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)
PCV13			
Bonten 2015	The Netherlands	RCT, ≥65	75 (41, 91)
Pilishvili 2018	United States	Case-control, ≥65	59 (11, 81); VT-IPD +6C
Pilishvili 2018	United States	Case-control, ≥65	67 (11, 88); VT-IPD +6C, minus st3
Lewis 2019	United States	Cohort, ≥65	68 (37.7, 83.6)
PPSV23			
Dominguez 2005	Spain	Case-control, ≥65	72 (50, 85)
Kim 2019	South Korea	Case-control, ≥65	42 (-2, 67)
Vila-Corcoles 2006	Spain, Tarragona	Case-control, ≥65	39 (-176, 87)
Vila-Corcoles 2009	Spain, Tarragona	Case-control, ≥50	76 (34, 91)
Vila-Corcoles 2010	Spain, Tarragona	Case-control, ≥60	77 (40, 92)
Andrews 2012	England/Wales	Indirect cohort, ≥65	31 (17, 44)
Djennad 2018	England/Wales	Indirect cohort, ≥65	27 (18, 35)
Gutiérrez-Rodriguez 2014	Spain, Madrid	Indirect cohort, ≥65	45 (19, 62)
Rudnick 2013	Canada	Indirect cohort, ≥65	42.2 (28.6, 53.2)
Shimbashi 2020	Japan	Indirect cohort, ≥65	39.4 (−6.1, 65.3)
Su 2021	Taiwan	Indirect cohort, ≥75	39 (15.5, 55.9)
Wright 2013	England	Indirect cohort, ≥65	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.

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

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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

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Session: P-02. Adult Vaccines

Background. Adults ≥ 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 ≥ 50 YOA.

Methods. ZOE-50 (NCT01165177) and ZOE-70 (NCT01165229) were phase III, observer-blind, placebo-controlled, 1:1 randomized studies in adults ≥ 50 YOA (ZOE-50) and ≥ 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 (≥ 50 YOA) and pooled ZOE-50/70 (≥ 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 ≥ 50 YOA and 284 patients ≥ 70 YOA were included in the mTVC HZ-confirmed cases for the ZOE-50 and ZOE-70 pooled analysis, respectively. In HZ patients ≥ 50 YOA, 94.6% reported any pain (ZBPI pain score > 0), 87.6% clinically significant pain (ZBPI pain score ≥ 3) and 65.1% severe pain (ZBPI pain score ≥ 7). Similarly, in HZ patients ≥ 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 ≥ 50 and ≥ 70 YOA, respectively, had clinically significant pain 3 months after the onset of HZ. The mean AUC at 182 days was 137.24 (≥ 50 YOA) and 190.68 (≥ 70 YOA), for the ZBPI worst pain score and 92.75 (≥ 50 YOA) and 130.89 (≥ 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.

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

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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 ≥ 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 ≥ 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 ≥ 1 lifetime record(s) of vaccination by 12/2018. The Pneu < 65 and ≥ 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; ≥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 ≥ 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 ≥ 65 cohort (59.0%). The proportions of subjects with < $10k in annual household

income (AHI) were largest among Pneu < 65 (17.1%) and smallest among Pneu ≥ 65 (3.8%). In contrast, the largest proportion of subjects with ≥ $100k AHI was among Pneu ≥ 65 (25.3%) and the smallest among Pneu < 65 (15.8%).

Table 1. Sociodemographic characteristics of subjects in the All of Us research program based on vaccine receipt

