

2008 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

Sunday, May 4 ~ Monday, May 5

Sunday, May 4

11:00am–3:00pm

4464 Late Breakers I Poster Session

Exhibit Hall

265A Seroreponse to 2-Dose Hepatitis B Immunization Among Youth at Adolescent Clinics (ATN). C.K. Cunningham, B.J. Rudy, J. Bethel, B.G. Kapogiannis, S. Ahmad, C.M. Wilson, P.M. Flynn.

Publication 4464.15

265B MMRVaccine and the Risk of Febrile Seizures. Nicola P. Klein, Katherine Yih, Edwin Lewis, Sharon Greene, Ruihua Yin, Eric Weintraub, Paula Ray, Martin Kullendorff, Bruce Fireman, Roger Baxter, Liisa Lyon, Steven Black, James Baggs, Karen Broder, John Iskander, Tracy Lieu.

Publication 4464.16

Monday, May 5

8:00am–10:00am

5127 Late Breakers I: Neonatology

PAS Platform Session ~ Ballroom C

8:00 Caffeine for Apnea of Prematurity (CAP) Trial: Benefits May Vary in Subgroups. Peter Davis, Barbara Schmidt, Robin Roberts, Lex Doyle, Elizabeth Asztalos, Ross Haslam, Sunil Sinha, Win Tin, The CAP Investigators.

Publication 5127.1

8:15 Does High-Dose Dietary Docosahexaenoic Acid (DHA) Improve the Neurodevelopmental Outcome of Preterm Infants? Maria Makrides, Robert A. Gibson, Carmel T. Collins, Andrew J. McPhee, Philip Ryan, Peter G. Davis, Lex W. Doyle, Karen Simmer, Noel French, Scott Morris, Paul B. Colditz, Lisa G. Smithers, Kristyn Willson, Karen P. Best.

Publication 5127.2

8:30 A Multicenter, Randomized Trial on Prophylactic Bovine Lactoferrin in Preterm Neonates: Preliminary Data. Paolo Manzoni, Fabio Mosca, Hubert Messner, Rosario Magaldi, Silvia Cattani, Mauro Stronati, Daniele Farina.

Publication 5127.3

8:45 Effects of Early Aggressive Nutrition on Growth and Neurodevelopment of Infants with Birth Weight (BW) <1250g: A Randomized Controlled Trial. Sudha Kashyap, Elizabeth Matthews, Tove Rosen, Rakesh Sahni, Stephen Holleran, Rajasekhar Ramakrishnan.

Publication 5127.4

9:00 Room Air Versus Oxygen Administration During Resuscitation of Preterm Infants (ROAR Study). Yacov Rabi, Alberto Nettel-Aguirre, Nalini Singhal.

Publication 5127.5

9:15 * Stem Cell-Based Therapy Prevents Alveolar Injury In Vitro and In Vivo. Roisin Byrne, Juliana Rey, Tim van Haaften, Farah Eaton, Bernard Thebaud.

Publication 5127.6

9:30 Role of Nicotine as an In-Vivo Mediator of Fetal Hypoxemia. Shabih U. Hasan, Anita Rigaux, Yolanda MacKinnon, Kamran Yusuf.

Publication 5127.7

9:45 * Physiologic Mechanisms of High Flow Nasal Cannula Therapy (HFT) with Two Degrees of Leak Around Nasal Prongs. M.A. Frizzola, K. Dysart, E. Rodriguez, Y. Zhu, J. Rojas, A. Heseck, A. Stump, T.H. Shaffer, T.L. Miller.

Publication 5127.8

3:00pm–5:00pm

5628 Late Breakers II: General

PAS Platform Session ~ Room 323A

3:00 Heavy Metal Exposure Among Children Living near an Open Pit Mine: A Combined Approach Towards Risk Assessment. Cerro De Pasco, Peru – May 2007. Laura M. Conklin, Carlos Sanchez, Antonio Neri, Jeffrey Jarrett, Paula Staley, Wendy Blumenthal, Rebecca LePrell, James Durant, Rene Suarez-Soto, Mary Jean Brown, Jim Lando.

Publication 5628.1

3:15 * A Double Blinded Randomized Controlled Trial for the Management of Pediatric Community Acquired Skin Abscesses – To Treat or Not To Treat with Antibiotics. Myto Duong, John Peter, Donna Halloran, Stephen Barenkamp.

Publication 5628.2

3:30 Efficacy of Subcutaneous Hydration Augmented with Recombinant Human Hyaluronidase in Children. Coburn H. Allen, Andrea T. Cruz, Binita Patel, Erin E. Endom, Troy Bush.

Publication 5628.3

3:45 * The Effect of Probiotic (OHHIRA-OMX) as Adjunct Treatment in Patient with Febrile Neutropenia Among Children 2-18 Year Old: A Randomized, Double-Blind, Placebo-Controlled, Clinical Trial. Christine Natalita.

Publication 5628.4

4:00 Immunogenicity of Live Attenuated Influenza Vaccine (LAIV) Compared with Trivalent Inactivated Influenza Vaccine (TIV) in Children 12-35 Months of Age. Bryan M. Harvey, Christopher S. Ambrose, Tingting Yi, Yihong Yao, Robert E. Walker, Bahija Jallal, George Kemble for the Influenza Vaccine Comparative Immunogenicity Trial Group.

Publication 5628.5

4:15 Shedding and Safety of Live Attenuated Influenza Vaccine in Healthy Subjects 6 to <60 Months of Age. Stan L. Block, Keith S. Reisinger for the LAIV Study Group.

Publication 5628.6

4:30 Efficacy of the Pentavalent Rotavirus Vaccine Between Doses: Potential Benefits of Early Protection. Penelope H. Dennehy, Timo Vesikari, David O. Matson, Robbin Itzler, Michael Dallas, Michelle Goveia, Mark DiNubile, Penny Heaton, Jody Lawrence, Max Ciarlet.

Publication 5628.7

4:45 A Phase III Study Comparing the Safety and Immunogenicity of a Novel Quadrivalent Meningococcal Conjugate Vaccine, MenACWY-CRM, with the Licensed MCV4, Menactra™, in Adolescents. Lisa Jackson, Roger Baxter, Keith Reisinger, Jina Shah, Lisa Bedell, Peter M. Dull, V59P13 Study Group.

