

against all IPD. Pooled VE estimates from 12 observational studies showed PPSV23 effectiveness against VT-IPD was 38% (95% CI: 28% to 46%;  $I^2=40.8$ ).

Table. Efficacy and effectiveness studies against vaccine-type invasive pneumococcal disease

Author	Country	Study Design and Population	Per Protocol or Adjusted VE% (95% CI)
<b>PCV13</b>			
Bonten 2015	The Netherlands	RCT, 265	75 (41, 91)
Pillshvili 2018	United States	Case-control, 265	59 (11, 81); VT-IPD +6C
Pillshvili 2018	United States	Case-control, 265	67 (11, 88); VT-IPD +6C, minus st3
Lewis 2019	United States	Cohort, 265	68 (37.7, 83.6)
<b>PPSV23</b>			
Dominguez 2005	Spain	Case-control, 265	72 (50, 85)
Kim 2019	South Korea	Case-control, 265	42 (-2, 67)
Vila-Corcoles 2006	Spain, Tarragona	Case-control, 265	39 (-176, 87)
Vila-Corcoles 2009	Spain, Tarragona	Case-control, 250	76 (34, 91)
Vila-Corcoles 2010	Spain, Tarragona	Case-control, 260	77 (40, 92)
Andrews 2012	England/Wales	Indirect cohort, 265	31 (17, 44)
Djennad 2018	England/Wales	Indirect cohort, 265	27 (18, 35)
Gutiérrez-Rodríguez 2014	Spain, Madrid	Indirect cohort, 265	45 (19, 62)
Rudnick 2013	Canada	Indirect cohort, 265	42.2 (28.6, 53.2)
Shimabashi 2020	Japan	Indirect cohort, 265	39.4 (-6.1, 65.3)
Su 2021	Taiwan	Indirect cohort, 275	39 (15.5, 55.9)
Wright 2013	England	Indirect cohort, 265	29 (-17, 56); unadjusted

Abbreviations: CI: confidence interval; RCT: randomized-control trial; VE: vaccine efficacy or effectiveness; st: serotype

**Conclusion.** Evidence suggests both pneumococcal vaccines are effective against VT-IPD in adults. Given that PCV15 and PCV20 are expected to be licensed based on immunogenicity data and no clinical efficacy data are available for these new vaccines, the findings from this review will help inform policy discussions on use of the new PCVs among adults.

**Disclosures.** All Authors: No reported disclosures

## 22. An Innovative Approach to Examining the Waning of Vaccine Effectiveness Using Automated Healthcare Data

Laurie Aukes, RN, CCRA<sup>1</sup>; Joan Bartlett, MPH, MPP<sup>1</sup>; Bruce Fireman, MA<sup>2</sup>; John Hansen, MPH<sup>3</sup>; Ned Lewis, MPH<sup>3</sup>; Morgan Marks, PhD, ScM<sup>4</sup>; Patricia Saddier, MD, PhD<sup>5</sup>; Nicola P. Klein, MD, PhD<sup>5</sup>; <sup>1</sup>Kaiser Permanente Vaccine Study Center, Oakland, California; <sup>2</sup>Kaiser Permanente Vaccine Study Center, Oakland, California, Oakland, California; <sup>3</sup>Kaiser Permanente Northern California, Oakland, California; <sup>4</sup>Merck and Co Inc., North Wales, PA; <sup>5</sup>Merck & Co., Inc., Kenilworth, New Jersey

**Session:** P-02. Adult Vaccines

**Background.** We conducted a large real-world study of the long-term vaccine effectiveness (VE) of the live attenuated zoster vaccine (Zostavax; ZVL). Using an innovative approach with automated observational data we measured VE for incident herpes zoster (HZ) and severe HZ outcomes including post-herpetic neuralgia (PHN), herpes zoster ophthalmicus (HZO), and hospitalized HZ. This approach could be useful in long-term effectiveness studies of other vaccines.

**Methods.** We assessed VE against HZ, PHN, HZO and hospitalized HZ for up to 10+ years after vaccination at Kaiser Permanente Northern California. We identified incident cases using diagnoses, laboratory tests and prescriptions, and validated a sample by chart review. For each outcome, we used a Cox regression model with a calendar timeline to estimate VE in relation to year since vaccination. The model for HZ included 11 time-varying vaccination status indicators to denote -- at each timepoint during follow-up -- either the number of years since ZVL vaccination (30 days to < 1 year, 1 to < 2 years, . . . , and 10+ years) or that the individual is unvaccinated (reference group). Analyses were adjusted for demographics and time-varying measures of immune compromise status, healthcare use and comorbidities.

