Disclosures. Maria Deloria Knoll, PhD, Merck (Research Grant or Support); Pfizer (Research Grant or Support)

1183. Serum Bactericidal Activity Induced by Live Attenuated Pertussis Vaccine
BPZE1 is Comparable to Boostrix™
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Session: P-69. Pediatric Vaccines

Background. In a Phase 2b, multi-center, placebo-controlled, randomized study, intranasal BPZE1 induced mucosal and serum antibodies to pertussis antigens and protected against subsequent colonization following attenuated challenge with BPZE1 3 months later. Boostrix™ also induced serum but not mucosal antibodies and did not protect against BPZE1 challenge. We have evaluated the induction of serum bactericidal activity (SBA) for Bordetella pertussis by BPZE1 or Boostrix vaccination. A previous study showed that Boostrix induction of SBA is dependent on Pn on whereas B. pertussis infection induces SBA targeting Pn and other antigens. Methods. A convenience set of subjects who had a broad range of Pn and PT IgG serum concentrations from treatment groups who received BPZE1+BPZE1 or Boostrix+Placebo (Day 1 and 85 vaccination) were randomly selected to assess SBA using B. pertussis strain B1917. Three timepoints (baseline, 28 days following first and second vaccination) were analyzed and interpolated 50% killing titers determined. The relationship to Pn IgG concentration was assessed. Results. BPZE1 and Boostrix elicited similar and significant increases in SBA following vaccination. BPZE1 and Boostrix elicited anti-Pn IgG, with Boostrix eliciting higher concentrations. A greater SBA response relative to PRN IgG was observed for BPZE1 compared to Boostrix. SBA-Pn correlations were high post-Boostrix (0.74) as previously reported; correlation was lower (0.35) following BPZE1, suggesting the involvement of broader antigenic protection beyond Pn alone.

Table of GMT and GMFR in SBA and Pn IgG

Conclusion. In this exploratory investigation, the novel intranasal live-attenuated pertussis vaccine BPZE1 induced SBA titers that were similar to Boostrix using a B. pertussis strain representative of current disease states. SBA-Pn correlations were high post-Boostrix, consistent with prior reports showing Pn is the acelluar vaccine antigen that mediates SBA. In contrast, BPZE1 bactericidal antibodies appear broader than Pn which may be important given the global rise of Pn-deficient B. pertussis strains.

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1184. A Phase 3, Multicenter, Randomized, Double-blind Study to Evaluate the Interchangeability of V114 and Prevnar 13™ with Respect to Safety, Tolerability, and Immunogenicity in Healthy Infants (PNEU-DIRECTION)
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Session: P-69. Pediatric Vaccines

Background. Pneumococcal diseases (PD) caused by Streptococcus pneumoniae are a major health concern globally. In children, currently licensed pneumococcal conjugate vaccines (PCVs) provide protection against PD from vaccine serotypes, but other non-vaccine serotypes have emerged and contribute to most residual disease. V114 is a 15-valent investigational PCV containing serotypes 22F and 33F in addition to the 13 serotypes shared by Prevnar 13™ (PCV13). This phase 3 study evaluated safety and immunogenicity of mixed PCV13/V114 regimens when changing from PCV13 to V114 in two sequential 4-dose or 5-dose regimens.

Methods. In this double-blind trial, 900 infants were randomized in equal ratios to five treatment groups using a 3 + 1 immunization schedule (3-dose infant primary series followed by one toddler dose). Groups 2, 3, and 4 started with PCV13 and switched to V114 at doses 4, 3, and 2, respectively. Groups 1 and 5 received four doses of PCV13 and V114, respectively. Immunoglobulin G (IgG) responses to the 15 pneumococcal serotypes in V114 were measured at 30 days post-dose 3, prior to dose 4, and 30 days post-dose 4 (PD4). Primary immunogenicity analysis was based on 13 shared serotype responses at PD4. Safety was evaluated as the proportion of participants with adverse events (AEs).

Results. At 30 days PD4, IgG geometric mean concentrations (GMCs) for the 13 shared serotypes were generally comparable between V114/PCV13 mixed regimens (Groups 2-4) and participants that received the 4-dose PCV13 regimen (Group 1). Additionally, IgG GMCs for the 13 shared serotypes were generally comparable for participants that received the 4-dose V114 regimen (Group 5) and participants that received the 4-dose PCV13 regimen (Group 1). Infants given at least one dose of V114 mounted immune responses to two unique serotypes in V114 (22F and 33F). Frequency of injection-site and systemic AEs among study participants were generally comparable across all study groups.

Conclusion. V114 was well tolerated with a generally comparable safety profile to PCV13. For the 13 shared serotypes, both mixed-dose and 4-dose regimens of V114 induced generally comparable antibody responses to a PCV13 4-dose regimen. Study results support interchangeability of V114 with PCV13 in infants.

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1185. Oseltamivir Prescribing Patterns for Infants with Influenza and Factors Associated with Guideline Adherence
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Session: P-70. Pediatric Viral Studies (natural history and therapeutic)

Background. The Centers for Disease Control and Prevention (CDC) recommends oseltamivir be given to children < 2 years old with confirmed or suspected influenza as they are at high risk for complications. We sought to analyze oseltamivir prescribing patterns and to describe factors associated with adherence and non-adherence to CDC guidelines.