Publication 5628.8

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



2008 PAS Annual Meeting

Late-Breaker Abstract Presentations

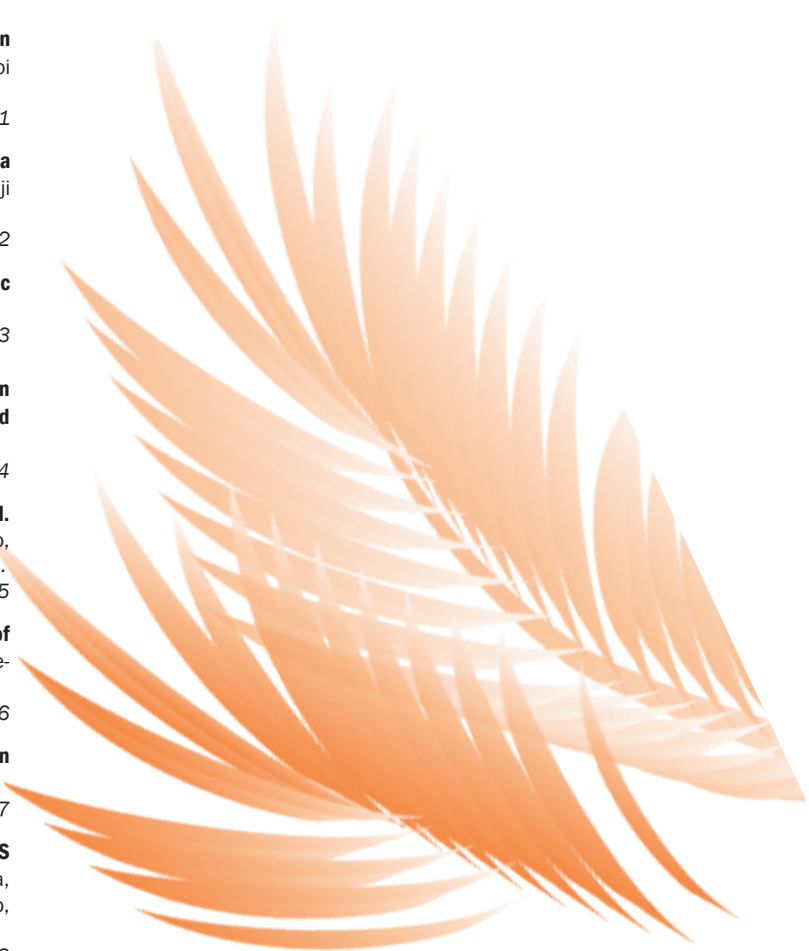
Monday, May 5

3:00pm-6:45pm

5855 Late Breakers II Poster Session

Exhibit Hall

- 763 *** **Accurate Diagnosis of Kawasaki Disease: Color Flow Mapping in Lymphadenopathy.** Ogata Shouhei, Bando Yuki, Kimura Sumito, Yayoi Nakahata, Ishii Masahiro.
Publication 5855.1
- 764** **Problems and Future Prospects Regarding the Mild Brain Hypothermia Therapy Protocol for Infant.** George Imataka, Hitoshi Katashio, Kouji Wake, Hideo Yamanouchi, Osamu Arisaka.
Publication 5855.2
- 765*** **Effects of Dihydrofolate Reductase Gene Knock-Down on the Cardiac Development of Zebrafish.** Shu-na Sun, Yong-hao Gui, Hou-yan Song.
Publication 5855.3
- 766 *** **The Effect of Probiotic – Protexin Restore Supplementation in Children more than 2 Months Old with Atopic Dermatitis: A Randomized Controlled Trial.** Rhodalyn R. Atis, Vicky Wee E. Binas.
Publication 5855.4
- 767** **The Histological Features of the Liver of Citrin Deficiency in Childhood.** Ayano Inui, Takuji Hashimoto, Hidenori Sugawara, Tsuyoshi Sogo, Haruki Komatsu, Keiko Kobayashi, Takeyori Saheki, Tomoo Fujisawa.
Publication 5855.5
- 768 *** **Does Haemophilus Influenzae Type B Vaccination Increase the Risk of Atopic Disorders in Young Infants?** I-Jen Wang, Wu-Shiun Hsieh, Yue-Liang Guo, Yi-Li Chuang, Shio-Jean Lin, Pau-Chung Chen.
Publication 5855.6
- 769** **Lower Birth Weight Is Related to Evaluated Systolic Blood Pressure in Chinese Population.** Haili Yao, Xuejuan Jin, Huirong Li, Yunqin Chen.
Publication 5855.7
- 770** **Stool Microflora in Extremely Low Birthweight Infants Analyzed by 16S rRNA Real-Time PCR.** Masako Kitsunozaki, Yuki Bando, Tatsuya Ishida, Kenichi Hojo, Masato Nonoyama, Masahiko Nowatari, Keiko Nomoto, Masahiro Ishii.
Publication 5855.8
- 771** **Urinary Tract Infection in Infants and Children: An Etiologic Study.** Orpheus C. Monakil.
Publication 5855.9



Late Breakers I Poster Session:

Sunday, May 4

11:00am-3:00pm

Exhibit Hall

4464.15

Poster Board 265A

Seroresponse to 2-Dose Hepatitis B Immunization Among Youth at Adolescent Clinics (ATN)

C.K. Cunningham, B.J. Rudy, J. Bethel, B.G. Kapogiannis, S. Ahmad, C.M. Wilson, P.M. Flynn, Ped, Duke, Durham, NC; Ped, CHOP, Philadelphia, PA; Westat, Inc., Rockville, MD; NICHD, Bethesda, MD; Epi & Ped, UAB at Birmingham, Birmingham, AL; ID, St. Jude Children's Research Hospital, Memphis, TN.

BACKGROUND: Controlled trials indicate that more than 95% of healthy adolescents will seroconvert after 2 or 3 doses of Recombivax HB (Merck Vaccine) or Twinrix (GlaxoSmithKline). However, in a previous study among adolescents at risk for HIV-infection, response rates were much lower (38-70%).

OBJECTIVE: This study was designed to determine immunogenicity of 2-doses of Recombivax HB or Twinrix in HIV-uninfected youth age 12-17 years.

DESIGN/METHODS: This was a multicenter, randomized trial. HIV and Hepatitis B negative youth age 12-17 years were randomized to 2 doses of Recombivax or Twinrix at 0 and 24 weeks; antibody to Hepatitis B surface antigen was measured at 28 weeks. A positive antibody response was defined as >10mIU/ml.

RESULTS: 123 youth were enrolled and 100 received 2 doses of vaccine and had pre and post-immunization titers; 20 discontinued prematurely (10 due to Hurricane Katrina) and 3 had samples missing. The 60 who received Recombivax HB did not differ from the 63 who received Twinrix in terms of age (mean ± SD; 15.1 ± 1.6 years), gender (63% male), ethnicity (70% Hispanic), race or Tanner stage. Overall, 91/100 responded (HBSAB >10 mIU/mL) with 40/46 (87.0%; 95% CI= 73.7-95.1%) responders among those receiving Recombivax and 51/54 (94.4%; 95% CI= 84.6-98.8%) responders in the Twinrix group. In univariate analysis, response rates did not vary by age, gender, Tanner stage, race, or cigarette smoking. There was a non-significant trend for decrease response in those with BMI >25 (OR 0.37 (0.09-1.5); p=0.16) and in those who ever smoked marijuana (OR 0.25 (0.06-1.03); p=0.06). Response rate was significantly increased in Hispanics (OR 6.67 (1.5-29.0); p=0.01) and decreased in those who identified as gay, bisexual or not sure (OR 0.14 (0.03-0.71); p=0.02) and in those with ≥6 life-time sex partners (p=0.002).

CONCLUSIONS: Response rate to a 2-dose immunization schedule in this population is lower than published response rates among youth receiving Recombivax HB but not for those receiving Twinrix. Although sample size is small, we observed reduced seroresponse to Hepatitis B immunization in adolescents who identify as gay, bisexual or not sure and in youth with ≥6 lifetime sexual partners.

4464.16

Poster Board 265B

MMRV Vaccine and the Risk of Febrile Seizures

Nicola P. Klein, Katherine Yih, Edwin Lewis, Sharon Greene, Ruihua Yin, Eric Weintraub, Paula Ray, Martin Kulldorff, Bruce Fireman, Roger Baxter, Liisa Lyon, Steven Black, James Baggs, Karen Broder, John Iskander, Tracy Lieu, Kaiser Permanente Vaccine Study Center, Oakland, CA; Department of Ambulatory Care and Prevention, Harvard Pilgrim Health Care, Boston, MA; Immunization Safety Office, Centers for Disease Control, Atlanta, GA; Stanford University School of Medicine, Stanford, CA.

BACKGROUND: The combination measles-mumps-rubella-varicella (MMRV) vaccine is associated with higher rates of fever 5-12 days post-vaccination than are separately administered same day MMR and varicella vaccines. After licensure, it was unknown whether MMRV vaccine is associated with increased risk of febrile seizures.

OBJECTIVE: To monitor for seizures following MMRV vaccine among children aged 12-23 months.

DESIGN/METHODS: In the initial phase, we used Rapid Cycle Analysis methods developed by the Vaccine Safety Datalink to monitor rates of inpatient and emergency department seizures in children aged 12-23 months during the 42 days post-MMRV vaccine as compared to historical seizure rates after MMR vaccine. In the analytic phase, we used temporal scans to check for clustering of seizures, chart review to confirm febrile seizures, and logistic regression to evaluate the risk of post-vaccination febrile seizures.

RESULTS: In the initial phase, the number of observed seizures (n=59) exceeded the number expected (n=38) during the 42 days post vaccination after administration of 25,779 MMRV doses. In the analytic phase, temporal scan statistics revealed significant seizure clustering 7-10 days after vaccination following both MMRV and separate MMR and varicella vaccines (P=0.00001). The adjusted odds ratio for having a confirmed febrile seizure 7-10 days post-MMRV vaccine compared with separate MMR and varicella vaccines was 2.3 (95% confidence interval [CI] 1.6, 3.2) (n for MMRV =43,353, separate MMR and varicella =314,599). The increased risk was not explained by concomitant vaccines, temporal trends, VSD site, age or influenza season. The attributable risk for febrile seizures during days 7-10 after MMRV was 5.2 per 10,000 doses (95% CI 2.2, 8.1) when compared to separate MMR and varicella vaccines.

CONCLUSIONS: Among 1 year-olds, MMRV vaccine is associated with a 2 fold increased risk of febrile seizures 7-10 days after vaccination when compared with separate MMR and varicella vaccines administered separately at the same visit.

Late Breaker Abstract Session I: Neonatology Platform Session

Monday, May 5

8:00am-10:00am

Ballroom C

5127.1

Presentation Time 8:00 AM

Caffeine for Apnea of Prematurity (CAP) Trial: Benefits May Vary in Subgroups

Peter Davis, Barbara Schmidt, Robin Roberts, Lex Doyle, Elizabeth Asztalos, Ross Haslam, Sunil Sinha, Win Tin, The CAP Investigators, Royal Women's Hospital, Melbourne, Australia; Univ of Pennsylvania, Philadelphia; McMaster University, Hamilton, Canada; Univ of Toronto, Canada; Women's and Children's Hospital, Adelaide, Australia; James Cook Univ Hospital, Middlesbrough, United Kingdom.

BACKGROUND: Caffeine therapy reduces BPD and improves survival without neurodevelopmental disability in VLBW infants (N Engl J Med 2006;354:2112 and 2007;357:1893). It is uncertain if these effects are consistent across clinically relevant subgroups.

OBJECTIVE: To determine in 2006 CAP trial participants if the benefits of caffeine vary according to 1) the indication for study drug, 2) respiratory support and 3) age at randomization

DESIGN/METHODS: Post hoc subgroup analyses were performed based on:

- 1) Indication: treat apnea, prevent apnea or facilitate extubation
- 2) Positive pressure ventilation (PPV) at randomization: endotracheal tube (ETT), non-invasive or none
- 3) Start of study drug: early or late (≤3 vs >3 days).

Outcomes assessed were those showing treatment effects in the original analyses. We investigated the consistency of caffeine effects using regression models that incorporated treatment/subgroup factor interactions and report p values for the statistical tests of interaction.

RESULTS: 1) There was little evidence of a differential treatment effect of caffeine over subgroups defined by the clinical indication for starting study drug.

2) The size and direction of the caffeine effect on death or disability differed depending on PPV at randomization (p=0.032). ORs (95% CI) were: no support 1.32 (0.81, 2.14); non-invasive support 0.73 (0.52, 1.03); ETT 0.73 (0.57, 0.94). Adjustment for baseline factors strengthened this effect (p=0.017).

3) Starting study drug early resulted in larger reductions in days of respiratory support. Postmenstrual age at time of discontinuing positive pressure ventilation was shorter with earlier treatment (p=0.014). Mean differences (95% CI) were: early 1.35 (0.90, 1.81) weeks; late 0.55 (-0.11, 0.99) weeks. Adjustment for baseline factors weakened this effect (p=0.032).

