1488. Post-licensure Surveillance of 13-Valent Pneumococcal Conjugate Vaccine (PCV13) in Children under 6-months old, Vaccine Adverse Event Reporting System (VAERS), United States, 2010–2017

For the Food and Drug Administration (FDA) licensed the 13-valent pneumococcal conjugate vaccine (PCV13) for use in children under 5-months old in 2010. Since then, media have reported to the VAERS approximately 59 months. The Vaccine Adverse Event Reporting System (VAERS) documented a list of recommended vaccine use for all children ages 2, 4, and 6 months with a booster at 12–15 months. There are currently three case definitions: death, disease, and hospitalization. Post-vaccination periods were 59 months. Signs and symptoms of AEAs were coded using the Medical Dictionary for Regulatory Activities. Physicians reviewed the VAERS forms and available medical records of serious reports. The data were analyzed for adverse events (AEs) following PCV13 from February 24, 2010 through February 24, 2017, in children aged 6 weeks through 6 months.

**Methods.** We searched the Vaccine Adverse Event Reporting System (VAERS), a U.S. passive surveillance system, for reports of adverse events (AEs) following PCV13 from February 24, 2010 through February 24, 2017, in children aged 6 weeks through 6 months. Significant and common symptoms of AEs were compared with the Vaccine Monitoring Program (VMP) tool.

**Results.** VAERS received 10,007 reports after PCV13; 1,706 (17.0%) were serious events. The most frequently reported symptoms were pyrexia (26.4%), injection site erythema (15.3%) and irritability (14.6%). Injection site erythema (25.4%), injection site swelling (20.6%) and pyrexia (20.1%) were the most common symptoms among children who were given PCV13 alone. Most symptoms from vaccination to start of symptoms was 1 day (range: day of vaccination to 2,033 days). There were 222 (2.2%) death reports with sudden infant death syndrome as the most common cause (37.8%). Pyrexia (45.1%), irritability (40.4%), and vomiting (39.7%) were most commonly reported among death reports. There were 20 (0.2%) reports of Kawasaki disease and 20 (0.2%) reports of anaphylaxis.

**Conclusion.** AEs reported to VAERS following PCV13 were consistent with AEs previously observed in other post-licensure clinical trials and other post-licensure studies of PCV13. No new or unexpected patterns of AEs were identified.

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1489. Invasive Pneumococcal Disease in a Population with Underlying Comorbidities

Daniel Jarovsky, MD; Eitan Naaman Berezin, MD and Rodrigo José Sini De Almeida, MD, Pediatric, Santa Casa de Misericórdia de São Paulo, São Paulo, Brazil

**Session:** 165. Pneumococcal Immunization and Epidemiology-North America

**Background.** Streptococcus pneumoniae (Spn) is a major cause of severe and life-threatening diseases in children and particularly among individual with high-risk illnesses at all ages. As there is limited clinical data on IPD in high-risk patients and indirect effect of vaccination in the post-PCV era in developing countries, we‘ assessed the epidemiology of IPD in patients with and without underlying diseases before and after PCV10 introduction at Santa Casa de São Paulo (SCSP), Brazil.

**Methods.** We performed a prospective hospital-based surveillance study of patients with IPD from January 2000 to April 2017, including all cases of IPD (i.e., isolation of Spn from a normally sterile body fluid) among patients at all ages. Selected cases were stratified into 5 age groups to evaluate comorbidities and the effect of the PCV10 on different ages. Identified serotypes were grouped according to the available pneumococcal vaccines and further analyzed into pre-vaccination (2000–2009) and post-vaccination periods (2010–2017). Clinical information was extracted from patient’s records, then stratified based on their IPD risk profile. Ethical approvals to conduct the study were obtained from the SCSP institutional review board.

**Results.** 571 episodes were identified in 561 patients in all age groups, of which 459 (78.4%) had clinical data for analysis: 20.7% healthy, 79.3% had comorbidities. IPD decreased from 35.9 to 30.3 cases/year (-15.6%) at all ages after PCV10 introduction. Among healthy individuals and those with underlying comorbidities, annual cases decreased from 6.8 to 2.9 (57.3% reduction) and 18.6 to 20.5 cases/year (9.7% increase), respectively, between same periods; 30-day mortality through pre-vaccine period was 25% and 7.5% and in post-PCV10 period 27% and 8.7%, for comorbidity and healthy groups, respectively. IPD significantly decreased among healthy and comorbid children <5y, without evidence of serotype replacement. Significant increase in bacteraemia and pneumococcal meningitis, also in serotypes included in all vaccines and NVT was evident at ages over 5y.

**Conclusion.** High rates of IPD have persisted in older subjects and in patients with undetermined risk factors for IPD, despite children vaccination with PCV10. No herd effect was detected and serotype replacement is ongoing in this specific groups.

