against all IPD. POOLED VE estimates from 12 observational studies showed PPSV23 effectiveness against VT-IPD was 38% (CI: 28% to 46%; F1 = 0.80).

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

| Author | Country | Study Design and Population | Per Protocol or Adjusted VE% (95% CI) |
|--------|---------|----------------------------|-------------------------------------|
| Burden 2015 | The Netherlands | RCT, n=450 | 70 (95% CI: 60-80) |
| Piffaretti 2018 | United States | Case-control, n=455 | 79 (95% CI: 72-86) |
| Totsch 2018 | United States | Case-control, n=445 | 77 (95% CI: 70-84) |
| Lorenzo 2018 | United States | Case-control, n=455 | 68 (95% CI: 63-73) |
| Donoguranski 2009 | Spain | Case-control, n=455 | 72 (95% CI: 62-82) |
| Kaim 2010 | South Korea | Case-control, n=455 | 42 (95% CI: 36-48) |
| Vile-Gontran 2006 | Spain, Tampere | Case-control, n=455 | 240 (95% CI: 226-254) |
| Vile-Gontran 2007 | Spain, Tampere | Case-control, n=455 | 70 (95% CI: 64-76) |
| Vile-Gontran 2008 | Spain, Tampere | Case-control, n=455 | 27 (95% CI: 20-34) |
| Andrewes 2012 | England/Wales | Indirect cohort, n=455 | 33 (95% CI: 20-46) |
| Durand 2013 | France | Indirect cohort, n=455 | 36 (95% CI: 27-45) |
| Guido-Morlingh 2013 | France, Madrid | Indirect cohort, n=455 | 45 (95% CI: 37-52) |
| Ruddish 2013 | Canada | Indirect cohort, n=455 | 42 (95% CI: 36-50) |
| Barlow 2020 | Japan | Indirect cohort, n=455 | 26 (95% CI: 20-34) |
| To 2022 | Taiwan | Indirect cohort, n=455 | 39 (95% CI: 35-43) |
| Wingrave 2018 | England/Wales | Indirect cohort, n=455 | 20 (95% CI: 17-24) |

Abbreviations: CI = confidence interval, RCT = randomized control trial, VE = vaccine efficacy or effectiveness, at any type.

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 the use of 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 time to estimate VE in relation to year since vaccination. For 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 (referent group). Analyses were adjusted for demographics and time-varying measures of immune compromise status, healthcare use and comorbidities.

Results. From 1/1/2006 to 9/12/2018, 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 ≥ 65 n=15217; ≥ 70 YOA n=7022; ≥ 85 YOA n=3090, hospitalized HZ (HZH). The mean AUC at 182 days was 137.24 (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, respectively, had clinically significant pain 3 months after the onset of HZ. The mean AUC at 182 days was 137.24 (90.9% ≥ 50 YOA and 190.6 ± 70 YOA), for the ZOPIE worst pain score and 92.75 (72.5% ≥ 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 with 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

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. Other vaccine cohorts comprised subjects with ≥ 1 lifetime vaccination.

Results. We analyzed 315297 subjects in the AoU dataset R2020Q4R2. The characteristics of those with documented vaccinations are shown in Table 1. For educational attainment, the Pneu < 65 (36.5%) had the smallest proportion of whites and non-Hispanics/Latinos were statistically higher than the general AoU cohort, the largest being from the Pneu ≥ 65 cohort (Table 2). 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 were significantly different across vaccine cohorts (Table 3).

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

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

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.

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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 hospitalization/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 1,665,979 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: -3.8%–6.8%) 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.

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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, that enhances gE-specific immune responses through stimulating innate immunity. AS01 may contribute to the development of transient local or systemic post-vaccination reactions. A hypothesis that the magnitude of such 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 (NCT01615177, NCT01655229).

Methods. Reactogenicity was calculated as a single score per symptom (maximum grade recorded over 7 days post-vaccination). A global score was obtained by adding each maximum severity for all reported symptoms (multivariate reactogenicity model) 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 protection 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 at least the same degree as earlier doses. For meningococcal vaccines, HyR has classically been associated with unconjugated 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 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