CONCLUSIONS: There is evidence of variable beneficial effects of caffeine. Infants receiving respiratory support appeared to derive more neurodevelopmental benefits from caffeine than unsupported infants. Infants who started caffeine early had a greater reduction in time on ventilation.

5127.2

Presentation Time 8:15 AM

Does High-Dose Dietary Docosahexaenoic Acid (DHA) Improve the Neurodevelopmental Outcome of Preterm Infants?

Maria Makrides, Robert A. Gibson, Carmel T. Collins, Andrew J. McPhee, Philip Ryan, Peter G. Davis, Lex W. Doyle, Karen Simmer, Noel French, Scott Morris, Paul B. Colditz, Lisa G. Smithers, Kristyn Willson, Karen P. Best, Women's & Children's Health Research Institute, Adelaide, Australia; The University of Adelaide, Adelaide, Australia; Women's and Children's Hospital, Adelaide, Australia; University of Melbourne, Melbourne, Australia; University of Western Australia, Perth, Australia; Flinders Medical Centre, Adelaide, Australia; University of Queensland, Brisbane, Australia.

BACKGROUND: Despite the universal addition of DHA to preterm formulas there are few data supporting the neurodevelopmental effect of dietary DHA in preterm infants.

OBJECTIVE: To determine whether supplementing preterm infants to achieve the estimated *in utero* accretion of DHA (≈1% of dietary fatty acids) improves neurodevelopment.

DESIGN/METHODS: Infants born <33 weeks' gestation were randomly allocated to high- or standard-DHA according to a concealed schedule stratified for sex and birth weight (<1250 g and ≥1250 g). Mothers providing breast milk consumed capsules containing 3 g of either tuna oil (900 mg DHA) or soy oil (no DHA) that resulted in milk with either high (1.0%) or standard (0.3%) DHA. A formula with a matching high vs. standard DHA concentration was used for infants requiring supplemental feeds. The intervention was from day 2-5 of life until due date. Primary outcome was Bayley Mental (MDI) and Psychomotor Developmental Indices (PDI) at 18 months' corrected age. *A priori* subgroup analyses were conducted based on randomization strata.

Late Breaker Abstract Session I: Neonatology Platform Session

RESULTS: 657 infants were randomized to high- (n=322) or standard- (n=335) DHA groups. 639 (97.3%) infants completed the treatment phase and 96.4% completed the 18 month follow-up. Unadjusted analyses showed no overall differences in MDI or PDI between groups (mean difference, MD, 1.6, 95% CI -1.2, 4.4), but interactions for MDI between diet and sub-groups were evident. In the <1250 g sub-group, infants fed high-DHA had higher MDI scores than controls (MD 4.6, 95% CI 0.1, 9.0 p<0.05). Girls fed high-DHA also had higher MDI scores than control girls (MD 4.6, 95% CI 0.5, 8.7 p<0.05). The MDI of boys did not differ between groups.

CONCLUSIONS: Infants born <1250 g benefit from high-DHA in the neonatal period and high-DHA improves the MDI scores of girls.

5127.3

Presentation Time 8:30 AM

A Multicenter, Randomized Trial on Prophylactic Bovine Lactoferrin in Preterm Neonates: Preliminary Data

Paolo Manzoni, Fabio Mosca, Hubert Messner, Rosario Magaldi, Silvia Cattani, Mauro Stronati, Daniele Farina, Neonatology, S. Anna Hospital, Torino, Italy; NICU, IRCCS Mangiagalli, University of Milano, Milano, Italy; NICU, Ospedale Regionale, Bolzano/Bozen, Italy; UTIN, Ospedali Riuniti, Foggia, Italy; NICU, University of Modena, Modena, Italy; Pat.Neonatale, IRCCS San Matteo, Pavia, Italy.

BACKGROUND: Lactoferrin (LF) is a human milk glycoprotein that plays a major role in innate immune host defenses, with a wide array of biological (including anti-infective) properties. In animal models, its activity has been found to be emphasized by the combination with *Lactobacillus Rhamnosus*GG (LGG).

OBJECTIVE: We performed a multicenter, double-blind, placebo-controlled RCT to assess effectiveness and safety of prophylactic LF supplementation (alone or in combination with LGG) to preterm neonates in NICU for prevention of late-onset sepsis (LOS), and here we present the preliminary data.

DESIGN/METHODS: During 6 months, all preterm VLBW neonates from 11 Italian NICUs were randomized to receive since birth either Bovine LF alone (100 mg/day, gr.A1; n=99) or in combination with LGG (10⁶ CFU/day, A2; n=99), or placebo (B, n=104) till the 30th day of life (45th for those <1000g at birth). Drugs and placebo were administered orally, once a day. Systematic surveillance for detection of sepsis and adverse effects was performed. LOS was defined as episodes occurring >5 days after birth, and microbiologically confirmed by isolation of a pathogen (any type) from blood, urine or cerebrospinal fluid.

RESULTS: A total of 302 neonates (65% of the planned enrolment) were analysed. Their clinical, demographical and management characteristics did not differ, particularly related to the type of feeding and to the amounts of maternal milk intakes. Overall, LOS incidence was significantly lower in groups A1 and A2 (9.3% and 5.9% respectively) than in B (26.1%) (R.R. 0.304; 95% C.I. 0.16-0.77; p=0.008 in A1; R.R. 0.19; 95% C.I. 0.08-0.39; p<0.001 in A2). The decrease in LOS incidence was similar both for episodes caused by bacterial and fungal agents. However, group A2 showed a slightly higher (although not significant) efficacy than A1 when considering the effect on fungal sepsis alone. No adverse effects or intolerances occurred. CONCLUSIONS: Based on preliminary data, bovine LF (alone, or in combination with LGG) orally administered to preterm VLBW neonates significantly and safely reduces the incidence of LOS.

5127.4

Presentation Time 8:45 AM

Effects of Early Aggressive Nutrition on Growth and Neurodevelopment of Infants with Birth Weight (BW) <1250g: A Randomized Controlled Trial

Sudha Kashyap, Elizabeth Matthews, Tove Rosen, Rakesh Sahni, Stephen Holleran, Rajasekhar Ramakrishnan, Pediatrics, College of Physicians and Surgeons, Columbia University, New York, NY.

BACKGROUND: Last year we reported that early aggressive nutritional regimen providing higher protein (P) vs a conventional regimen was well tolerated and resulted in improved growth in infants BW <1250g. Long term safety and efficacy of this strategy is not known.

OBJECTIVE: To determine the effects of early higher P intake on growth and neurodevelopment of infants BW <1250g at 18 m corrected age (CA).

DESIGN/METHODS: Appropriate for gestational age infants BW <1250g were prospectively randomized to an early total parenteral nutritional (TPN) regimen providing 18% (Group A) or a conventional regimen providing 12.5% (Group C) of energy as P. Once the target P intakes (Group A: 4g/kg.d and Group C: 3g/kg.d) was achieved, it was maintained. TPN was discontinued when feeds reached 120ml/kg.d and feeds were advanced to provide P intake of 4g/kg.d for both groups. Growth and neurodevelopment as determined by Bayley II Scales of Infant development were evaluated at CA 18 m.

Group comparisons were made for growth. Neurodevelopment data was analyzed by multiple regression relating MDI and PDI of each subject to BW, GA, sex, income, caretaker's education and human milk received. The diet effect was determined with adjustment for significant covariates (income for MDI; income, GA and sex for PDI).

RESULTS: The 18m follow up visit data were available in 68 of 102 infants. 2 infants from Group A were untestable (blindness and autism). There were no differences in MDI, PDI, and weight (W), length (L) and headcircumference (HC) between the two groups at CA of 19.5±2.2 vs 20.9±4.4 m. The neurodevelopment and growth data are summarized below.

Group	MDI	PDI	MDI <70	PDI <70	W (kg)	L (cms)	HC (cms)
A (n=34)	75.6±16.4	78.9±14.5	11 (33%)	8 (23.5%)	11.2±1.4	81.8±3.7	47.4±1.9
C (n=32)	77.1±19.0	75.5±15.0	12 (37.5%)	11 (34.4%)	11.4±1.6	83.2±5.0	46.4±1.9

CONCLUSIONS: Despite the differences in early growth in the neonatal ICU no differences in growth or neurodevelopment were observed between the two groups at 18 m follow up visit. However, it is reassuring that the neurodevelopmental outcome was not worse in the infants randomized to the higher early P intake. How the early growth advantage in these infants will affect outcomes beyond 18 m needs to be evaluated.

5127.5

Presentation Time 9:00 AM

Room Air Versus Oxygen Administration During Resuscitation of Preterm Infants (ROAR Study)

Yacov Rabi, Alberto Nettel-Aguirre, Nalini Singhal, Pediatrics, University of Calgary, Calgary, AB, Canada.

BACKGROUND: Clinicians are becoming increasingly concerned about the potential dangers of hyperoxia during newborn resuscitation. Studies of room air resuscitation have used static concentrations of oxygen (O₂) and focused almost exclusively on term and late preterm asphyxiated infants.

OBJECTIVE: To determine which of three O₂ strategies is most effective at maintaining a target oxygen saturation (SpO₂) range of 85 to 92% in preterm infants.

