, 34% from unrelated donors and 26% from alternative related donors. Busulfan and cyclophosphamide was the most commonly used conditioning regimen (74%) and bone marrow the predominant graft source (87%).

**RESULTS:** The cumulative incidence of neutrophil recovery at day +100 was 75% (93 of 124) with similar rates across the three donor sources. Fifty-four children are alive with a median follow up of 7.5 years and an 8-year probability of survival of 43%. The 8-year probabilities of survival were 54%, 39% and 35% after HLA-matched sibling, alternative related and unrelated donor transplantation, respectively. Early mortality rates were high regardless of donor type; 34% at day 100 and 50% at 1-year after HCT. Common causes of mortality were graft failure (33%), interstitial pneumonitis or ARDS (34%), infections (12%) and GVHD (10%). Nineteen patients underwent a second HCT for either primary or late graft failure. Six of these patients are alive. Most second transplants occurred within 6 months (n=15) and the remaining 4 occurred at 4, 4.5, 5 and 9 years after the first transplant.

**CONCLUSIONS:** We conclude that long term survival for arOP can be obtained with HCT. Peri-transplant mortality and graft failure remain significant obstacles in this population. Second transplantation is a viable option if engraftment is not initially achieved.

## 8455.12

Poster Board 557

### A Needs Assessment of Pediatric Medical School Faculty: Comparing Academic Ranks and Tracks

Charles B. Pelshaw, Ronald L. Thomas, Bonnie Stanton, Ambika Mathur, Deepak Kamat, Edward R. Dabrowski, Department of Pediatrics, Wayne State University-Detroit Medical Center/Children's Hospital of Michigan, Detroit, MI.

**BACKGROUND:** Expectations for performance among physicians in academic medicine have increased across the clinical, research and educational areas. Faculty are expected to develop curricula, teach, evaluate, perform research, provide leadership skills, understand the latest in medical informatics as well as be administrators. Many have had little or no training in many of these areas. In determining the needs for faculty, input from faculty is needed.

**OBJECTIVE:** An assessment of need for development of faculty in the Department of Pediatrics at Wayne State University was performed to 1) examine whether or not reported needs differed by rank and track and 2) whether the survey instrument we employed was a valid and reliable instrument to perform the task.

**DESIGN/METHODS:** A 76-item questionnaire, previously constructed by the WSU- SOM, was employed to elicit specific responses in nine domains of perceived faculty need. To validate the usefulness of the survey, a factor analysis using principal components methodology was performed.

**RESULTS:** Assistant professors listed needs necessary for career development and promotion, regardless of academic track. Areas of need fell into the scholarship or teaching domains, both important for promotion. Professors/Associate Professors on the same track cited a majority of needs contained in the Management and Organizational Structure domain. Assistant Professors on the Research Educator track were most interested in the Research and Scholarship domain. Similarities existed between Professors/Associate Professors among both tracks relative to organizational and management issues. Those on the Research Track suggested areas with a direct focus on mentoring young investigators and fostering collaboration among colleagues. Regardless of rank or track, a commonly selected need was information/assistance regarding motivating and empowering others to learn. The factor analysis of the faculty assessment instrument revealed an underlying pattern reflecting the multi-dimensional yet interrelated structure of faculty needs and desires. Five major item domains were obtained.

**CONCLUSIONS:** Differences in needs exist both by academic rank and track. A faculty needs assessment should consider these differences before implementing a faculty development model.

## 8455.13

Poster Board 558

### Impact of Hospital Disaster Exercises on Emergency Department Patient Flow

Nathan L. Timm, Stephanie S. Kennebeck, Department of Pediatric Emergency Medicine, Cincinnati Children's Hospital Medical Center, Cincinnati, OH.

**BACKGROUND:** Hospital disaster exercises are mandated by JCAHO to be conducted twice yearly. Community involvement and influx of patients must be incorporated into these drills. There is no data describing the potential negative impact on "real" patients in the emergency department during these exercises.

**OBJECTIVE:** Determine the impact disaster exercises have on non-disaster patient flow in a pediatric emergency department (ED).

**DESIGN/METHODS:** Since 2001, our hospital has conducted 8 disaster exercises that involve mass casualties to the ED. We conducted data analysis during a 10 and 24 hour block of time surrounding these events and collected the following: length of stay in ED, time to nurse, and time to physician. Disaster dates were compared with control dates (picked as the same weekday on the following week). Paired t-tests were used to compare data between disaster and control days.

