

**06. United States Healthcare Provider Preferences for Adult Pneumococcal Vaccine Recommendations**

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

**Background.** Pneumococcal vaccine recommendations for US adults are complex, varying by age and underlying conditions, and include both 23-valent polysaccharide vaccine (PPSV23) and 13-valent pneumococcal conjugate vaccine. The Advisory Committee on Immunization Practices (ACIP) will vote on new recommendations in October after the 15- (PCV15) and 20-valent (PCV20) conjugate vaccines are approved. Stakeholder acceptability is part of ACIP's evidence to recommendation framework, but few data are available on health care providers' (HCPs) preferences for potential recommendations.

**Methods.** 752 HCPs (300 physicians, 150 nurse practitioners, 150 physician assistants, & 152 pharmacists) were surveyed. Object case best-worst scaling (BWS) was used to elicit preferences for hypothetical recommendations for 1) adults 19-64 years with chronic conditions and 2) immunocompetent adults ≥65 years. Presented recommendations included combinations of PCV15/PCV20 either as routine or after shared clinical decision making (SCDM), and PPSV23 as routine, SCDM, or no recommendation. Following BWS, HCPs were asked to assume ACIP was considering implementing both of their preferred recommendations for the age/risk groups. HCPs were then given the opportunity to change their selections and propose recommendations not included in the BWS exercise. Additional information was collected using conventional survey items.

**Results.** Routine use of higher-valent PCVs in sequence with PPSV23 was most often preferred for both adults 19-64 with chronic conditions (40%) and immunocompetent adults ≥65 (49%) when elicited separately for each age/risk group. Most respondents (63%) revised their recommendations after considering implementation, which resulted in most (59%) favoring recommendations harmonized across the age/risk groups, and 75% favoring routine use of PCV15 or PCV20 among immunocompetent adults ≥65. When asked directly, HCPs generally approved of the idea of simplifying adult pneumococcal vaccine recommendations, harmonizing the interval between vaccines, and lowering the cutoff for age-based recommendations below 65 years.

**Conclusion.** US HCPs generally prefer simplification of the adult pneumococcal recommendation, favoring broad routine use of both higher-valent PCVs and PPSV23.

**Disclosures.** Jeffrey Vietri, PhD, Pfizer Inc (Employee, Shareholder) Kelley Meyers, PhD, RTI Health Solutions (Independent Contractor) Christine Poulos, PhD, Pfizer Inc (Other Financial or Material Support, Employee of RTI-HS, which received funds from Pfizer to conduct the study) Erica Chilson, PharmD, Pfizer, Inc (Employee, Shareholder) Vincenza Snow, MD, Pfizer Vaccines (Employee)

**07. Recombinant Zoster Vaccine (RZV) Second-Dose Completion in Adults Age 50-64 Years in the United States**

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

**Background.** In 2018, CDC recommended a highly efficacious adjuvanted recombinant zoster vaccine (RZV, Shingrix) as a 2-dose series for prevention of herpes zoster (HZ) for immunocompetent persons age ≥50 years, with the 2<sup>nd</sup> dose recommended 2-6 months after the 1<sup>st</sup> dose. Among Medicare beneficiaries, 2-dose series completion 6 months and 12 months post initiation was 78% and 86%, respectively. Here we estimate the proportion of adults age 50-64 years who completed the 2-dose RZV series within 6 or 12 months after receiving their 1<sup>st</sup> dose, by using two administrative claims databases.

**Table 1. Demographics of Patients Vaccinated with 1 or 2 doses of Recombinant Zoster Vaccine (RZV) among 50-64-year-olds in the United States, IQVIA<sup>a</sup> and IBM MarketScan<sup>b</sup> Databases, 2017-2020**