DESIGN/METHODS: Blinded, randomized control trial of delivery room resuscitation in infants ≤32 weeks gestation comparing three O₂ strategies. The High O₂ Burden (HOB) group received a static concentration of 100% O₂. In the Moderate O₂ Burden (MOB) and Low O₂ Burden (LOB) groups, resuscitation started with 100% O₂ and 21% O₂, respectively, and the inspired O₂ concentration was titrated by 20% every 15 seconds until the target SpO₂ range of 85 to 92% was reached. SpO₂ measurements were recorded every 2 seconds from the right wrist (pre-ductal). Peak inspiratory pressure, respiratory rate, end-tidal CO₂ concentration and inspired O₂ concentration were continuously monitored.

RESULTS: We enrolled 106 infants (HOB n=38, MOB n=34, LOB n=34). All three groups had a mean gestational age of 29 weeks and had similar birth weights and cord pH. The mean proportions of resuscitation time spent in the target SpO₂ range (95% CI) were 11%* (9-14), 21%* (16-26) and 16% (13-20) for the HOB, MOB and LOB groups, respectively (*p<0.01). The LOB group spent the greatest proportion of time (61%) below the target SpO₂ range (p<0.001) and the HOB group spent the greatest proportion of time (49%) above the target SpO₂ range (p<0.001). The mean inspired O₂ concentrations at the end of resuscitation (mean, 95% CI) for the MOB (33%, 27-39) and LOB (36%, 27-45) groups were similar. There were no significant differences between the three groups for the peak inspiratory pressure, rate of positive pressure breaths or end-tidal CO₂ concentration.

CONCLUSIONS: The strategy of starting resuscitation with 100% O₂ followed by titration of the inspired O₂ concentration was most effective at maintaining the SpO₂ in the target range of 85 to 92%. This study also showed that pulse oximetry can be used to guide titration of the inspired O₂ concentration during delivery room resuscitation of preterm infants.

5127.6

Presentation Time 9:15 AM

Fellow in Training

Stem Cell-Based Therapy Prevents Alveolar Injury In Vitro and In Vivo

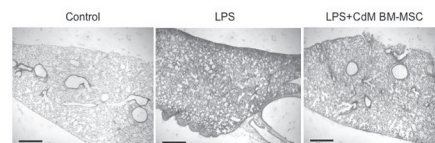
Roisin Byrne, Juliana Rey, Tim van Haaften, Farah Eaton, Bernard Thebaud, Pediatrics, U of Alberta, Edmonton, AB, Canada.

BACKGROUND: Acute and chronic lung injury remains a major cause of morbidity of extreme prematurity. We showed that bone-marrow derived mesenchymal stem cells (BM-MSC) prevent oxygen-induced lung injury in newborn rats, but the proportion of donor-derived cell engraftment was low.

OBJECTIVE: To investigate the contribution of soluble factors secreted by BM-MSC in lung injury.

DESIGN/METHODS: We tested the protective effect of conditioned media (CdM) obtained from cultured BM-MSC in vitro in oxygen-induced injury of freshly isolated rat alveolar epithelial cells (AEC), in an AEC wound healing assay, and in a rat lung microvessel endothelial cell (RLMVEC) cord formation assay. We also tested the protective effect of BM-MSC CdM in vivo in LPS-induced lung injury in mice.

RESULTS: In vitro, BM-MSC CdM decreased oxygen-induced apoptosis (TUNEL) and increased proliferation (BrdU) of AEC, and accelerated the wound-healing rate of a scratched monolayer of AEC, as compared to control media. BM-MSC CdM increased the number of intersections and cord length of RLMVEC, as compared to control media. In vivo, BM-MSC CdM reduced body weight loss of mice instilled intratracheally with LPS and improved lung histology.



CONCLUSIONS: BM-MSC CdM prevents AEC apoptosis, accelerates AEC wound healing, enhances endothelial network formation and prevents LPS-induced lung injury. MSC may exert their beneficial effects through a paracrine activity.

5127.7

Presentation Time 9:30 AM

Role of Nicotine as an In-Vivo Mediator of Fetal Hypoxemia

Shabih U. Hasan, Anita Rigaux, Yolanda MacKinnon, Kamran Yusuf, Pediatrics, University of Calgary, Calgary, AB, Canada.

BACKGROUND: Cigarette smoke (CS) is the most common chemical insult to the developing fetus causing both short and long term adverse effects on fetal and neonatal development. It is well established that CS exposure leads to low birth weight (LBW), which is the key reason d'etre of infant mortality and morbidity. Despite little or no convincing evidence in humans, LBW has been consistently attributed to the vasoconstrictive effects of nicotine (NIC) present in CS leading to fetal hypoxemia.

OBJECTIVE: To investigate the dose-response of NIC on plasma NIC concentrations (conc) and fetal gas exchange to test the null hypothesis that maternal exposure of NIC does not lead to fetal hypoxemia after moderate or high doses.

DESIGN/METHODS: We studied 14 fetal sheep at gestation d 127-135 (term ~147 d). The fetal instrumentation included implantation of electrodes to obtain and define fetal sleep states and breathing movements. Arterial catheters were placed to record maternal and fetal blood pressure, heart rate and to draw samples for NIC assays and measure pH, PaO₂ and PaCO₂, and acid base status. In addition, maternal venous catheter was placed for NIC administration. NIC was infused daily for ten days on an hourly basis over five minutes to mimic human smokers and to achieve maternal plasma NIC conc. equivalent and 2-fold higher than those observed in heavy human smokers.

RESULTS: Plasma NIC conc. varied 10-60 ng/ml with low dose and >100 ng/ml with high dose. The trough and peak NIC conc. were similar to those observed in human smokers in a pulsatile fashion. By 10 d, NIC steady state was reached and fetal plasma NIC conc. were higher than those observed in maternal plasma. Our 3-compartment model showed that total NIC clearance increased with chronic NIC administration. We observed no significant effect on maternal or fetal arterial pH, blood gas tensions or acid base balance regardless of the duration of NIC administration, the dose or the plasma conc. in maternal or fetal compartments.

CONCLUSIONS: We provide unequivocal and critical evidence that NIC has no effects on materno-fetal gas exchange. Our data confirms and extends our recent observations (2006 and 2007) that constituents other than NIC mediate the postulated fetal hypoxemia in CS exposed fetuses. **Our data provides the critical evidence to perform clinical trials utilizing nicotine replacement therapy as an aid to smoking cessation programs in pregnant mothers.**

5128.8

Presentation Time 9:45 AM

Fellow in Training**Physiologic Mechanisms of High Flow Nasal Cannula Therapy (HFT) with Two Degrees of Leak Around Nasal Prongs**

M.A. Frizzola, K. Dysart, E. Rodriguez, Y. Zhu, J. Rojas, A. Heseck, A. Stump, T.H. Shaffer, T.L. Miller, Research/Pediatrics, Nemours, Wilmington, DE; Pediatrics, Jefferson Medical College, Philadelphia, PA; Pediatric, Nashville, TN; Physiology/Pediatrics, Temple University, Philadelphia, PA; Vapotherm, Stevensville, MD.

BACKGROUND: HFT (>2 l/min) has been shown to be more effective than CPAP in reducing intubations and ventilator days. HFT likely provides mechanisms to support respiratory efficiency beyond the application of distending pressure. We reason that with HFT washout of nasopharyngeal dead space impacts carbon dioxide removal (ventilation) as well as oxygenation.

OBJECTIVE: To demonstrate the flow dependence of carbon dioxide reduction and improved oxygenation during HFT, and the dependence on leak around the nasal prongs.

DESIGN/METHODS: Neonatal piglets (n=8; 2-6kg) were injured with IV oleic acid and supported with HFT at 2,3,4,6,8 L/min (Vapotherm 2000i). High and low leak around the nasal prongs was accomplished by using single (SP) and double (DP) prong cannulae, respectively. Measurement of hemodynamic, respiratory (inductive plethysmography) and blood gas parameters were made at each setting following 5-10 minutes for physiologic equilibration. Tracheal pressures and waveforms were recorded by transmural catheters.

RESULTS: With HFT, carbon dioxide trended downward in a flow dependent manner independent of leak (Slopes=-0.48). Oxygenation and tracheal pressures increased in a flow dependent manner (p<0.05 and p<0.001) with the greatest effect during DP. At 8L/min, tracheal pressures did not exceed 6±1 cmH₂O. There was no flow dependent change in breathing frequency or relative tidal volume.

CONCLUSIONS: HFT improves oxygenation in a flow dependent manner, where low leak has greater impact on oxygenation. In clinical application, HFT can be used to improve oxygenation while enhancing carbon dioxide elimination.

Late Breaker Abstract Session II: General Pediatrics Platform Session

Monday, May 5

3:00pm-5:00pm

Room 323A

5628.1

Presentation Time 3:00 PM

Heavy Metal Exposure Among Children Living near an Open Pit Mine: A Combined Approach Towards Risk Assessment. Cerro De Pasco, Peru – May 2007

Laura M. Conklin, Carlos Sanchez, Antonio Neri, Jeffrey Jarrett, Paula Staley, Wendy Blumenthal, Rebecca LePrell, James Durant, Rene Suarez-Soto, Mary Jean Brown, Jim Lando, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Atlanta, GA.

BACKGROUND: Children living in mining communities are at high risk of exposure to toxic levels of lead and other heavy metals. In 2006, Ministry of Health (MINS) officials in the lead-mining town of Cerro de Pasco, Peru, requested assistance from the Centers for Disease Control and Prevention (CDC) in identifying risk factors for exposure so that interventions could be made to reduce heavy metal toxicity among the city's children.

OBJECTIVE: To use municipal maps, biological, and environmental samples to assess heavy metal exposures among children and identify risk factors associated with toxicity.

DESIGN/METHODS: A cross-sectional assessment was performed in two communities.

Participants were drawn from households in randomly selected lots using municipal maps.