	Influenza (N=15346)		Hepatitis B (N=6123)		Human papillomavirus (N=2125)		Pneumococcal (<65) (N=15217)		Pneumococcal (≥65) (N=15300)		All (N=152297)	
	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI
Race												
White	10611 (69.1)	68.4-69.9	3907 (61.8)	60.6-63.0	1308 (61.6)	59.5-63.6	8404 (55.2)	54.4-56.0	12116 (80.2)	79.6-80.9	116917 (52.9)	52.8-53.1
Black or African American	2181 (14.2)	13.7-14.8	1092 (17.5)	16.4-18.2	371 (12.8)	11.4-14.3	3996 (26.9)	25.6-27.0	1321 (8.7)	8.3-9.2	68112 (21.6)	21.5-21.8
Asian	360 (2.3)	2.1-2.6	159 (2.5)	2.1-2.9	108 (5.1)	4.2-6.1	236 (1.6)	1.4-1.8	219 (1.5)	1.3-1.7	10562 (3.4)	3.3-3.4
Ethnicity												
Not Hispanic or Latino	13941 (86.9)	86.4-87.5	5218 (82.7)	81.7-83.6	1741 (81.9)	80.2-83.5	12782 (84.0)	83.4-84.6	13758 (91.1)	90.7-91.6	246940 (78.3)	78.2-78.5
Hispanic or Latino	1561 (10.3)	9.8-10.8	900 (14.2)	13.4-15.1	345 (16.2)	14.7-17.9	1950 (12.9)	12.3-13.4	865 (5.7)	5.4-6.1	59285 (18.8)	18.7-18.9
Highest education level												
No high school degree	948 (6.2)	5.8-6.6	498 (7.9)	7.2-8.6	80 (3.8)	3.0-4.7	1494 (9.8)	9.4-10.3	655 (4.3)	4.0-4.7	31984 (10.1)	10.0-10.3
High school graduate	2535 (16.5)	15.9-17.1	1081 (17.1)	16.2-18.1	360 (16.9)	15.4-18.6	3344 (22.0)	21.3-22.6	1891 (12.4)	12.0-13.1	64006 (20.3)	20.2-20.4
College One to Three	3763 (24.5)	23.9-25.2	1556 (24.6)	23.6-25.7	525 (24.7)	22.9-26.6	4476 (29.4)	28.7-30.2	3414 (22.6)	21.9-23.3	80110 (25.4)	25.3-25.6
College graduate or advanced degree	7814 (50.9)	50.1-51.7	3059 (48.3)	47.1-49.5	1150 (53.2)	51.0-55.3	5548 (36.5)	35.7-37.2	8907 (59.0)	58.2-59.8	131462 (41.7)	41.5-41.9
Annual household income												
Less than $10,000	1446 (9.4)	9.0-9.9	873 (13.8)	13.0-14.7	271 (12.8)	11.4-14.3	2597 (17.1)	16.5-17.7	571 (3.8)	3.5-4.1	49697 (15.8)	15.6-15.9
$10,000 - $49,999	4614 (30.1)	29.3-30.8	1874 (29.6)	28.5-30.8	676 (31.8)	29.8-33.8	4926 (32.4)	31.6-33.1	4250 (28.1)	27.2-28.7	85941 (27.2)	27.1-27.4
$50,000 - $99,999	3188 (20.8)	20.1-21.4	1156 (18.5)	17.3-19.3	416 (19.6)	17.9-21.3	2517 (16.5)	16.0-17.1	3768 (24.9)	24.1-25.5	55640 (17.6)	17.5-17.8
$100,000 or more	3572 (23.3)	22.6-24.0	1419 (22.4)	21.4-23.5	464 (21.8)	20.1-23.7	2405 (15.8)	15.2-16.4	3827 (25.3)	24.5-25.9	61287 (19.4)	19.3-19.6
Prefer not to answer, skipped, or missing	2526 (16.5)	15.9-17.1	1001 (15.8)	14.9-16.8	298 (14)	12.6-15.6	2772 (18.2)	17.6-18.8	2684 (17.8)	17.0-18.3	62832 (19.9)	19.8-20.1

Conclusion. Racial and ethnic disparities in vaccinations were apparent. Pneumococcal vaccination at age 65 years and above was more prevalent among white, non-Hispanic/Latino subjects who were also more educated and affluent. Conversely, those receiving pneumococcal vaccination before age 65 years were less educated and had lower AHI.

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

25. Relative Effectiveness of Adjuvanted Trivalent Influenza Vaccine Compared to Egg-Based Trivalent High-Dose Influenza Vaccine among U.S. Older Adults during 2019-20 Influenza Season

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Session: P-02. Adult Vaccines

Background. According to the Centers for Disease Control and Prevention (CDC), during the 2019-20 U.S. influenza season, influenza resulted in almost 180,000 hospitalizations and over 13,000 deaths in adults ≥ 65 years. The current study evaluated the relative vaccine effectiveness (rVE) of adjuvanted trivalent influenza vaccine (aTIV) compared to high-dose trivalent influenza vaccine (TIV-HD), against influenza-related hospitalizations/emergency room (ER) visits, all-cause hospitalizations and hospitalizations/ER visits for cardio-respiratory disease (CRD) among adults ≥65 years for the 2019-20 influenza season.

Methods. A retrospective cohort analysis of older adults (≥ 65 years) was conducted using IQVIA's professional fee, prescription claims and hospital charge master data in the U.S. Baseline characteristics included age, gender, payer type, geographic region, Charlson Comorbidity Index (CCI), comorbidities, indicators of frail health status, and pre-index hospitalization rates. To avoid any influenza outcome misclassification with COVID-19 infection, the study period ended March 7, 2020. Adjusted analyses were conducted through inverse probability of treatment weighting (IPTW) to control for selection bias. Poisson regression was used to estimate the adjusted pairwise rVE against influenza-related hospitalizations/ER visits, all-cause hospitalizations and any hospitalization/ER visit for CRD. An unrelated negative control outcome, urinary tract infection (UTI) hospitalization was included.