**RESULTS:** Eight disaster days and 8 control days were studied. Length of stay on disaster days was 2 hours 42 minutes (SD 0:14), and control days was 2 hours 49 minutes (SD 0:25), which were not significantly different from each other. Mean patient volume was similar, 245 in 24 hours on disaster days versus 241 on control days.

**CONCLUSIONS:** Our findings show no difference in specific benchmarks of patient flow through our emergency department during disaster drills. Explanation for this lack of difference could be that most exercises were conducted when emergency department volumes were low to moderate. In addition, during hospital-wide disaster exercises, additional resources were allocated to the emergency department to assist in patient care for disaster patients, leaving most previous ED resources in place to care for current patients. We were limited by the specific number of disaster drills that actually occurred, so power may be a limitation. Disaster exercises at our institution as currently practiced have not negatively impacted patient care, as measured by standard patient flow benchmarks. Conducting disaster exercises during less convenient, high-volume times with limited staffing may provide an alternative view of patient impact, and may more closely simulate staff needs during a true disaster.

## 8455.14

Poster Board 559

### Infant Mortality Rate (IMR) Reaches Single Digit in a District in South India, Can It Be Sustained?

Shantharam B. Baliga, Pediatrics, Kasturba Medical College, Mangalore, Karnataka, India.

**BACKGROUND:** In many pilot and other population projects around the country, it has been shown that refined health care delivery system, not necessarily involving expensive and

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sophisticated technology, can bring down the IMR to around 20-50/1000 live births. Infant mortality rate (IMR) stood around 100/1000 live births in the 1980s in many parts of India, as per the Health Intelligence Bureau. Improvements in health care delivery infrastructure, with the Primary Health Care system now reaching all over the country and a strong private sector have improved the IMR further, now approximately 70/1000 live births. Districts of Dakshina Kannada and its neighbor Udipi, in Karnataka State in South India, which were carved out of a single district, have now reached an IMR of less than 10/1000 live births in 2005, equaling that in industrialized countries. In late 1990s tertiary neonatal care was introduced in the district headquarters hospital.

**OBJECTIVE:** 1. To present the decline of the IMR and its components-neonatal (NMR) and postneonatal mortality rates (PNMR) for years 1998-2005, and 2. To speculate the possible reasons for such a rapid decline.

**DESIGN/METHODS:** Data were obtained from the District Headquarters Bureau of Vital Statistics for the years 1998-2005 completed, which included infant deaths by age (< 28 days and 29-364 days) for the Dakshina Kannada district.

**CONCLUSIONS:** In our district with a population of 1.9 million (2001 census), IMR declined by approximately 42% within one year. We believe that the rapid economic development, efficient communication system; nearly 80% female literacy; and the introduction of advanced neonatal services; the various tiers of available health system, along with strong private sector that caters to 80% of the health needs of maternal/infant dyads are the principal reasons for this decline. It remains to be seen if this can be sustained.

Infant Mortality Categorized as Neonatal (NMR) and Post-neonatal Mortality Rates(PNMR) by Years

	1998	2000	2001	2002	2003	2004	2005
NMR	11.8	13.8	10.7	11.3	11.1	11.3	6.3
PNMR	4.6	4.8	4.5	4.9	4.7	4.5	2.8
IMR	16.4	18.6	15.2	16.2	15.8	15.8	9.1

### 8455.15

#### Poster Board 560

#### **Pain Ease® Vapocoolant Spray Versus Placebo in Reducing Pain Associated with Intravenous Insertion in Children: RCT**

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**BACKGROUND:** Intravenous (IV) insertion is a distressing experience for many children. Topical anaesthetic agents have been developed to reduce the pain of IV insertion, but the application time required for good effect makes them often impractical in the Emergency Department (ED). Pain Ease® is a vapocoolant spray that quickly (within seconds) numbs the skin to reduce the conduction of pain stimuli, thus potentially reducing the pain and distress associated with IV insertion.

**OBJECTIVE:** To assess the efficacy of Pain Ease® in reducing the pain associated with IV insertion in children.

**DESIGN/METHODS:** Children 6-12 yrs requiring urgent (not emergent) IV's in the ED were randomized to receive Pain Ease® spray or placebo spray. The primary outcome was the child's rating of IV insertion pain using a visual analogue scale (VAS). Other outcomes included the successful cannulation rate on 1st attempt, as well as the rating of the child's pain by the parent, treating nurse and CLS. Following standard patient preparation and distraction by a Child Life Specialist (CLS), a research assistant sprayed the treatment product on the insertion site chosen by the treating nurse (dorsum of the hand or antecubital fossa) while all others briefly turned away. The IV attempt was then made within 60 secs.