Demographic data and exposure risk factors were obtained. Blood and urine samples were analyzed for lead, cadmium, mercury, antimony, total arsenic, barium, beryllium, cesium, cobalt, molybdenum, platinum, thallium, tungsten and uranium. Soil, water and dust samples from a subset of households were analyzed for lead and plotted on municipal maps. Risk factors for elevated levels were evaluated using conditional logistic regression.

RESULTS: Of 123 children enrolled, 60% had blood lead levels (BLL) greater than the CDC recommended level of 10ug/dL. Over 50% of children also had elevated levels of cesium and thallium. Of 53 household soil samples analyzed, 79% had lead levels over the Environmental Protection Agency limit of 400ppb. Mapping of soil results revealed areas of lead contamination. Risk factors for elevated BLL included age <5years (OR=3.9, 95%CI: 1.6, 9.6), soil lead level >1200ppb (OR=9.0, 95%CI: 1.8, 44.6) and residence in community B (OR=7.6, 95%CI: 2.7, 21.4). Risk factor analysis of cadmium and thallium is ongoing.

CONCLUSIONS: Cerro de Pasco children are at high risk for elevated levels of heavy metals. Recommendations to the MOH included individual and community-level interventions to decrease exposures and stressed the importance of regulating mining activities to decrease environmental contamination.

5628.2

Presentation Time 3:15 PM

Fellow in Training**A Double Blinded Randomized Controlled Trial for the Management of Pediatric Community Acquired Skin Abscesses – To Treat or Not To Treat with Antibiotics**

Myto Duong, John Peter, Donna Halloran, Stephen Barenkamp, Pediatric Emergency Medicine, Cardinal Glennon Children's Medical Center, St Louis, MO; Pediatric, Cardinal Glennon Children's Medical Center, St Louis, MO; Pediatric Infectious Disease, Cardinal Glennon Children's Medical Center, St Louis, MO.

BACKGROUND: In children, skin abscesses due to community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) are a growing concern. Controversy and a paucity of data exist on the effectiveness of antibiotic (abx) therapy following incision and drainage (I&D) of these abscesses.

OBJECTIVE: Determine the utility of abx in the management of skin abscesses following I&D.

DESIGN/METHODS: This is a double-blind, randomized controlled trial at an urban pediatric emergency department. Sample size (162) was based on a threshold equivalence of 7% ($\alpha = 0.05$, power = 80%). Inclusion criteria: non-toxic, immunocompetent, 3 months to 18 years old, English-speaking patients (pts) with clinical or ultrasound identified skin abscesses who were not on abx. Pts were block randomized to receive placebo or trimethoprim/sulfamethoxazole following I&D. Follow-up was a call at 2-3 days & a repeat visit or call at 10-14 days. Treatment (tx) failure: persistent erythema, tenderness, and/or draining lesions.

New lesion: primary resolution with development of an abscess at a different location.

Compliance was evaluated by the return of the study medication or by pt report.

RESULTS: 161 patients enrolled (12 lost to follow-up). Main pathogens: CA-MRSA (119, 80%) with 15% clindamycin resistance, methicillin-sensitive *Staphylococcus aureus* (13, 9%), *Proteus mirabilis* (6, 4%) & Group A streptococcus (2, 1%).

Overall tx failure rate was 5% (7/149) - 4/76 on placebo (5%) & 3/73 on abx (4%) (RR = 0.99, 95%CI 0.93, 1.06). New lesions occurred in 28 pts (19%) - 18 on placebo (25%) & 10 on abx (14%) (RR = 0.87, 95%CI 0.75, 1.04).

Ninety-nine patients (66%) took >50% of the medication - 54 on placebo & 45 on abx. In this compliant population, tx failure rate was 2/54 on placebo and 0/45 on abx (RR=0.96, 95%CI 0.97, 1.03). New lesions occurred in 14 pts - 12/54 on placebo and 2/45 on abx (RR=0.81, 95%CI 0.74, 0.96).

CONCLUSIONS: After I&D of skin abscesses in children, antibiotics do not appear to be helpful in resolving the primary abscess but may be beneficial in preventing the appearance of new lesions. Larger trials are needed to validate these results.

5628.3

Presentation Time 3:30 PM

Efficacy of Subcutaneous Hydration Augmented with Recombinant Human Hyaluronidase in Children

Coburn H. Allen, Andrea T. Cruz, Binita Patel, Erin E. Endom, Troy Bush,

Pediatrics – Sections of Emergency Medicine & Infectious Diseases, Baylor College of Medicine, Houston, TX.

BACKGROUND: Establishing an intravenous (IV) line is challenging in dehydrated children who need parenteral fluids, especially those with difficult venous access (DVA). An alternative is subcutaneous (SC) hydration augmented with an enzymatic spreading agent, recombinant human hyaluronidase (rHuPH20), which increases the dispersion and absorption of SC fluids by enhancing connective tissue permeability.

OBJECTIVE: The Increased Flow Utilizing Subcutaneously Enabled (INFUSE) Pediatric Rehydration Study was designed to assess the clinical utility and safety of rHuPH20 in infants and children with dehydration.

DESIGN/METHODS: Patients in this Phase IV, ongoing, open-label study were children 2 months to 10 y.o. with mild to moderate dehydration (1 to 5 on the Gorelick scale) requiring parenteral fluids administered in the ED. They received 1 mL (150 U) SC rHuPH20 thru a 24-ga catheter placed in the thigh or upper back, followed by a 20 mL/kg SC bolus infusion of isotonic fluid over the first hour. Subsequent SC maintenance hydration was continued as needed until discharge to home or an alternative treatment was started.

RESULTS: 17 patients were enrolled (anticipated total sample size = 50), ages 0.4-8.6 yr (mean, 2.0 yr) weighing 5.1-29.6 kg (mean, 11.7 kg). Fourteen patients (82%) were successfully rehydrated (discharged from ED to home without the need for alternative hydration therapy). Two patients discontinued due to parental withdrawal of consent (one needed IV hydration), and one was hospitalized due to refusal of oral fluids. In the 14 patients who completed the bolus infusion, the mean volume given in the first hour was 19.5 mL/kg. The total volume of initial bolus plus maintenance fluids ranged from 21-979 mL (mean, 339 mL) and infusion duration ranged from 0.2-18.1 hr. Mean change in Gorelick score was -2.8 points. Median time to first urine output was 1.5 hours and median time to discharge or transfer to hospital was 3.4 hours. No patient required readmission to the ED or hospital due to dehydration during the 7-day follow-up period. All patients had typical infusion site reactions, but the procedure appeared to be safe, with no serious AEs.

CONCLUSIONS: In infants and young children with mild to moderate dehydration, SC fluids augmented with rHuPH20 achieved clinically indicated fluid volumes.

5628.4

Presentation Time 3:45 PM

Medical Student

The Effect of Probiotic (OHHIRA-OMX) as Adjunct Treatment in Patient with Febrile Neutropenia Among Children 2-18 Year Old: A Randomized, Double-Blind, Placebo-Controlled, Clinical Trial

Christine Natalita, Pediatric, Cardinal Santos Medical Center, Manila, Philippines.

BACKGROUND: Febrile Neutropenia is a serious complication among children with malignancy undergoing chemotherapy session. Mechanisms to prevent complication apart from administration of toxic antimicrobials are investigated in several studies. We present a probiotic intervention (OHHIRA-OMX) composed of lactobacilli and nutritive additives as an adjunct treatment.

OBJECTIVE: To determine the role of probiotics in children with febrile neutropenia as adjunct therapy.

DESIGN/METHODS: In a randomized, double-blind, placebo-controlled, clinical trial study conducted in 3 tertiary hospital in Metro Manila, a total of 42 episodes febrile neutropenia among children 2-18 year old, fulfilling Infectious Disease society of America criteria, admitted at hospital, with antibiotics therapy, with or without given GCSF, without known Human Immunodeficiency Virus Infection or Chronic Benign Neutropenia were randomized to probiotic (n=18) and placebo (n=24) taken orally 1 capsule twice a day for 7 days were included in the final analysis. All subjects were comparable in terms of age, sex, disease severity, baseline absolute neutrophil count, antibiotics and result of bacteriologic work up. All of clinical signs and symptoms were assessed during trial included absolute neutrophil counts, urinalysis, blood culture, stool exam, stool culture and chest x ray.

RESULTS: Patients taking the probiotic compared with placebo had statistically reached afebrile states as early as the 5th day of treatment (p=.004), had shown earlier increased ANC responses especially during the 3rd to the 4th day of treatment (p=.57) and had shorter duration hospital stay by a mean difference of 3 days (p=0.049) but no statistically significant difference were noted in the proportion of subjects with resolved UTI, diarrhea and mucositis.

CONCLUSIONS: Probiotic produced clinical reduction in mean body temperature, showed shorter hospital stay and it was tolerated without any adverse effects but failed to show a statistically significant increase in ANC when compared with placebo.

5628.5

Presentation Time 4:00 PM

Immunogenicity of Live Attenuated Influenza Vaccine (LAIV) Compared with Trivalent Inactivated Influenza Vaccine (TIV) in Children 12–35 Months of Age

Bryan M. Harvey, Christopher S. Ambrose, Tingting Yi, Yihong Yao, Robert E. Walker, Bahija Jallal, George Kemble for the Influenza Vaccine Comparative Immunogenicity Trial Group, Harvey Pediatric Research, Jonesboro, AR; MedImmune Inc., Gaithersburg, MD.

BACKGROUND: Children <5 years are at high risk for influenza-related complications. Recent trials have demonstrated higher efficacy of LAIV compared with TIV in children against matched and mismatched strains of influenza.