Variable	All RZV Vaccinees		IQVIA <sup>a</sup> 1 dose		2-doses		MarketScan <sup>b</sup> 1 dose		2-doses	
	#	%	#	%	#	%	#	%	#	%
<b>Total #</b>	422,641		127,865		294,776		497,893		161,672	336,221
Median Age (y)	60		59		60		59		59	60
<b>Sex</b>										
Male	176,191	42%	55,983	44%	120,208	41%	216,076	43%	72,526	45%
Female	246,448	58%	71,881	56%	174,567	59%	281,817	57%	89,146	55%
Unknown	2	----	1	----	1	----	----	----	----	----
<b>Region</b>										
Northeast	69,469	16%	21,160	17%	48,309	16%	83,525	17%	25,668	16%
Midwest	129,176	31%	40,603	32%	88,573	30%	120,159	24%	39,257	24%
West	165,600	39%	50,077	39%	115,523	39%	212,362	43%	70,004	43%
South	58,380	14%	16,017	13%	42,363	14%	80,636	16%	26,260	16%
Unknown	16	----	8	----	8	----	1,211	----	483	----

<sup>a</sup>1<sup>st</sup> RZV dose received during October 2017 to September 2019, and 2<sup>nd</sup> RZV dose received within 6 months of the 1<sup>st</sup> dose, at any time through March 2020

<sup>b</sup>1<sup>st</sup> RZV dose received during October 2017 to April 2020, and 2<sup>nd</sup> RZV dose received within 6 months of the 1<sup>st</sup> dose, at any time through October 2020

**Methods.** We used medical and pharmaceutical claims data from October 2017-March 2020 IQVIA<sup>a</sup> PharMetrics Plus and October 2017-October 2020 IBM<sup>b</sup> MarketScan<sup>b</sup> databases. RZV vaccination was defined using Current Procedural Terminology and National Drug Codes. We allowed for sufficient follow-up time by examining 1<sup>st</sup> doses given at least 6 or 12 months prior to the end of the study period in both databases. Place of administration was available in IQVIA data.

**Results.** Among persons age 50-64 years, in IQVIA and MarketScan, 70% and 68% received their 2<sup>nd</sup> RZV dose within 6 months, respectively, and 79% and 81% received their 2<sup>nd</sup> dose within 12 months, respectively. The median age of 1<sup>st</sup> dose of RZV vaccination was 60 years and ~60% were female [Table 1]. When the 2<sup>nd</sup> dose was administered within 12 months, the median interval between 1<sup>st</sup> and 2<sup>nd</sup> doses was 104 and 98 days in the IQVIA and MarketScan databases, respectively. Characteristics by age, sex, or region were similar in persons who received 1 RZV dose vs. 2 RZV doses [Table 1]. Among those who received only 1 RZV dose with at least 12 months of follow-up time, 55% of vaccinations occurred at ambulatory medical provider offices and 40% at pharmacies; among 2 doses recipients, 33% of vaccinations occurred at provider offices and 62% at pharmacies.

**Conclusion.** Among 50-64-year-olds, 2-dose RZV series completion was ~70% within 6 months and 80% within 12 months of initiation. The findings were similar across two administrative claims databases. Availability of RZV at pharmacies has potentially helped to increase RZV 2<sup>nd</sup> dose completion rates.

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

**08. Concomitant Administration of the Adjuvanted Recombinant Zoster Vaccine (RZV) with 13-Valent Pneumococcal Conjugate Vaccine (PCV13) Is Safe and Does Not Interfere with Immunogenicity of Either Vaccine in Adults Aged ≥ 50 Years**

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

**Background.** This study assessed non-inferiority of humoral immunogenicity, reactivity, and safety of RZV when the 1<sup>st</sup> dose was co-administered with PCV13 in adults ≥ 50 years of age (YOA) compared to sequential administration.

**Methods.** In this phase 3b, open-label, multi-center study (NCT03439657), adults were randomized 1:1 to receive either the 1<sup>st</sup> RZV dose co-administered with PCV13 at day (D)1 and the 2<sup>nd</sup> RZV dose at month (M)2 (Co-Ad group), or PCV13 at D1, the 1<sup>st</sup> RZV dose at M2 and the 2<sup>nd</sup> RZV dose at M4 (Control group). Co-primary confirmatory objectives were: (i) vaccine response rate (VRR) to RZV at 1 month post-dose 2 in Co-Ad group; (ii) non-inferiority of

humoral responses to RZV (1 month post-RZV dose 2) and PCV13 (1 month post-PCV13) in Co-Ad group compared to Control group. Solicited adverse events (AEs) until D7 post-vaccination and unsolicited AEs until D30 post-vaccination were recorded. Serious AEs (SAEs) and potential immune-mediated diseases (pIMDs) were collected through 12 months post-RZV dose 2. Immunogenicity was performed in the per-protocol set (PPS) and safety analyses in the exposed set.