**RESULTS:** Eighty children were randomized and completed the trial, 40 in each group. Baseline characteristics and pre-procedure anxiety scores were similar between groups. Pain with IV insertion was significantly less with Pain Ease® (mean VAS 3.69 vs 5.61, p=0.005); this remained significant when adjusted for needle size (p=0.009). Successful cannulation on 1st attempt was significantly higher with Pain Ease® (85% vs 63%, p=0.026); again this remained significant when adjusted for needle size (p=0.017). The parent, nurse and CLS all rated the child's pain as less with Pain Ease® (p=0.04, p=0.012, p=0.003 respectively).

**CONCLUSIONS:** Pain Ease® quickly and effectively reduces pain associated with IV insertion in children and improves success of IV insertion.

### 8455.16

#### Poster Board 561

#### **CT Scan with IV Contrast Alone for Evaluation of Pediatric Appendicitis**

Madelyn Garcia, George T. Drugas, Lynn Babcock-Cimpello, Luann Teschmacher. Emergency Medicine, University of Rochester, Rochester, NY; Surgery, University of Rochester, Rochester, NY; Imaging Sciences, University of Rochester, Rochester, NY.

**BACKGROUND:** Numerous CT protocols are used to diagnose pediatric appendicitis. A protocol using IV contrast alone (CT IV) examined whether elimination of PO contrast impacted CT diagnostic performance and time to imaging.

**OBJECTIVE:** 1. Determine the performance of CT IV for diagnosing appendicitis in clinically equivocal cases 2. Prospectively compare the performance of CT IV among radiologists of different training levels (attendings vs. residents) 3. Determine time saved in the ED by the elimination of oral contrast.

**DESIGN/METHODS:** ED patients (3-18 years) with indeterminate abdominal pain were prospectively enrolled and imaged. CT interpretations were appendicitis or no appendicitis/indeterminate. Final diagnoses were confirmed by pathology or phone follow-up. Test performance characteristics were determined and inter-observer agreement was calculated using kappa statistic. Study power was 89% to detect a 15% difference in sensitivity between readers ( $\alpha = 0.05$ ). Time to CT was compared to a retrospective cohort imaged using CT with IV and oral contrast.

**RESULTS:** 250 patients were enrolled (122 male, 128 female), mean age 12.7 years (range 3.1-18.9). The incidence of appendicitis was 30.0% with a negative appendectomy rate of 13.8%. There was no significant difference between resident and attending performance: sensitivity (83% vs. 79%), specificity (96% vs. 90%) and accuracy (92% vs. 90%). Resident and attending agreement on CT interpretation was high: weighted kappa = 0.72. Attendings read 26.8% of the scans as indeterminate compared to 17.8% for residents, with NPV of 93% and 90% respectively. 31% of CTs had alternate diagnoses (Table). Mean time to CT was 4 hours vs. 5 hours, 36 minutes for CT using oral and IV contrast (p<0.0001).

**CONCLUSIONS:** CT IV is diagnostically reliable for excluding appendicitis in equivocal cases. CT IV saves ~1.5 hours per patient and performs well, independent of reader experience level, making it suitable for busy emergency departments.

Alternate Diagnoses on CT IV

Location	N	Description
GU	12	renal cyst/stone, hydronephrosis, pyelonephritis
GYN	30	ovarian cyst, teratoma, ectopic, torsion, PID
GI	32	colitis, malrotation, duplication cyst, FB, GB hydrops
CHEST	4	pneumonia, rib fracture
TOTAL	78	

### 8455.17

#### Poster Board 562

#### **Predicting Imminent Menarche from Salivary Steroid Hormones and Body Mass Index: A Pilot Study**

Susan H. Gray, Lauren K. Ebe, Henry A. Feldman, S. Jean Emans, Marc R. Laufer. Pediatrics, Boston Medical Center, Boston, MA; Gynecology, Children's Hospital Boston, Boston, MA; Clinical Research Program, Children's Hospital Boston, Boston, MA.

**BACKGROUND:** Prediction of menarche is based on clinical conjecture, using Tanner staging, weight, and body-mass index (BMI). Little is known about the biochemical events that precede menarche. Ovulatory cycles are well studied, but menstrual cycles in the first years after menarche are often anovulatory. An improved ability to predict menarche would be clinically useful for girls with bleeding disorders or developmental delay as well as normal girls anxious about menarche.

**OBJECTIVE:** To determine if levels of salivary 17- $\beta$  estradiol, testosterone, progesterone, and 17-hydroxyprogesterone (17-OHP) and BMI, alone or in combination, can predict menarche in healthy premenarcheal girls.