OBJECTIVE: To evaluate immune responses to 2006-2007 formulations of LAIV and TIV in influenza vaccine-naïve children 12–35 months of age.

DESIGN/METHODS: 101 children were randomized to receive either LAIV (n=50) or TIV (n=51) in May/June 2007. 58 received 2 doses 35±7 days apart; 43 received only 1 dose primarily due to TIV expiry. Serum HAI responses to CDC reference antigens (wt) for 3 vaccine-like (matched) and 2 mismatched strains, A/Solomon Islands/3/2006 (H1N1) and A/Brisbane/10/2007 (H3N2), were evaluated at baseline and 28-35 days after each dose. Because of known amino acid differences between the TIV and LAIV A/H1 vaccine strains, responses to matched cold-adapted (ca) A/H1 were also evaluated. Serum mRNA responses were evaluated at baseline and 7-10 days after each dose.

RESULTS: Seroconversion rates were significantly higher with LAIV vs TIV post-dose 1 for matched ca H1 (75% vs 38%) and matched B (64% vs 35%) and post-dose 2 for mismatched H1 (73% vs 36%). Seroconversion rates were significantly higher with TIV vs LAIV post-dose 1 and 2 for matched wt H1 (83% vs. 24%, 90% vs. 33%). After dose 1, more LAIV than TIV recipients (88% vs 20%) had a ≥2-fold increase in interferon-inducible gene signature score (P<0.05); for both vaccines, post-dose 2 gene signature responses were minimal.

CONCLUSIONS: Both LAIV and TIV were immunogenic by HAI in seronegative children 12–35 months of age. LAIV was more immunogenic against matched B post-dose 1 and mismatched H1 post-dose 2. Responses to matched A/H1 were similar when seroconversion to the respective vaccine antigens was compared. The LAIV immune response was significantly different than the TIV response as evidenced by increased interferon-inducible gene expression in LAIV recipients after dose 1. This interferon response may partly explain previous clinical study observations of protection against influenza-like illness in the first 2 weeks after LAIV administration. Funded by MedImmune.

5628.6

Presentation Time 4:15 PM

Shedding and Safety of Live Attenuated Influenza Vaccine in Healthy Subjects 6 to <60 Months of Age

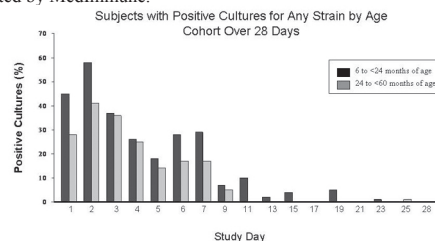
Stan L. Block, Keith S. Reisinger for the LAIV Study Group, Kentucky Pediatric/Adult Research, Bardstoen, KY; Primary Physicians Research, Pittsburgh, PA.

BACKGROUND: Live attenuated influenza vaccine (LAIV) is now indicated for prevention of influenza in children as young as 2 years of age in the U.S. This study describes the occurrence and duration of vaccine virus shedding after receipt of LAIV in children 6 to <60 months of age.

DESIGN/METHODS: A single open-label dose of LAIV (~7 log₁₀ FFU of each vaccine strain) was administered intranasally to subjects in 2 age groups: 6 to <24 and 24 to <60 months of age. Shedding was determined by culturing virus from nasal swabs (taken daily on Days 1–7, every other day on Days 9–25, and on Day 28).

RESULTS: Shedding data were available for 199 of 200 enrolled subjects. Comparing the 6- to <24-month group (n=99) to the 24- to <60-month group (n=100), viral shedding was detected in 89% vs. 69%, respectively (p<0.001). The mean number of positive shedding samples per subject was similar: 2.9 vs. 2.7, respectively. Shedding incidence was highest on Day 2 for both groups (see figure). Shedding titers peaked on Day 2 (<6 and <5 log₁₀ TCID₅₀/mL) and shedding titers became undetectable (<1.5 log₁₀ TCID₅₀/mL) after Day 13 and after Day 9 respectively. Runny nose/nasal congestion (56%), irritability (20%) and cough (18%) were the reactogenicity events (REs) most commonly noted during Days 0-10 after vaccination.

CONCLUSIONS: Shedding of vaccine virus after LAIV vaccination is common and occurs less frequently in older children. For children >24 months of age the highest titers were 100-fold less than the vaccine dose and not quantifiable after Day 9. These findings may help to explain why secondary transmission has been observed infrequently in controlled studies in young children. REs in this study were common and similar to those seen in previous studies of LAIV. Supported by MedImmune.



5628.7

Presentation Time 4:30 PM

Efficacy of the Pentavalent Rotavirus Vaccine Between Doses: Potential Benefits of Early Protection

Penelope H. Dennehy, Timo Vesikari, David O. Matson, Robbin Itzler, Michael Dallas, Michelle Gouveia, Mark DiNubile, Penny Heaton, Jody Lawrence, Max Ciarlet, Pediatric Infectious Diseases, Hasbro Children's Hospital, Providence, RI; University of Tampere, Tampere, Finland; Pediatrics, Eastern Virginia Medical School, Norfolk, VA; Merck & Co., Inc., West Point, PA.

BACKGROUND: The Rotavirus Efficacy & Safety Trial (REST) demonstrated that 3 doses of the pentavalent rotavirus vaccine (PRV) significantly reduced the per-protocol rate of healthcare resource utilization (HCRU), defined as hospitalizations and emergency department (ED) visits due to rotavirus gastroenteritis (RGE), measured ≥ 14 days postdose (PD) 3, by 95% (95% confidence interval [CI]: 91,97) relative to placebo.

OBJECTIVE: To evaluate if PRV confers early protection to infants before completion of the 3-dose regimen.

DESIGN/METHODS: ~70,000 healthy 6-12 week-old infants were randomized (1:1) in a blinded fashion to receive 3 doses of PRV or placebo at 4-10 week intervals. RGE was defined as forceful vomiting and/or ≥ 3 watery or looser-than-normal stool within a 24-hour period and detection of rotavirus antigen by enzyme immunoassay. Among ~59,000 evaluable subjects, the efficacy, measured by rate reduction in HCRU, between doses of PRV against RGE due to rotavirus strains of serotypes G1-G4, or any serotype, was evaluated using the exact binomial method for ratios of Poisson counts in several post-hoc analyses of REST: (A) ≥ 14 days PD1 up to Dose 2 and ≥ 14 days PD2 up to Dose 3; (B) ≥ 14 days PD1 up to Dose 2 and immediately following Dose 2 up to Dose 3; and (C) ≥ 14 days PD1 through 13 days PD2 and from ≥ 14 days PD2 through 13 days PD3. In all analyses, case counting started 14 days PD1 to allow time for an immune response to develop after the first dose.

RESULTS: The efficacy (%) between doses of PRV was:

Analysis	Dose 1 to Dose 2 (95% CI)		Dose 2 to Dose 3 (95% CI)	
	G1-G4 Serotypes	Any Serotype	G1-G4 Serotypes	Any Serotype
A	100 (72,100)	82 (39,97)	91 (63,99)	84 (54,96)
B	same as Analysis A		95 (78,99)	88 (68,96)
C	100 (87,100)	88 (65,97)	91 (72,98)	88 (69,96)

CONCLUSIONS: Post-hoc analyses of REST indicate that PRV provides consistently high protection against RGE-attributable hospitalizations and ED visits between doses, starting ≥ 14 days PD1. PRV's early protection against severe RGE may be particularly beneficial to infants vaccinated during rotavirus epidemic seasons.

5628.8

Presentation Time 4:45 PM

A Phase III Study Comparing the Safety and Immunogenicity of a Novel Quadrivalent Meningococcal Conjugate Vaccine, MenACWY-CRM, with the Licensed MCV4, Menactra™, in Adolescents

Lisa Jackson, Roger Baxter, Keith Reisinger, Jina Shah, Lisa Bedell, Peter M. Dull, V59P13 Study Group, Group Health Center for Health Studies, Seattle, WA; Kaiser Permanente Vaccine Study Center, Oakland, CA; Primary Physicians Research, Pittsburgh, PA; Novartis Vaccines & Diagnostics, Emeryville, CA. BACKGROUND: Meningococcal disease causes significant morbidity and mortality, with highest incidence in infants and adolescents. Quadrivalent meningococcal conjugate vaccine (MCV4) is recommended for routine immunization of adolescents and high-risk groups. OBJECTIVE: This study compares the safety and immunogenicity of Novartis Vaccines quadrivalent meningococcal CRM₁₉₉ conjugate vaccine, MenACWY-CRM, with the licensed MCV4, Menactra.

DESIGN/METHODS: In this Phase III US study, 2170 subjects (11-18y) received 1 dose of MenACWY-CRM or Menactra. Solicited local and systemic reactions up to 7 days post-vaccination and medically significant AEs were recorded. Immunogenicity was assessed 1 month post-vaccination by serum bactericidal activity using human complement (hSBA). Statistical superiority was based on group differences in the proportion of subjects with an hSBA titer $\geq 1:8$ (lower limit [LL] of 95% CI $>0\%$) and GMT ratios (LL 95% CI >1).

RESULTS: Both vaccines were well tolerated with comparable reactogenicity. One month post-vaccination, more MenACWY-CRM than Menactra recipients achieved an hSBA titer $\geq 1:8$ for serogroups A, W-135, and Y (LL 95% CI $\geq 3\%$) (non-inferior for C [LL 95% CI -3%]) (Table 1). Results were similar on restriction of analysis to subjects with undetectable baseline hSBA. For all serogroups, 1-month post-vaccination GMTs were higher after MenACWY-CRM than Menactra vaccination.

