Results. 780 patients met study inclusion criteria and 86% (667/780) received vaccine. Characteristics of PLWH with and without vaccine are presented in Table 1. Older age, lower HIV viral load, and virologic suppression had a statistically significant (p < 0.05) association with vaccine receipt in unadjusted analysis. Only older age (p < 0.01) was significantly associated with vaccine in logistic regression modeling (Table 2), however this relationship was non-linear.

Table 1. Characteristics of patients living with HIV during the 2020-2021 Influenza vaccination season

| Characteristic | No Vaccine | Vaccine | p-value |
|---------------|------------|---------|---------|
| Age, years, median (IQR) | 40 (37-43) | 64 (41-81) | 0.015 |
| Gender | Male | Female | 0.122 |
| Race, n (%) | Black | White | 0.032 |
| HIV status | HIV-positive | HIV-negative | 0.007 |
| C.D.C-defined AIDS | Yes | No | 0.179 |
| % Federal Poverty Level | Yes | No | 0.002 |
| % Female | Male | Female | 0.006 |
| AIDS-defined | Yes | No | 0.003 |
| Insurance | Medicare: Medicaid | Private: Medicaid | 0.092 |

Note: *p* < 0.05 is statistically significant. IQR = interquartile range.

Table 2. Multivariable Analysis of Baseline Characteristics

| Characteristic | Odds Ratio (95% Confidence Interval) | p-value |
|----------------|-------------------------------------|---------|
| Age* | 1.10 (0.75, 1.21) | 0.692 |
| % Federal Poverty Level | 1.07 (0.62, 1.83) | 0.822 |
| Virologic Suppression | Yes | No | 0.017 |
| Sex | Male | Female | 0.117 |
| Race | White | Black | 0.17 (0.74, 1.84) |
| AIDS-defined | Yes | No | 0.179 |
| Insurance | Medicare: Medicaid | Private: Medicaid | 0.029 |

*Age was found to be associated with vaccine, with increasing likelihood of vaccine up to 55 years of age and decreasing likelihood in those over 55 years of age based on flexible restricted cubic spline of age in model.

Conclusion. A high rate of PLWH received vaccine, far exceeding local and national benchmarks, with EMR data unlikely to have fully captured all vaccines. The role of the COVID-19 pandemic in vaccine amongst PLWH is not yet known. While older age was associated with vaccine in adjusted analysis, the number of unvaccinated patients was small, confidence intervals wide, and associations consequently weak.

Session: P-02. Adult Vaccines

Background. Two pneumococcal vaccines are currently recommended for use in U.S. adults: 23-valent pneumococcal polysaccharide vaccine (PPV23) and 13-valent pneumococcal conjugate vaccine (PCV13). Recommendations for adult PCV13 use were supported by a large randomized-controlled trial (RCT) demonstrating PCV13 efficacy against pneumococcal pneumonia (PnPn) and vaccine-type (VT) PnPn in older adults. New pneumococcal conjugate vaccines are expected to be licensed for adults in late 2021 and recommendations for use among adults will be reviewed and revised, as needed. We conducted a systematic review to summarize evidence on the vaccine efficacy and effectiveness (VE) of PPV23 and PCV13 against PnPn among adults.

Methods. We conducted a search of literature published from 1998 to February 2021 on PCV13 and PPV23 VE studies using eight reference databases. Studies targeting adults with immunocompromising conditions were excluded. VE results with 95% confidence intervals (CI) were abstracted and stratified by vaccine product, outcome evaluated (PnPn and VT PnPn), study design, and effect measure. Where applicable, random effects models were used to estimate pooled VE and I-squared statistic was reported to assess heterogeneity.

Results. Of 3,422 screened studies, we included 15 studies: three on PCV13 and 12 on PPV23 (Table 1). In addition to the RCT, we identified two observational studies for PCV13 (Table 1); however, pooled VE of the observational studies was not estimated due to differences in methods for reporting results. Pooled PPV23 VE against PnPn from two RCTs was 63% (95% CI: 31, 80 I-squared 0%), Pooled VE of PCV13 against VT PnPn from three observational studies was 18% (95% CI: 35, 35 I-squared 70%), and PPSV23 effectiveness against PnPn was limited with a pooled VE of 25% (95% CI: 7, 39 I-squared 78%) from nine observational studies.