**DESIGN/METHODS:** We enrolled 63 premenarcheal females ages 9-15 yr, with BMI >5<sup>th</sup> percentile for age and Tanner Stage  $\geq$ III for both pubic hair and breast development. Weekly saliva samples were collected for 12 mo or until first menses, and monthly height and weight were recorded. Enzyme-Linked Immunosorbent Assay determined salivary 17- $\beta$  estradiol, testosterone, progesterone, and 17-OHP concentrations. Multiple logistic regression analysis was used to construct prediction formulas for menarche within 30, 45, 60, and 90 days of a given saliva sample, with the four hormone levels and BMI as predictors.

**RESULTS:** Of 63 girls enrolled, 41 were Tanner Stage III, 20 stage IV and 2 stage V for breast development at entry; 38 were stage III and 25 stage IV for pubic hair. Fifty-five girls completed protocol, 43 with menarche and 12 without. Eight dropped out or were lost to follow-up. Of 60 girls observed  $\geq$  60 days, 12 (20%) reached menarche within that interval. The best prediction formula showed sensitivity 80%, specificity 83%, positive predictive value (PPV) 54%, and negative predictive value (NPV) 94% for prediction of menarche within 60 days.

**CONCLUSIONS:** In a population comparable to our sample of Tanner III-IV girls, we can reliably determine that menarche will not occur within 60 days using salivary hormone levels and BMI. This method's high NPV may be useful in clinical situations where it would be ideal to plan for menarche. More research is needed to validate this method in a larger sample and to improve its PPV.

### 8455.18

#### Poster Board 563

#### **Therapy Intensification Improves Outcome in Multisystem Langerhans Cell Histiocytosis: Results of the Histiocyte Society LCH-II Trial**

Stephan Ladisch, Nicole Grois, Ulrike Pötschger, Milan Minkov, Maurizio Aricò, Jorge Braier, Valerie Broadbent, Jean Donadieu, Jan-Inge Henter, Robert McCarter, Helmut Gadner. Children's Research Institute, Children's National Medical Center, Washington, DC; Children's Cancer Research Institute, St. Anna Children's Hospital, Vienna, Austria; University of Palermo, Italy; Hospital Nacional de Pediatría J. Garrahan, Buenos Aires, Argentina; Addenbrookes Hospital, Cambridge, United Kingdom; Hopital Trousseau, Paris, France; Karolinska Hospital, Stockholm, Sweden.

**BACKGROUND:** Multisystem Langerhans cell histiocytosis, a disseminated disease, is generally considered as particularly devastating with a potentially fatal prognosis when risk organs are involved or the patient is <2 years old.

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**OBJECTIVE:** To test the hypothesis that intensified therapy will improve outcome in MS-LCH.

**DESIGN/METHODS:** Following randomized treatment of MS-LCH in LCH-I (J Pediatr 138:728, 2001), in LCH-II we intensified treatment of patients with risk of mortality (either risk organ involvement (RO+) or age <2 years): LCH-II Arm A consisted of 6 weeks daily prednisone and weekly vinblastine followed by 18 weeks daily 6-mercaptopurine with vinblastine/prednisone pulses; etoposide was added in Arm B.

**RESULTS:** 193 randomized risk patients, median 4.9 years observation, had similar outcomes: rapid (6 weeks) response (A vs B, 63%/71%), 5-year survival probability (74%/79%), disease reactivation frequency (46%/46%), and permanent consequences (43%/37%). 100% survival and uniformly high (>80%) rapid response characterized patients <2 years old without RO involvement (RO-) while highest mortality was among RO+ patients not responding within 6 weeks. Importantly, the more intensive therapy (Arm B) reduced mortality in RO+ patients (relative hazard rate, accounting for differences in risk organ involvement, of 0.54; 95%CI=0.29-1). Comparison of RO+ patients in LCH-I and LCH-II confirmed that increasing treatment intensity increased rapid responses (from 43%, Arm A LCH-I, to 68%, Arm B LCH-II; p=0.027) and survival (from 56%, Arm A LCH-I, to 73%, Arm B, LCH-II; p=0.042).

**CONCLUSIONS:** Intensified treatment and rapid response significantly reduces mortality in high risk MS-LCH patients. Lack of rapid response should lead to early institution of more intensive/experimental treatment. With contemporary therapy, young age alone does not portend poor prognosis.