CONCLUSIONS: Novartis Vaccines MenACWY-CRM vaccine is well tolerated in adolescents and provides higher GMTs 1 month post-vaccination against all 4 serogroups, compared with Menactra.

Study funded by Novartis Vaccines.

Table 1. One-month post-vaccination serum bactericidal activity

	A		C		W-135		Y	
	% hSBA titer $\geq 1:8$ (95% CI)							
MenACWY-CRM	n=1075	75 (73-78)	n=1483	84 (82-86)	n=1024	96 (95-97)	n=1036	88 (85-90)
Menactra	n=359	67 (62-72)	n=501	84 (80-87)	n=288	88 (84-92)	n=294	69 (63-74)
Group difference	-	8 (3-14)*	-	1 (-3-5)	-	8 (4-12)*	-	19 (14-25)*
GMT (95% CI)								
MenACWY-CRM	n=1075	29 (24-35)	n=1483	59 (48-73)	n=1024	87 (74-102)	n=1036	51 (42-61)
Menactra	n=359	18 (14-23)	n=501	47 (36-61)	n=288	44 (35-54)	n=294	18 (14-23)
GMT ratio	-	1.63 (1.31-2.02)†	-	1.27 (1.01-1.60)†	-	2.00 (1.66-2.42)†	-	2.82 (2.26-3.52)†

*LL 95% CI $>0\%$
†LL 95% CI >1.0

Late Breakers II Poster Session:

Monday, May 5

3:00pm-6:45pm

Exhibit Hall

5855.1

Poster Board 763

Medical Student Accurate Diagnosis of Kawasaki Disease: Color Flow Mapping in Lymphadenopathy

Ogata Shouhei, Bando Yuki, Kimura Sumito, Yayoi Nakahata, Ishii Masahiro, Pediatric, Kitasato University, Sagamihiro, Kanagawa, Japan.

BACKGROUND: Kawasaki disease (KD) is an acute vasculitis syndrome of childhood characterized by fever, bilateral nonexudative conjunctivitis, erythema of the lips and oral mucosa, changes in the extremities, rash, cervical lymphadenopathy. Accurate diagnosis of incomplete KD was often difficult. There was no report about the blood flow lymphadenopathy in KD patients detected by color Doppler ultrasound imaging.

OBJECTIVE: The objective of this study was to evaluate the blood flow of cervical lymphadenopathy using color Doppler flow mapping.

DESIGN/METHODS: For 13 KD patients, including complete KD 6 cases, incomplete KD 7 cases, were studied. As control 8 patients with suppurative lymphadenitis and 1 patients Kikuchi-Fujimoto disease were studied.

RESULTS: In all KD patients, both complete and incomplete KD patients, increased blood flow in cervical lymphadenopathy were detected by color flow mapping. In contrast, in other 9 patient, blood flow in cervical lymphadenopathy could not be detected by color flow mapping.

CONCLUSIONS: Color flow mapping in lymphadenopathy of KD patients may be useful tool for accurate diagnosis of KD.

5855.2

Poster Board 764

Problems and Future Prospects Regarding the Mild Brain Hypothermia Therapy Protocol for Infant

George Imataka, Hitoshi Katashio, Kouji Wake, Hideo Yamanouchi, Osamu Arisaka, Pediatrics, Dokkyo Medical University, Tochigi, Japan; Critical Care and Medicine, Dokkyo Medical University, Tochigi, Japan.

BACKGROUND: To investigate the problems and future prospects of the mild brain hypothermia and steroid pulse therapy, the Dokkyo Medical University Emergency Center has been working proactively after creating a protocol for mild brain hypothermia therapy to respond to epilepsy, acute encephalitis/encephalosis, severe head injuries, near-drowning, and similar conditions that occur during infancy.

OBJECTIVE: When we first began using this therapy, our hospital had staff members, including pediatric neurologists, ICU doctors, and nurses, familiarize themselves with the general overview of this protocol and then established a system to be able to implement the protocol at any hour whenever necessary.

DESIGN/METHODS: Consequently, over a term of two years and nine months between February 2004 and November 2006, this protocol was implemented in a total of 26 cases of infantile epilepsy, acute encephalitis, and cases with symptoms similar to acute encephalopathy. In all cases, after performing such standard procedures such as the placement of intravenous hyperalimentation catheter, steroid pulse therapy and mild brain hypothermia therapy could actually be performed for each patient within three hours after they entered the ICU. The treatment period for hypothermia ranged from 48 to 72 hours, during which time steroid pulse therapy was concomitantly performed in all cases.

RESULTS: Although a diverse range of complications were observed, including segmental pneumonia and hypotension, all 26 cases were transferred from the ICU into general wards by concomitantly using a variety of drugs.

CONCLUSIONS: The detailed preparation and sharing of this protocol ahead of time was thus found to be effective for clinically implementing this method both safely and smoothly. The cooperation of staff members who were familiar with ICU pediatric emergency and critical care medicine and pediatric neuroscience was essential for successfully implementing this protocol as promptly as possible.

5855.3

Poster Board 765

Effects of Dihydrofolate Reductase Gene Knock-Down on the Cardiac Development of Zebrafish

Shu-na Sun, Yong-hao Gui, Hou-yan Song, Department of Pediatrics, Children's Hospital of Fudan University; Department of Molecular Genetics, Shanghai Medical College of Fudan University, Shanghai, China.

BACKGROUND: Folic acid is very important for embryonic development, and dihydrofolate reductase (*DHFR*) is one of the key enzymes responsible for the biological functions of folic acid. Therefore, the dysfunction of *DHFR* can impair the function of folic acid and can finally disrupt the embryonic development. *DHFR* is conserved during vertebrate evolution. By studying the effects of *DHFR* knock-down on cardiac development in zebrafish, we provided clues to investigate the relationship between folic acid dysfunction and congenital heart disease in human fetus.

OBJECTIVE: In zebrafish, we aimed (1) to observe the abnormal cardiac phenotypes induced by *DHFR* knock-down, (2) to detect the expression of genes which are important to cardiac development including *NKX2.5*, *MEF2C*, *TBX20* and *TBX5* in *DHFR* knock-down embryos, and (3) to investigate the effect of *DHFR* knock-down in *Hedgehog* pathway by detecting the expression of down-stream and up-stream factors of *Hedgehog* pathway including *SHH*, *EHH*, *FOXA2* and *PTC-1*.

DESIGN/METHODS: Morpholino oligonucleotides were microinjected into zebrafish to knock down the functions of *DHFR* (n=100). The cardiac morphology, heart rate and ventricular shortening fraction were observed and recorded under the microscope at 48 hpf. Using microangiography, the development of outflow tract was observed at 60 hpf. Whole-mount in situ hybridization and real-time PCR were performed to detect the expression of genes. Vehicle microinjection was used in the control group (n=100).

RESULTS: The cardiac development of control zebrafish embryos was normal. *DHFR* knock-down embryos developed abnormal cardiac phenotypes including ventricular and atrial dilation or dysplasia as a linear tube, and the malformation of outflow tract. The heart rate and ventricular shortening fraction were reduced in *DHFR* knock-down embryos (55±6 beats/min vs. 165±8 beats/min and 18±3% vs. 26±4% of controls, respectively). *DHFR* knock-down decreased the expression of *NKX2.5*, *MEF2C*, *TBX20*, *TBX5* and disrupted the *Hedgehog* pathway by reducing the expression of *PTC-1*.

CONCLUSIONS: *DHFR* plays a crucial role in cardiac development of zebrafish. The reduced expression of *NKX2.5*, *MEF2C*, *TBX20*, *TBX5* and the disruption of *Hedgehog* pathway relate with the cardiac malformation which is induced by *DHFR* knock-down.

5855.4

Poster Board 766

Resident

The Effect of Probiotic – Protexin Restore Supplementation in Children more than 2 Months Old with Atopic Dermatitis: A Randomized Controlled Trial

Rhodalyne R. Atis, Vicky Wee E. Binas, Pediatrics, De La Salle University Medical Center, Dasmariñas, Philippines.

BACKGROUND: Probiotics are suggested to reduce the clinical severity of Atopic Dermatitis. This could be an important breakthrough for health care and wellbeing of atopic patients.

OBJECTIVE: To determine the efficacy of Probiotic – Protexin Restore supplementation in reducing the clinical severity of Atopic Dermatitis in children more than 2 months old, as measured by change in SCORAD index from the beginning of study treatment to the end of the treatment.

DESIGN/METHODS: Randomized double blinded placebo controlled study

SETTING: Secondary and Tertiary Hospitals in Cavite

PARTICIPANTS: Children more than 2 months with Atopic dermatitis (AD) who fulfill the Hanifin and Rajka diagnostic criteria for Atopic Dermatitis and who met the inclusion criteria, of whom 9 were dropped out. Utilizing a randomization list, 25 children were given Protexin-Restore and 26 children given placebo.

METHODOLOGY: Subjects were randomized into two groups, the Probiotic Protexin-Restore group and the placebo group. All participants were followed over a 2 week period. SCORAD assessment was performed to all the participants from baseline (day 0), after 4 days, at weeks 1 and 2.

OUTCOME MEASURES: The primary outcome measure is change in the severity of Atopic Dermatitis among children receiving probiotic and placebo as assessed by the SCORAD index.

RESULTS: Reduction in the SCORAD index over time was significant both in probiotic and placebo group. There was a distinct improvement with greater proportion among the probiotic group at weeks 1 and 2, however this does not reach statistical significance. Analysis on proportion for improvement after each assessment period showed no significant difference between the groups, the probiotic group was not significantly likely to improve than placebo group.