**Results.** From 2007-2018, 1.5 million people contributed to analyses; 507,000 (34%) were vaccinated. During 9 million person-years of follow-up, we observed 75,135 HZ cases, including 4,982 (7%) with PHN, 4,418 (6%) with HZO, and 555 (< 1%) who were hospitalized. VE for HZ was 67% (95% Confidence Interval [CI]: 65-69%) in the first year after vaccination, waned to 50% (CI: 47-52%) in the second year after vaccination, and then waned more gradually to 15% (CI: 5-24%) by 10+ years after vaccination. Initial VE was higher against PHN (83%; CI: 78-87%) and hospitalized HZ (89%; CI: 67-97%) with less waning observed over time (42% by Year 8 for PHN and 53% in Years 5 to < 8 for hospitalized HZ). VE against HZO was 71% in Year 1 and waned to 29% in Years 5 to < 8.

**Conclusion.** Our large population, long follow-up and innovative methods let us estimate VE against HZ, PHN, HZO and hospitalized HZ for 10+ years after vaccination. Our approach could help assess waning and need for boosters for vaccines against other agents including COVID-19.

**Disclosures.** Morgan Marks, PhD, ScM, Merck & Co Inc. (Employee) Patricia Saddier, MD, PhD, Merck & Co Inc (Employee) Nicola P. Klein, MD, PhD, GlaxoSmithKline (Grant/Research Support)MedImmune (Grant/Research Support)Merck & Co Inc (Grant/Research Support)Pfizer (Grant/Research Support)Protein Sciences (now Sanofi Pasteur) (Grant/Research Support)Sanofi Pasteur (Grant/Research Support)

## 23. ZOE-50 and ZOE-70 Placebo Groups Data Shows that Burden of Pain Associated with Herpes Zoster Interferes with Activities of Daily Living

Eliazar Sabater Cabrera, MSc<sup>1</sup>; Desmond Curran, PhD<sup>1</sup>; Sean Matthews, MSc<sup>2</sup>; Céline Boutry, PhD<sup>3</sup>; Nicolas Lecrenier, Ing, PhD<sup>3</sup>; Anthony L. Cunningham, F.A.H.M.S., MD, M.B.B.S., B. Med. Sci. (Hons), F.R.A.C.P.,

F.R.C.P.A., F.A.S.M.<sup>4</sup>; <sup>1</sup>GSK, Wavre, Brabant Wallon, Belgium; <sup>2</sup>Freelance c/o GSK, Wavre, Brabant Wallon, Belgium; <sup>3</sup>Aixial, Bruxelles, Belgium, on behalf of GSK, Bruxelles, Brussels Hoofdstedelijk Gewest, Belgium; <sup>4</sup>The Westmead Institute for Medical Research and the Institute's Centre for Virus Research, The University of Sydney, Sydney, New South Wales, Australia

**Session:** P-02. Adult Vaccines

**Background.** Adults  $\geq 50$  years of age (YOA) are at increased risk of herpes zoster (HZ), a condition which can cause long-term pain and discomfort. In this analysis, we assessed the burden of pain associated with HZ and its interference with activities of daily living (ADL) in patients  $\geq 50$  YOA.

**Methods.** ZOE-50 (NCT01165177) and ZOE-70 (NCT01165229) were phase III, observer-blind, placebo-controlled, 1:1 randomized studies in adults  $\geq 50$  YOA (ZOE-50) and  $\geq 70$  YOA (ZOE-70) who received 2 doses of the adjuvanted recombinant zoster vaccine or placebo, 2 months apart. To correctly evaluate HZ pain, the analysis was performed only on the placebo groups data of ZOE-50 ( $\geq 50$  YOA) and pooled ZOE-50/70 ( $\geq 70$  YOA pooled data) in the modified total vaccinated cohort (mTVC, primary population for efficacy analysis) HZ-confirmed cases. HZ pain and interference with ADL was assessed by the Zoster Brief Pain Inventory (ZBPI) instrument completed daily by patients for the first 28 days and then weekly until resolution. Time to resolution of clinically significant pain was analyzed using Kaplan Meier methods. We estimated the cumulative area under curve (AUC) of the ZBPI worst pain score and the ZBPI ADL score up to 182 days post-HZ rash onset. A high AUC reflects a higher severity/longer duration of pain.