### 8455.19

Poster Board 564

Fellow in Training

#### Procalcitonin To Predict Vesico-Ureteral Reflux in Children with Acute Pyelonephritis: A European Study

S. Leroy, A. Galetto-Lacour, C. Romanello, A. Fernandez-Lopez, D. Tuerlinckx, V. Smolkin, A. Gervaix, M. Contardo, C.L. Cubells, T. Vander Borght, R. Halevy, D. Gendrel, G. Breart, M. Chalumeau. Clinical Epidemiological Unit, Department of Pediatrics, AP-HP, University Paris Descartes, Saint-Vincent-de-Paul Hospital, Paris, France; INSERM U149, Paris, France; Department of Pediatrics, University Hospital of Geneva, Geneva, Switzerland; Department of Pediatrics, University of Udine, Udine, Italy; Department of Pediatrics, Hospital San Joan de Deu, Barcelona, Spain; Department of Pediatrics, UCL Mont-Godinne, Yvoir, Belgium; Department of Pediatrics, Ha Emek Medical Center, Afula, Israel.

**BACKGROUND:** Predicting vesico-ureteral reflux (VUR) after a first febrile UTI urinary tract infection in children would allow to avoid unnecessary cystourethrographies. Procalcitonin (PCT) has been validated as a strong and sensitive predictor of VUR in patients with a first febrile UTI diagnosed by positive urine culture alone. However, this new predictor needs also to be validated among patients with pyelonephritis assessed by early DMSA scan.

**OBJECTIVE:** To study the relationship between VUR and PCT in children with a first episode of acute pyelonephritis.

**DESIGN/METHODS:** This secondary analysis of prospective hospital-based published series included children aged 1 month to 4 years with a first febrile UTI and a positive early renal DMSA scan.

**RESULTS:** Data of 203 patients (62 boys, mean age 13.3 months, VUR 29%, high grade ( $\geq 3$ ) VUR 13%) were collected in 5 centers in 5 countries. The values of PCT increased significantly with the grade of VUR (p=0.005). No significant statistical association was found (p=0.2) comparing the PCT values of children with vs without VUR: median 2.3 vs 1.5 ng/mL. After dichotomisation of PCT values around the previously defined 0.5 ng/mL threshold, there was a significant association between high-grade VUR and high PCT [OR=14.6, 95% CI 1.6-247, p=0.004], but no significant statistical association (p=0.8) between all-grade VUR and high PCT. The sensitivity of high PCT was 78% (95% CI: 66-87) for all-grade VUR and 100% (95% CI: 88-100) for high-grade VUR, both with 21% specificity (95% CI: 15-28).

**CONCLUSIONS:** Among patients with a first episode of pyelonephritis, high serum PCT concentration is a significant and sensitive predictor of high-grade VUR, but a poor predictor of low-grade VUR.

### 8455.20

Poster Board 565

Fellow in Training

#### Utility of the Quantiferon-Gold In-Tube in the Diagnosis of TB in Children

Jennifer Lighter, Mona Rigaud, Thomas Miyoshi, Ed Fryer, Chia-Hui Peng, Henry Pollack. Department of Pediatrics, NYU Medical Center, New York City, NY.

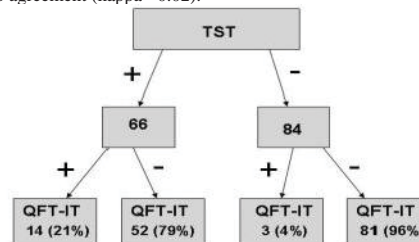
**BACKGROUND:** The Tuberculin Skin Test (TST) has been the standard diagnostic test for MTB exposure but its specificity is low in the context of BCG vaccination. A new blood test, the Quantiferon-Gold (QFT), has been FDA approved in adults to diagnose Latent TB Infection (LTBI).

**OBJECTIVE:** Determine the sensitivity and specificity of the QFT in children with TB and its concordance with TST in children with and without BCG.

**DESIGN/METHODS:** This is a prospective study. Children were enrolled at Bellevue Hospital. Risk factors for MTB exposure were obtained as well as BCG vaccination. Blood was drawn after informed consent into Quantiferon-Gold In-Tube (QFT-IT) and TST was performed.

**RESULTS:** So far 150 children, from ages 1 month to 18 years have been enrolled. Overall results are presented in (Figure 1). Children who had no risk factors for TB infection and were TST negative had negative QFT-IT results. Among the children who were TST positive, only 21% were QFT-IT positive. Including in this 21% were children with active TB, children who had a known index case source, and children with other risk factors. We found that TST size

directly correlated with QFT-IT positivity. The overall kappa between TST and QFT-IT was 0.20. In subjects who had not received BCG, kappa was 0.48; while in those who had received BCG there was no agreement (kappa =0.02).