CONCLUSIONS: This study fails to describe statistically significant clinical effect of Probiotic Protexin-Restore in children with AD when its effect is assessed only for a duration of two weeks. The results indicate that oral supplementation with this probiotic bacterial strain will not have a significant impact in reducing its clinical severity for a short duration of time.

5855.5

Poster Board 767

The Histological Features of the Liver of Citrin Deficiency in Childhood

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BACKGROUND: Citrin deficiency causes adult-onset type 2 citrullinaemia and a type of neonatal intrahepatic cholestasis by Citrin deficiency (NICCD). Between these phenotypes, there is an apparently healthy state in childhood.

OBJECTIVE: To evaluate the pathological features of Citrin deficiency in children during apparently healthy states (> 1 year of age).

DESIGN/METHODS: Five patients, who were proven to be homozygotes or compound heterozygotes for *SLC25A13* gene mutations, were enrolled in this study. The phenotype of the 3 patients (2-3 months of age) was NICCD and the other 2 patients (3 and 8 years of age) with mild chronic liver dysfunction were diagnosed after 1 year of age. Light microscopic and electron microscopic features were evaluated.

RESULTS: The histological findings of the NICCD patients presented slightly giant cell formation, fat droplet accumulation of liver cells (30-50%), periportal iron deposition of liver cells and mild fibrosis. The electron microscopic findings showed the decline of microvilli of bile canaliculi which means intrahepatic cholestasis. In two children, follow-up liver biopsy with normal biochemical findings of their blood tests at 2 year of age presented fat droplet accumulation (5%) and mild fibrosis. On the other hands, the both light and electron microscopic histological findings of 3-year-old patient during apparently healthy states was compatible with non alcoholic steatohepatitis (NASH). Histological findings of 8-year-old patient were compatible with chronic hepatitis, while electron microscopic findings showed very tiny fat droplet in hepatocytes.

CONCLUSIONS: The children during apparently healthy states seem to have abnormal histological findings of the liver with large varieties.

5855.6

Poster Board 768

Ph.D. Student

Does Haemophilus Influenzae Type B Vaccination Increase the Risk of Atopic Disorders in Young Infants?

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BACKGROUND: Epidemiologic evidence for an association between vaccinations and atopy development is inconsistent.

OBJECTIVE: The aim of this study was to determine the influence of neonatal Haemophilus influenzae type b (Hib) vaccination on the prevalence of atopic disorders in addition to diphtheria-tetanus-pertussis-inactivated poliomyelitis (DTP-IPV) and other vaccinations.

DESIGN/METHODS: We used multistage, stratified systematic sampling to recruit 24,200 mother-newborn pairs from Taiwan national birth registration in 2005. Vaccination status and risk factors for atopic disorders were ascertained through official registration and questionnaires at 6 months of age. Information about development of physician-diagnosed atopic dermatitis (AD) and recurrent wheezing (> 3 episodes, excluding structural airway abnormalities) was also gathered. Multiple logistic regression was performed to estimate the association of Hib vaccination and atopic disorders.

RESULTS: There were 21,010 (86.8%) participants completed the follow-up study. AD was noted in 1460 (6.9%) infants while recurrent wheezing was found in 154 (0.8%), 11156 (53.1%) of the infants received at least one dose of Hib vaccine. In the univariate analysis, Hib vaccination was associated with a higher risk of AD (OR, 1.65; 95% CI, 1.48-1.85). Statistical significance retained even after adjusting for various potential confounders (adjOR, 1.29; 95% CI, 1.15-1.45). Hib vaccination was positively associated with recurrent wheezing (adjOR, 1.31; 95% CI, 0.94-1.83), though failed to reach statistical significance.

CONCLUSIONS: These results demonstrate a higher risk of infantile AD after Hib vaccination in the early life in addition to DTP-IPV vaccination. The potential of Hib vaccination to increase the risk of atopic disorders warrants further investigation.

5855.7

Poster Board 769

Lower Birth Weight Is Related to Evaluated Systolic Blood Pressure in Chinese Population

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BACKGROUND: Studies in developed countries have shown that reduced fetal growth is related to increased risk of high blood pressure in later life; however, little is known in developing countries such as China where hypertension is becoming an epidemic problem.

Aims To investigate the prospective association between birth weight and blood pressure in Chinese population.

OBJECTIVE: We conducted re-cross-sectional study in 1111 individuals aged 16 to 26 year old from Jan. 2006 to 2007 Dec, all of these individuals had been enrolled in Shanghai infant feed and growth survey (SIFGS) during 1980-1990, the population of SIFGS was randomly selected one community of Shanghai.

DESIGN/METHODS: Blood pressure, weight, height and waist were measured by trained nurses or doctors. A lifestyle questionnaire was also conducted for all the participants. All the data was duplicate inputted by epidata. Statistical analyses were performed with the SAS 8.2.

RESULTS: Among 1111 individuals, 551(49.6%) were male. The mean birth weight for male was (3305.7±438.9) g, and for female was (3188.0±413.9) g. The prevalence of elevated blood pressure (defined as systolic blood pressure≥130mmHg or diastolic blood pressure≥85mmHg) was 5.3% in the re-examination. After adjusted for age, education, LDL-cholesterol, and body mass index (BMI), there was a linear regression between birth weight and systolic blood pressure both in male and female. Systolic blood pressure increased by 2.39mmHg (95% CI:0.3-4.5,) for every kilogram decrease in birth weight in male and 2.44mmHg(95% CI:0.6-4.3) in female. However no significant relationship was found between birth weight and diastolic blood pressure both in male and female.

CONCLUSIONS: Individuals with the decreased birth weight have significantly higher risk of developing high blood pressure. These data highlight the importance of pre-natal growth in the prevention of evaluated blood pressure in China.

5855.8

Poster Board 770

Stool Microflora in Extremely Low Birthweight Infants Analyzed by 16S rRNA Real-Time PCR

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BACKGROUND: To characterize the composition of fecal microflora in extremely low birthweight infants in early days of life.

OBJECTIVE: There have been many studies of fecal microflora in newborn. However, little information regarding the colonization pattern in premature infant, especially in extremely low birth-weight (ELBW) infant is available. To characterize the composition of fecal flora in ELBW infant, quantitative analysis using 16s rRNA real-time PCR were performed.

DESIGN/METHODS: Stool specimens from 17 ELBWI (<1000g) were collected on day <50(Group1 4 cases), 50-90(Group2 6 cases) and >90 (Group3 7cases). All of infants were clinically stable without any serious complications with full milk feeding. After samples treatment by previous method with minor modification, DNA samples were extracted and amplified using SYBR Green reaction mix (Bio Rad). The representative species-specific PCR primers for, *Enterococci*, *Enterobacteriaceae*, and *Bifidobacteria* were originally made. An iCycler iQ instrument was used for real-time quantitative PCRs. We also analyze the serially characterize the composition of microflora in early life day 1,3,5,7, from 2 of LBW (<2000g) infants.

RESULTS: (1)In Group 1, *Enterococci* were not detected from all 3 cases. *Bifidobacteria* were dominant except one case. In Group 2, total amount of three species showed *Bifidobacteria* > *Enterobacteriaceae* > *Enterococci* from 5 cases. No difference was seen in Group 3.

Birthweight, Maternal antibiotics or steroid treatment, prolonged antibiotics treatment, Nutrition did not seem to affect the composition of three species. (2) In LBW on day 0, total amount of bacteria were <10⁴. On day 1, 3, *Enterococci* was first seen and dominant. After on day 5-7, *Bifidobacteria* increased significantly.

CONCLUSIONS: The composition of three gut microflora species were not different after 1month. Factors that can increase *Bifidobacteria* colonization in LBW on day 5 may be of interest.

5855.9

Poster Board 771

Urinary Tract Infection in Infants and Children: An Etiologic Study

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BACKGROUND: Urinary tract infection has always been a significant cause of morbidity among infants and children. Long term complications such as arterial hypertension and end stage renal disease has been established as due to renal scarring as a consequence of infections involving the renal parenchyma regardless of cause. However, urinary infections are sometimes taken for granted and has been regarded as just a simple illness despite its potential to cause permanent and irreversible renal damage. Thus, identifying its cause is essential so as to prevent its complications as a consequence of renal scarring due to recurrent infections.

OBJECTIVE: To determine the causes of urinary tract infection in infants and children thereby identifying the risk factors that may contribute to its long term complications.

DESIGN/METHODS: Cross sectional/Pediatric patients suspected and/or has signs and symptoms suggestive of having urinary tract infection were recruited. Patients with positive urine culture results underwent a work-up protocol which included imaging studies such as ultrasound of the kidneys and urinary bladder, voiding cystourethrography, intravenous pyelography and/or DMSA renal scan.

RESULTS: Six hundred two subjects were included in the study. There were 265 males and 337 females with a mean age of 3.82 years and M:F ratio of 1:1.3. Fever and abdominal pain were the most common clinical manifestations. *Escherichia coli* is the most common etiologic organism. Voiding dysfunction(24%) in the form of pseudodyssynergia, unstable bladder, lazy bladder and its combination, is the most common identified cause. Other causes were vesicoureteral reflux(23.2%) and congenital defects(14.8%) while 18.4% were idiopathic. Among the patients who underwent DMSA renal scan, 48.6% were positive for renal scars, 88.2% of whom were associated with reflux.

CONCLUSIONS: This study showed that urinary infection occurs predominantly below 2 years of age with female preponderance. Fever and abdominal pain are the most common presentation with *E coli* as the most common etiologic agent. The identified causes were voiding dysfunction, vesicoureteral reflux and congenital defects. Renal scar formation, which has long term complications later in life, were noted in some particularly those with reflux. Systematic and thorough evaluation of infants and children with urinary tract infection is therefore recommended.