Methods. We used a retrospective cohort of infants ≤ 12 months old born from January 1, 2011 to December 31, 2019 within the University of Pittsburgh Medical Center health system in Southwestern Pennsylvania and who had ≥ 2 well-child visits during their first year. Infants with laboratory-confirmed influenza from January 1, 2011 to April 30, 2020 were included. Electronic health records were reviewed to describe oseltamivir prescriptions and influenza-related hospitalizations and to assess adherence and non-adherence to CDC influenza treatment guidelines were assessed with univariate logistic regression.

Results. Of 422 infants with laboratory-confirmed influenza, 86% were prescribed oseltamivir. The proportion of infants prescribed oseltamivir increased from an average of 63% during 2011-2016 to 90% during 2016-2020 (OR:5.2; 95%CI: 2.9-9.5). 96% of prescriptions instructed twice daily dosing, 2% had once daily, and 2% were unknown. 91% of prescriptions were for 5 days, 7% had no duration, and 2% were for > 5 days. Infants ≥ 6 months of age compared to < 6 months were less likely to be prescribed oseltamivir (83.3% vs. 100%; p = 0.001); tested for influenza in the emergency room/urgent care (OR: 0.3; 95%CI: 0.2-0.6), or admitted to the hospital (OR:0.5; 95%CI:0.2-0.9). Infants were more likely to be treated with oseltamivir if they had a known influenza positive contact (OR:2.9; 95%CI:1.0-8.5) or had fever ≥ 38.0°C (OR:2.0; 95%CI:1.2-3.5). There was no difference in prescribing practices based on history of prematurity or chronic medical conditions.

Conclusion. Adherence to CDC influenza treatment guidelines for infants is high and has improved over time. However, targeted education at high-risk contact points may further improve guideline adherence.

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1186. Increased Respiratory Syncytial Virus (RSV) Viral Replication Leads to Increased Cytokine Production and Polarized Interferon Response in Infant Mucosal Epithelium
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1187. Neurodevelopmental Outcomes of Children with Congenital Cytomegalovirus (cCMV) Infection: Does Antiviral Treatment Matter?  
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Introduction. Cytomegalovirus (CMV) infection is a common cause of congenital infection, with a prevalence of 1-2 per 1000 live births. Infected infants may present with a range of outcomes, including hearing loss, developmental delay, and neurological sequelae. Antiviral treatment with ganciclovir/valganciclovir has been shown to improve hearing outcomes in infants with congenital CMV (cCMV) infection, but its impact on neurodevelopmental outcomes remains uncertain.

Methods. In this retrospective cohort study, we evaluated the neurodevelopmental outcomes of 95 children with cCMV infection treated with antiviral therapy during the ﬁrst year of life. The Gross Motor Function Classiﬁcation System (GMFCS) was used to classify functional motor impairment. Neurodevelopmental outcomes were compared according to receipt of antiviral therapy in early infancy.

Results. Ninety-ﬁve (95) infants (mean ± SD; gestational age 35 ± 5 wk, birth weight 2121 ± 948 g; Table 1) with cCMV infection had follow-up neurodevelopmental assessments. Sixty-two (62) had neurodevelopmental outcomes, and 66% had were diagnosed with autism spectrum disorder. The majority had normal BSID-III scores (86%) in cognitive and motor domains (65% and 54%, respectively) while 48% had normal scores in the language domain. 35% had severe impairment (< 70) in ≥ 1 domain (Table 2). Nine children had clinically apparent cCMV infection; 22% had abnormalities on BSID testing (1, cognitive score: 60; 1, cognitive, language, and motor scores: 65, 68, 73, respectively). 11 (13%) children, including 6 who received antiviral therapy, had severe neurodevelopmental impairment, with CP and severe (< 70) BSID scores in both the cognitive and motor domains.

Conclusion. A substantial proportion of children with cCMV infection had moderate (29%) or severe (33%) neurodevelopmental impairment, CP, or autism spectrum disorder, irrespective of antiviral treatment. Urgency exists for antenatal preventive strategies and vaccine development.

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1188. The Effect Of The COVID-19 Pandemic On Inﬂuenza-Related Hospitalization, Intensive Care Admission And Mortality In Canadian Children  
Helen E. Groves, PhD, MBChB BA; Oliver Adunka, MD, MPH, DTM&H, FRCPC; IMPACT investigators

Conclusion. The COVID-19 pandemic resulted in unprecedented implementation of wide-ranging public health measures globally. During the pandemic, dramatic decreases in seasonal inﬂuenza virus detection have been reported worldwide. Information on pediatric inﬂuenza-related hospitalizations is limited. We describe inﬂuenza-related hospitalization in Canadian children during the 2020/2021 inﬂuenza season compared to ten previous seasons.

Methods. Data on inﬂuenza-related hospitalizations, intensive care unit (ICU) admissions and in-hospital deaths in children across Canada were obtained from the Canadian Influenza Surveillance Program, IMPACT (IMPACT). This national surveillance initiative comprises 90% of all tertiary care pediatric beds in Canada. The total study period included eleven inﬂuenza seasons from September 2010 to April