**CONCLUSIONS:** There was excellent correlation between a negative TST and a negative QFT-IT. There was good correlation between the likelihood of TB infection and the probability of a +QFT-IT. A positive QFT-IT was associated with a greater likelihood of actual TB exposure/infection. A +QFT-IT also correlated with a larger TST response. Use of the QFT assay in TST+ children would reduce the number of children treated with INH by 80%. Further studies are needed to assess performance in very young children.

### 8455.21

Poster Board 566

#### Prospective Multicenter Study of the Viral Etiology of Bronchiolitis in the Emergency Department

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**BACKGROUND:** The clinical utility of identifying the infectious agent(s) in children with bronchiolitis remains uncertain.

**OBJECTIVE:** To determine the viral etiology and associated clinical characteristics of bronchiolitis among children age <2 years presenting to the emergency department (ED).

**DESIGN/METHODS:** We conducted a 14-center prospective cohort study from 2005-2006 of ED patients age <2 years with bronchiolitis. The study was conducted in 10 states as part of the Emergency Medicine Network. Researchers collected nasopharyngeal aspirates, conducted structured interviews, medical record reviews, and 2-week follow-up telephone calls. Samples were tested using reverse transcription polymerase chain reaction for respiratory syncytial virus (RSV), rhinovirus (RV), human metapneumovirus (hMPV), and influenza viruses (Flu). Based on initial analyses and emerging data about the link between RV bronchiolitis and asthma, the data are presented as RV, RSV, RV + RSV, and other.

**RESULTS:** Testing of 277 samples revealed that 176 (64%) were positive for RSV, 44 (16%) for RV, 26 (9%) for hMPV, 17 (6%) for Flu A, and none for Flu B. These 277 children had a median age of 6.3 months (IQR, 3.1 to 10.2) and most were male (61%). When children were categorized as RSV only, RV only, RV and RSV, and all others (hMPV, Flu, no identified virus), children with RV only were more likely to be black (19%, 62%, 14%, and 40%, respectively; p<0.001) and have a history of wheezing (23%, 52%, 21%, 15%; p=0.01). In multivariate models, children with RV were more likely to receive corticosteroids (odds ratio 3.5; 95% confidence interval 1.5 - 8.15). The duration of illness was shorter for children with RV (days: 8, 3, 6, 8; p=0.07).

**CONCLUSIONS:** In this multicenter prospective cohort, children with rhinovirus bronchiolitis have a distinct clinical profile when compared to other children with bronchiolitis. Children with RV bronchiolitis have similar demographics, medical histories, and ED treatments as older children with an asthma exacerbation. Future studies of children with RV bronchiolitis are needed to determine if identification of this virus is critical to guiding short- and long-term treatment decisions to improve bronchiolitis outcomes.

### 8455.22

Poster Board 567

#### Oral Versus High Dose Pulse Corticosteroids in Problematic Infantile Hemangiomas: A Randomized Controlled Trial

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**BACKGROUND:** Oral systemic corticosteroids are the mainstay of treatment for problematic hemangiomas; however, current information is based on anecdotal experience and retrospective studies.

**OBJECTIVE:** We aimed to determine if systemic corticosteroids are efficacious in stopping the proliferation of infantile problematic hemangiomas and compare the efficacy and safety of two corticosteroid treatment modalities.

**DESIGN/METHODS:** Twenty patients with problematic hemangiomas of infancy were randomized to either daily oral prednisolone (2mg/kg/day) or monthly intravenous pulses of methylprednisolone (30mg/kg/daily dose, three doses/month). Their clinical outcomes (improvement using a visual analog score (VAS)) were assessed by blinded assessors and adverse events were compared at 3 months from baseline and 1 year of age. Data on possible surrogate markers of angiogenesis was available for the first 3 months.

**RESULTS:** At 3 months, orally treated patients had a median VAS of 70 (IQR, 54 to 80) compared with 12 (IQR, -18 to 39) in the intravenous group (p=0.002). This response

pattern was similar at patients' first birthday: 50 (IQR, 35 to 67) versus -1.5 (IQR, -35 to 22) (p=0.005). Additional treatment beyond 3 months was needed in 65% of patients (7 in the intravenous and 6 in the oral group). Six of eight patients with impaired vision at enrollment had an improved function at one year (4 patients in the intravenous and 3 patients in the oral group). Of the four surrogate markers of angiogenesis measured (plasma bFGF, VEGF, VCAM-1, endoglin and urine bFGF), the only two that decreased over time were VCAM-1 (p<0.001) and endoglin (p=0.03). Patients in the oral group had a higher rate of adverse effects such as hypertension (18.6% versus 13.1%), abnormal cortisol (78% versus 60%) and growth retardation (p=0.003 for weight and p<0.001 for height).