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1490. Pneumococcal Vaccination Provides Substantial Value for Money for Canadians

Francois Pelouquin, BSc,1 Marie-Claude Breton, MPPharm;1 Matt Wasserman, MSc;2 Michele Wilson, MSPh;1 Cheryl McDade, BA;1 and Raymond Farkouh, PhD;2

1Pfizer Canada, Kirkland, QC, Canada, 2Pfizer Inc., New York, New York, RTI Health Solutions, Research Triangle Park, North Carolina, Pfizer Inc, Collegeville, Pennsylvania

**Session:** 165. Pneumococcal Immunization and Epidemiology-North America

**Background.** Introduction of pneumococcal conjugate vaccines (PCV) to the Canadian childhood routine immunization schedules (RIS) resulted in significant benefits. The 7-valent PCV was added to all provinces’ RIS between 2002 and 2006. The 10-valent PCV was used in Ontario and Quebec for 12 to 18 months in 2009 and 2010. The 13-valent PCV was marketed in 2010 and rapidly adopted by all provinces. Direct vaccine protection reduced incidence of invasive pneumococcal disease (IPD), pneumonia (PNE) and acute otitis media (AOM) in vaccinated children. Indirect vaccine protection also reduced the burden of disease (BOD) in other age groups. Sensible public funds allocation motivates continued evaluation of public health programs.

**Objective:** To evaluate the economic impact of PCVs to Canadian society following nationwide RIS implementation.

**Methods.** Canadian databases and literature were reviewed to obtain pre- and post-PCV incidence of IPD, PNE and AOM, as well as direct and indirect medical costs (reported in 2017 $ CAD). Case counting index date was set to Jan 2005, at which point PCV RIS were implemented for over 90% of Canadians. A steady state scenario using pre-PCV incidence rates were projected to Dec 2015 to estimate the number of cases without PCVs. Averted cases were obtained by subtracting the cases reported from the estimated case count without PCVs. Disease specific costs were assigned to averted cases and vaccine spend was subtracted from the total to obtain net savings to Canadian society.

**Results.** Successive implementation of PCVs on the provinces’ RIS saved 2,365 lives and resulted in net savings of CAD $203 million between Jan 2005 and Dec 2015. These savings stem from averted direct and indirect medical costs and visual PNE and AOM costs.

| Table 1 – BOD and related costs avoided by PCV use, 2005–2015 |
|-------------------------------------------------------------|
| With PCVs | Without PCVs | Difference |
|-----------|--------------|------------|
| Case count | 270,417 | 36,208 | -9,767 |
| Bacteraemia | 14,461 | 19,685 | -5,223 |
| Meningitis | 366,927 | 386,413 | -19,486 |
| Hospitalized PNE | 545,230 | 589,251 | -44,021 |
| Bacteremia | 3,629,942 | 3,474,467 | -75,475 |
| Mortality | 36,917 | 39,282 | -2,365 |

**Conclusion.** Introduction of PCVs reduced pneumococcal burden of disease and net economic benefits to Canadian society.

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1491. The Risk of Febrile Seizures Following Influenza and 13-Valent Pneumococcal Conjugate Vaccines

Meghan Baker, MD, SCiD;1 Christopher Jankosky, MD, MPH, PhD;1 Susan Gruber, PhD,1 Lingling Li, PhD,1 Noelle Cocoros, DSc, MPH,1 Hana Lipowicz, MPH,1 Claudia Coronel-Moreno, MPH,1 Sandra Feibelmam, MPH,1 Nancy Lin, ScD,1 Cheryl McMahill-Walraven, PhD, MSW,1 David Menschik, MD, MPH,1 Marco Soliva, PhD,1 Nandini Selvam, PhD, MPH,1 Rong Chen Tiday, MS,1 Lauren Zichitella, MS,1 Grace Lee, MD, MPH, FPIDS1 and Alison Tse Kawai, ScD, SM,1

1Department of Population Medicine, Harvard Pilgrim Health Care Institute and Harvard Medical School, Boston, Massachusetts, 2Brigham and Women's Hospital, Boston, Massachusetts, 3Vaccine Center for Biologics Evaluation and Research, Silver Spring, Maryland, 4Sanofi Genzyme, Cambridge, Massachusetts, 5Optum Epidemiology, Boston, Massachusetts, 6Aetna, Blue Bell, Pennsylvania, 7Comprehensive Health Insights, Sugar Land, Texas, 8QuintilesIMS, Fairfax, VA, 9Division of Infectious Diseases, Boston Children's Hospital, Boston, Massachusetts

**Session:** 165. Pneumococcal Immunization and Epidemiology-North America

**Background.** Evidence on the risk of febrile seizures (FS) after vaccination with inactivated influenza vaccine (IIV) and PCV13 during the 2013–14 and 2014–15 influenza seasons, for which PCV13 is mixed. Among children 6–23 months, we examined the risk of FS following IIV and PCV13 during the 2013–14 and 2014–15 influenza seasons, for which vaccine virus strains were the same.