Table 1. Vaccine Efficacy and Effectiveness of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Against Pneumococcal Pneumonia Outcomes

| Author | Study Design | PPV23 | PCV13 |
|--------|--------------|-------|-------|
| Allison 2016 | RCT | 34 (24 to 44) | 35 (20 to 50) |
| Bozeman 2003 | RCT | 34 (24 to 44) | 35 (20 to 50) |
| Bridges 2011 | RCT | 27 (19 to 35) | 28 (21 to 35) |
| Cameron 2018 | RCT | 26 (18 to 35) | 28 (21 to 35) |
| Deeks 2003 | RCT | 27 (21 to 33) | 28 (21 to 35) |
| Epstein 2011 | RCT | 26 (18 to 35) | 28 (21 to 35) |
| Froesch 2010 | RCT | 25 (18 to 32) | 27 (21 to 35) |
| Hackett 2009 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Hackett 2004 | RCT | 40 (29 to 51) | 41 (30 to 52) |
| House 2012 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Lambe 2011 | RCT | 40 (29 to 51) | 41 (30 to 52) |
| McDonald 2013 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Noakes 2004 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Off 2004 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Pilishvili 2010 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Poston 2006 | RCT | 37 (27 to 47) | 38 (27 to 47) |
| Poston 2008 | RCT | 37 (27 to 47) | 38 (27 to 47) |

Abbreviations: CI confidence interval; NHI non-bacteremic; PnPn pneumococcal pneumonia; RCT randomized-controlled trial; VT vaccine-type; VE vaccine efficacy; VH vaccine effectiveness; VH vaccine effectiveness.
Conclusion. Findings from observational studies supported PCV13 VE against VT PnPn reported in the RCT. Differences in the study design made the magnitude of PPSV23 effectiveness against PnPn and VT PnPn difficult to assess; however, findings from recent observational studies suggest PPSV23 provides limited protection against VT PnPn.

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14. Postmarketing Safety Experience With MenACWY-TT
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Session: P-02. Adult Vaccines

Background. MenACWY-TT (Nimenrix®), a quadrivalent meningococcal tetanus toxoid conjugate vaccine, was first licensed in 2012 and is available in 82 countries but not in the United States. MenACWY-TT is administered in infants as a 2 + 1 (6 weeks to < 6 months of age) or 1 + 1 (6 to < 12 months of age) schedule with the booster dose at 12 months of age, and from 12 months of age as a single dose. In addition to its widespread use to protect against meningococcal serogroups A, C, W, and Y, MenACWY-TT is a constituent of an investigational pentavalent meningococcal (MenABCWY) vaccine currently undergoing clinical development.

Methods. Using the MenACWY-TT Periodic Safety Update Report (PSUR) with format and content in accordance with Good Pharmacovigilance Practice Module VII and International Council for Harmonisation Guideline E2C, for data up to April 19, 2020, postmarketing safety experience with MenACWY-TT is considered. The PSUR data included herein are spontaneous adverse events (AEs) from the Pfizer safety database. AEs were coded by system organ class (SOC) and preferred term (PT) using MedDRA v.22.1J.

Results. The cumulative estimated exposure of MenACWY-TT was nearly 26 million doses, with the majority administered in 0- to 16-year-olds and in the Western European Union (Figure 1). Over the reporting period, 13,301 cumulative AEs occurred. The most common SOCs in the reporting period were general disorders and administration site conditions (n=5169; 39%); nervous system disorders (n=1986; 15%); injury, poisoning and procedural complications (n=1266; 10%); and gastrointestinal disorders (n=1031; 8%) (Figure 2). By PT, the most common AEs were pyrexia (n=1613; 12%), headache (n=738; 6%), and vaccination site pain (n=394; 3%) (Figure 3). Of the 3299 serious AEs reported, the most common were pyrexia (n=317; 10%) and headache (n=209; 6%).

Figure 1. Cumulative Estimated MenACWY-TT Exposure* By Sex and Age Group

| Region/Country          | Doses, % | Total doses |
|-------------------------|----------|-------------|
| Western European Union  | 56.7     | 15,194,886  |
| Latin America           | 15.9     | 4,100,149   |
| Africa/Middle East      | 7.5      | 1,932,458   |
| Australia/New Zealand   | 7.1      | 1,829,817   |
| Central and Eastern Europe | 5.8   | 1,505,066   |
| Asia (excluding Japan)  | 3.1      | 800,105     |
| Canada                  | 1.9      | 502,829     |

*Due to various dosage regimens and country-specific vaccination schedules, it is not possible to determine with certainty the number of individuals who received Nimenrix vaccines, therefore worldwide distribution information is used to serve as a reasonable indicator of patient exposure

**Conclusion.** Based on cumulative safety data in conjunction with existing efficacy and effectiveness data, the benefit-risk profile of MenACWY-TT remains favorable and is consistent with the safety profile of MenACWY-TT established in clinical studies.

Disclosures. Lidia Serra, MS, Pfizer Inc (Employee, Shareholder) Susan Mather, MD, Pfizer Inc (Employee, Shareholder) Cindy Burman, PharmD, Pfizer Inc (Employee, Shareholder) Chris Webber, MD, Pfizer (Employee, Shareholder)

15. Evaluation of Retained Immunity for Tetanus-Diphtheria and Pneumococcal Vaccines in Recipients of Cellular Therapies
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