**CONCLUSIONS:** Systemic corticosteroids are efficacious in stopping the proliferation of infantile hemangiomas. The oral corticosteroids offered more clinical and biological benefit than the pulse steroids; however, with higher risk of side-effects.

This study has been funded by a grant from the Society for Pediatric Dermatology.

**8455.23**

**Poster Board 568**

**Impact of Fundoplication Versus Gastrojejunal Feeding Tubes on Mortality and in Preventing Aspiration Pneumonia in Young Children with Neurological Impairment Who Have Gastroesophageal Reflux Disease**

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**BACKGROUND:** Aspiration pneumonia (AP) is the most common cause of death in children with neurological impairment (NI) who have gastroesophageal reflux disease (GERD).

Funduplications (Fundo) and gastrojejunal feeding tubes (GJT) are commonly used to prevent AP. Which of these approaches is more effective in preventing AP and/or improving survival is unknown.

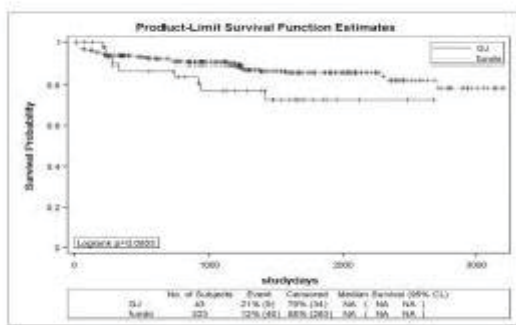
**OBJECTIVE:** To compare outcomes for children with NI and GERD following either a first Fundo or a first GJT.

**DESIGN/METHODS:** Retrospective, observational cohort study. Inclusion criteria included children with NI who had either a Fundo or GJT between 01/97 and 12/05 at a tertiary care children's hospital. The main outcome measures (followed until 10/06) were post-procedure AP-free survival and mortality. Propensity analyses were used to control for bias in treatment assignment and prognostic imbalances.

**RESULTS:** Of the 366 children with NI and GERD, 323 underwent a first Fundo. Median length of follow up was 3.4 years. Children who received a first Fundo had similar rates of AP [hazards ratio {HR} 0.71 (0.21-1.69)] and mortality [HR 0.49 (0.23-1.03)] post-procedure compared to those who had a first GJT, when adjusting for the treatment assignment.

**CONCLUSIONS:** AP and mortality occur at similar rates following either a first Fundo or a first GJT for the management of GERD in children with NI. This clinical scenario needs to be studied in a prospective, multi-center randomized control trial to evaluate definitively whether one of these two management options is more beneficial.

Survival for the Study Cohort who had either a First Fundoplication Compared to a First GJT.



**8455.24**

**Poster Board 569**

**Ph.D. Student**

**The Role of Lymphocytes in Pulmonary Inflammation in a Mouse Model of Sickle Cell Disease**

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**BACKGROUND:** Polymerization of deoxygenated HbS is the primary event in the molecular pathogenesis of sickle cell disease (SCD). Recently it has been proposed that chronic inflammation also plays an important role. SCD patients and transgenic mice (NY1DD) expressing human  $\beta^S$ -globin exhibit a pro-inflammatory phenotype. Vaso-occlusive crisis (VOC) is an acute painful ischemic episode that eventually resolves, but it is postulated that it occurs chronically in a sub-clinical manner. End-organ damage is believed to be due to the cumulative effects of ischemia-reperfusion injury (IRI). Recent studies have suggested that lymphocytes may be involved in the pathology of IRI.

**OBJECTIVE:** We postulate that lymphocytes may be involved in the pathogenesis of

pulmonary VOC in NY1DD mice. Furthermore, we predict that NY1DD mice will also display increased levels of the anti-inflammatory adenosine receptor,  $A_{2A}$ AR, to counter-balance the increased levels of inflammation.

**DESIGN/METHODS:** NY1DD and control mice were studied. Mice were untreated or treated with an  $A_{2A}$ AR agonist (ATL146e, 10ng/kg/min, osmotic pump, 48hrs). Mice were also treated with PK136, a pan NK cell depletion antibody (300ug, -48hrs and -24hrs). Normoxic mice or mice having undergone 4 hours of hypoxia (8%  $O_2$ ) followed by 30 minutes of reoxygenation were anesthetized. The pulmonary vasculature was perfused, the whole lung was removed, digested in collagenase, and WBCs were then isolated. Cells were stained for subsets and for activation markers, and then counted and analyzed via Flow Cytometry.