**Results.** Overall, 254 patients  $\geq 50$  YOA and 284 patients  $\geq 70$  YOA were included in the mTVC HZ-confirmed cases for the ZOE-50 and ZOE-70 pooled analysis, respectively. In HZ patients  $\geq 50$  YOA, 94.6% reported any pain (ZBPI pain score > 0), 87.6% clinically significant pain (ZBPI pain score  $\geq 3$ ) and 65.1% severe pain (ZBPI pain score  $\geq 7$ ). Similarly, in HZ patients  $\geq 70$  YOA, 93.2% reported any pain, 90.9% clinically significant pain and 68.4% severe pain. It was estimated that 11.6% and 18.3% of patients aged  $\geq 50$  and  $\geq 70$  YOA, respectively, had clinically significant pain 3 months after the onset of HZ. The mean AUC at 182 days was 137.24 ( $\geq 50$  YOA) and 190.68 ( $\geq 70$  YOA), for the ZBPI worst pain score and 92.75 ( $\geq 50$  YOA) and 130.89 ( $\geq 70$  YOA), for the ZBPI ADL score.

**Conclusion.** Analysis of data provided by patients with confirmed HZ shows that the burden of HZ pain is high and is associated with interference on patients' ADL.

**Funding.** GlaxoSmithKline Biologicals SA

**Acknowledgment.** M Maior/S Hulsmans provided medical writing/editorial support (Modis c/o GSK)

**Disclosures.** Eliazar Sabater Cabrera, MSc, GSK (Employee, Shareholder) Desmond Curran, PhD, The GSK group of companies (Employee, Shareholder) Sean Matthews, MSc, GSK (Independent Contractor) Céline Boutry, PhD, GSK (Employee) Nicolas Lecrenier, Ing, PhD, The GSK group of companies (Employee, Shareholder) Anthony L. Cunningham, F.A.H.M.S., MD, M.B.B.S., B. Med. Sci. (Hons), F.R.A.C.P., F.R.C.P.A., F.A.S.M., GSK group of companies (Grant/Research Support, Advisor or Review Panel member, Speaker's Bureau)

## 24. An analysis of the National Institutes of Health All of Us Research Database: Sociodemographic Disparities Among Patients Who Received Vaccinations

Ding Quan Ng, BSc (Pharm)(Hons)<sup>1</sup>; Stanley Jia, n/a<sup>1</sup>; Christine Cadiz, PharmD, MA, BCPS, APH<sup>1</sup>; Cheryl Wisseh, PharmD, MPH<sup>1</sup>; Megan H. Nguyen, PharmD<sup>1</sup>; Joyce Lee, PharmD, APh, FCCP, BCPS, BCACP<sup>1</sup>; Sarah McBane, PharmD, CDCES, BCPS, FCCP, FCPA, FCSHP, APH<sup>1</sup>; Lee Nguyen, PharmD, APh, BCPS-AQ ID, BCIDP<sup>1</sup>; Alexandre Chan, PharmD, MPH, FCCP, FISOPP, BCPS, BCOP, APH<sup>1</sup>; Kerri Hurley-Kim, PharmD, MPH, BCAC, APH<sup>1</sup>; <sup>1</sup>University of California Irvine, Irvine, California

**Session:** P-02. Adult Vaccines

**Background.** The National Institutes of Health All of Us (AoU) research program is building a diversified database of 1 million+ adult subjects. With this database, we seek to describe the sociodemographic characteristics of those with documented vaccinations.

**Methods.** The AoU recruited subjects  $\geq 18$  years beginning in 2018. Eligible subjects were subsequently divided into five vaccine cohorts based on their vaccine history [influenza, hepatitis B (HepB), pneumococcal (Pneu) < 65, Pneu  $\geq 65$ , human papillomavirus (HPV)]. The vaccine cohorts were compared to the general AoU cohort. Subjects in the influenza cohort had documented influenza vaccinations from 09/2017-05/2018. Other vaccine cohorts comprised subjects with  $\geq 1$  lifetime record(s) of vaccination by 12/2018. The Pneu < 65 and  $\geq 65$  cohorts comprised those who received pneumococcal vaccination before or after (inclusive) 65 years old, respectively. Descriptive statistics for all cohorts were generated using survey and electronic health record (EHR) data.

**Results.** We analyzed 315297 subjects in the AoU dataset R2020Q4R2. The cohort sizes were: influenza (n=15346), HepB (n=6323), HPV (n=2125), and Pneu (< 65 n=15217;  $\geq 65$  n=15100). For all vaccine cohorts, comparing the 95% confidence intervals (CIs), the proportions of whites and non-Hispanics/Latinos were statistically higher than the general AoU cohort, the largest being from the Pneu  $\geq 65$  cohort (Table 1). For educational attainment, the Pneu < 65 (36.5%) had the smallest proportion of college or advanced degree graduates while the largest was observed in the Pneu  $\geq 65$  cohort (59.0%). The proportions of subjects with < \$10k in annual household