Results. During the 2019-20 influenza season, following IPTW, 798,987 recipients of aTIV and 1,655,979 recipients of TIV-HD were identified. After IPTW adjustment and Poisson regression, aTIV was statistically comparable to TIV-HD for prevention of influenza-related hospitalizations/ER visits (3.1%; 95% CI: -2.8%-8.6%) and all-cause hospitalizations (-0.7%; 95% CI: -1.6%-0.3%). Similar comparable outcomes were found for reduction of any hospitalization/ER visit for CRD (0.9%; 95% CI: 0.0%-1.7%). No treatment effect was identified for the negative control outcome.

Conclusion. aTIV and TIV-HD demonstrated comparable reductions in influenza-related hospitalizations/ER visits, all-cause hospitalizations and hospitalizations/ER visits for CRD.

Disclosures. **myron J. levin, MD**, **GSK group of companies** (Employee, Research Grant or Support) **Victoria Divino, PhD**, **Seqirus** (Consultant) **Stephen I. Pelton, MD**, **Seqirus** (Consultant) **Maarten Postma, Dr.**, **Seqirus** (Consultant) **Drishti Shah, PhD**, **Seqirus** (Consultant) **Joaquin F. Mould-Quevedo, PhD**, **Seqirus** (Employee) **Mitchell DeKoven, PhD**, **Seqirus** (Consultant)

26. Is There a Correlation Between Reactogenicity and Immune Responses of the Adjuvanted Recombinant Zoster Vaccine (RZV)? A Post-hoc Analysis

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Session: P-02. Adult Vaccines

Background. RZV (GSK) contains the varicella-zoster virus antigen glycoprotein E (gE) and the adjuvant system $AS01_B$ that enhances gE-specific immune responses through stimulating innate immunity. $AS01_B$ may contribute to the development of transient local or systemic post-vaccination reactions. A hypothesis that the magnitude of those reactions is predictive of immunogenicity and efficacy (i.e., "no pain, no gain") remains untested. To evaluate potential correlations between RZV's reactogenicity and immunogenicity in adults aged ≥ 50 years, a *post-hoc* analysis was conducted using data from 2 large phase 3 studies (NCT01165177, NCT01165229).

Methods. Reactogenicity was calculated as a single score per symptom (maximum grade recorded over 7 days post-vaccination). A global score obtained by adding each maximum severity for all reported symptoms (multivariate reactogenicity models) and a score for each reactogenicity symptom (univariate reactogenicity models) were estimated.

Results. The analysis included 904 and 147 RZV recipients with completed post-vaccination symptom diary cards and with anti-gE antibody results or cell-mediated immunity (CMI) results, respectively. The global score of reactogenicity post-dose 2 was significantly associated with anti-gE antibody response (p< 0.001, estimate 0.112) although the absolute antibody increase associated with reactogenicity was minimal (1.29-fold increase), while the association with CMI response was not statistically significant (p=0.073, estimate 0.230). There was a weak, but statistically significant association between gE-specific immune responses and the maximum pain post-dose 2 score (p=0.001, estimate 0.041), irrespective of post-vaccination time. Nevertheless, there are observations of immune responses in participants for whom pain was not reported.

Conclusion. A weak but statistically significant correlation was found between injection site pain intensity and immune responses in adult RZV recipients aged ≥ 50 years. However, participants reporting no pain were also able to mount a strong immune response, therefore pain cannot be a surrogate marker to inform on the level of immune response or on likelihood of being protected against herpes zoster.

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27. Immunologic Hyporesponsiveness with Subsequent Dosing of Meningococcal Vaccines: Re-Evaluating the Current Paradigm

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Session: P-02. Adult Vaccines

Background. Immunologic hyporesponsiveness (HyR) is considered as an inability to mount immune responses to vaccination of at least the same degree as earlier doses. For meningococcal vaccines, HyR has classically been associated with unconjugated but not conjugated polysaccharide (PS) vaccine dosing, but the clinical relevance is unclear.

Methods. To characterize meningococcal vaccine HyR, a PubMed search was conducted without date limits as follows: (hyporespons*) AND (meningococcal) AND (vaccine OR mechanism OR MOA OR causes). Papers from the authors' files, including HyR insights with other vaccines, were included.

Results. Classic HyR with repeat unconjugated PS vaccine (MPV) dosing is thought to be associated with memory B-cell (BC) depletion, causing reduced responses on redosing with the same PS. This lack of immunologic memory and interference is seen years after MPV dosing across age groups. As data is added, other examples seem to fit the HyR definition but differ from the classical mechanism and its implications. First, passively transferred maternal antibodies (Abs) may interfere with neonatal adaptive immune response and ultimately those of childhood vaccination