**RESULTS:** Compared to control mice NY1DD mice displayed baseline pulmonary inflammation characterized by: 1) an increase in the absolute number of lymphocytes, macrophages, and neutrophils; and 2) high expression of activation markers (IFN- $\gamma$ , TNF- $\alpha$ , CD44, and CD69). This inflammation increased further after hypoxia induced VOC. Also, treatment with  $A_{2A}$ AR (ATL146e) agonist or depletion of NK and NKT cells decreased these markers of pulmonary inflammation.

**CONCLUSIONS:** Our data suggests that lymphocytes play an important role in pulmonary inflammation and VOC in SCD. Treatment with  $A_{2A}$ AR agonists or depletion of NK and NKT cells decreases the pulmonary inflammation in a similar manner. This suggests that  $A_{2A}$ AR agonists may be acting on these cells to decrease pulmonary inflammation in NY1DD mice. Importantly,  $A_{2A}$ AR agonists may be a promising therapy for SCD.

**8455.25**

**Poster Board 570**

**Study of Brain Function Compensation of Children with Cerebral Palsy Treated by Acupuncture and Nerve Growth Factor**

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**OBJECTIVE:** To investigate action and value of acupuncture in Cerebral Palsy rehabilitation.

**DESIGN/METHODS:** 100 spasm Cerebral Palsy patients from 2 to 7 years old were randomly divided into two groups. Acupuncture group: 50 patients were treated with head acupuncture and NGF and body acupuncture; Rehabilitation-training group: 50 patients were treated with physical therapy of Bobath and Vojta methods.

**RESULTS:** The total effective rate acupuncture and rehabilitation-training group were obvious higher than that of rehabilitation-training group. After treatment the DQ value of rehabilitation-training + acupuncture group were higher than that of rehabilitation group (p<0.01). In acupuncture and rehabilitation-training group were higher than that of rehabilitation group (p<0.01). In acupuncture and rehabilitation-training group, improvement rate of brain dysphasia, brain atrophy in skull CT and recovery normal rate of skull ECT were obvious higher than that of rehabilitation-training group (t=4.731 t=5.971 p<0.01).

**CONCLUSIONS:** Acupuncture can obviously increase cerebral blood flow (CBF) and improve cerebral cell metabolism, promote partial or complete compensation of cerebral function and the restoration and function of plasticity of cerebral tissue, improving the quality of life in children with cerebral palsy.

**8455.26**

**Poster Board 571**

**C-Reactive Protein Velocity – A New Inflammatory Marker?**

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**BACKGROUND:** Fever is considered the most common referral to pediatric emergency room. The main challenge of the physician is to discriminate between viral or bacterial source. Our newly defined CRP velocity parameter describes the speed of the incline of CRP levels during an acute illness.

**OBJECTIVE:** We investigated the accuracy of CRP velocity as a diagnostic tool to distinguish between bacterial and viral infections in children with acute febrile illness.

**DESIGN/METHODS:** Patients age between 2 weeks –12 years who were admitted with fever were included and clinical and laboratory data was obtained. The onset of fever was defined as CRP zero, and CRP velocity was defined as current CRP level divided by days of fever. Patients were divided into three groups – Definite bacterial, Probable bacterial and viral according to laboratory results. Analyzing the data we compared the three groups by demographics, main complaints, current illness history and laboratory tests.

**RESULTS:** Eighty one patients were studied. Twenty one were included in the definite bacterial group, twenty seven in the probable bacterial group and thirty three in the viral group. There were no demographic differences between the groups beside the age which was younger in the viral group. The chief complaints were similar in the three groups. White blood cell count and neutrophil count were significantly higher in both bacterial groups (P<0.05). Mean CRP level and Mean CRP velocity were significantly higher in the bacterial groups compared to the viral group With a P Value <0.001 (definite bacterial mean CRP 50.92 Mg/l, probable bacterial 61.7 Mg/l, viral 11.85 Mg/l and definite bacterial mean CRP velocity 37.83, probable bacterial 46.7 and viral 14.83). Area under the curve by ROC curve analysis was 0.837 and 0.805 for CRP level and CRP velocity respectively showing good sensitivity and specificity for both parameters.

**CONCLUSIONS:** We propose that CRP velocity is a highly accurate method which provides another feasible tool to be used by the physician challenged by distinguishing a bacterial to a viral source of infection. The method is reliable, fast and requires small amount of blood and there for is highly suitable to the pediatric population.