**Results.** Of 912 vaccinated adults, 863 were included in PPS (Co-Ad: 427; Control: 436). VRR for anti-glycoprotein E antibody concentrations was 99.1% in Co-Ad group. The predefined non-inferiority criteria for the humoral immune responses to RZV and PCV13 were met (Table 1). The overall frequency of solicited local AEs after RZV and PCV13 was comparable between Co-Ad and Control groups. Pain was the most common solicited local AE (Figure 1). The frequency of solicited general AEs for the 1st RZV dose when co-administered with PCV13 or alone (57.4% vs 54.6%). Myalgia and fatigue were the most common solicited general AEs (Figure 2). The frequency (Co-Ad: 21.2%; Control: 23.1%) and nature of unsolicited AEs were balanced between groups. None of the reported SAEs, fatal SAEs, or pIMDs were vaccine-related.

Table 1. Co-primary confirmatory objectives: vaccine response rate (VRR), and non-inferiority of the immune responses to RZV (1 month post-dose 2) and to PCV13 (1 month post-vaccination) in the Co-Ad group vs the Control group (per-protocol set)

Statistical criteria	Antigen - Outcome
<b>VRR to RZV</b>	
Lower limit (LL) of the 1-sided 95% confidence interval (CI) of the VRR for anti-glycoprotein E (anti-gE) antibody enzyme-linked immunosorbent assay (ELISA) concentrations in the Co-Ad group was $\geq 60\%$	Anti-gE <span style="float: right;">97.6</span>
Upper limit (UL) of the 1-sided 95% CI of anti-gE antibody ELISA geometric mean concentration (GMC) ratio $< 1.5$	Anti-gE <span style="float: right;">1.16</span>
UL of the 1-sided 95% CI of the multiplex opsonophagocytosis assay (MOPA) geometric mean titer (GMT) ratio $< 2$ , for each of the 13 pneumococcal vaccine serotypes	Anti-1: 1.33 Anti-3: 1.22 Anti-4: 1.52 Anti-5: 1.32 Anti-6A: 1.56 Anti-6B: 1.73 Anti-7F: 1.44 Anti-9V: 1.39 Anti-14: 1.42 Anti-18C: 1.34 Anti-19A: 1.22 Anti-19F: 1.32 Anti-23F: 1.50

Note: Co-primary confirmatory objectives were assessed sequentially. \*Adjusted for age and baseline concentration/titer; VRR, the percentage of adults who had a  $\geq 4$ -fold increase in the anti-gE antibody concentrations post-RZV dose 2 as compared to the anti-gE antibody concentrations pre-vaccination, for adults who were seropositive at baseline, or a  $\geq 4$ -fold increase in the anti-gE antibody concentrations post-RZV dose 2 as compared to the anti-gE antibodies cut-off value for seropositivity, for adults who were seronegative at baseline. The dotted lines represent the non-inferiority criteria.

Figure 1. The incidence of solicited local adverse events (AEs) occurring within 7 days post-vaccination (overall/adult, exposed set)

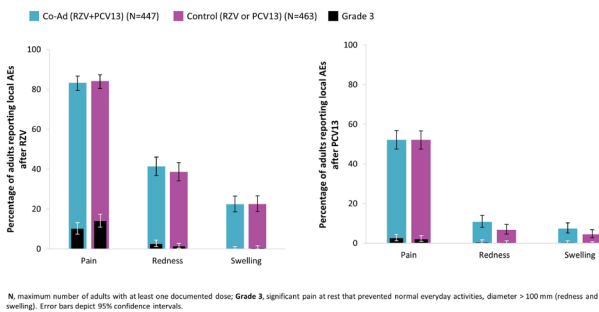
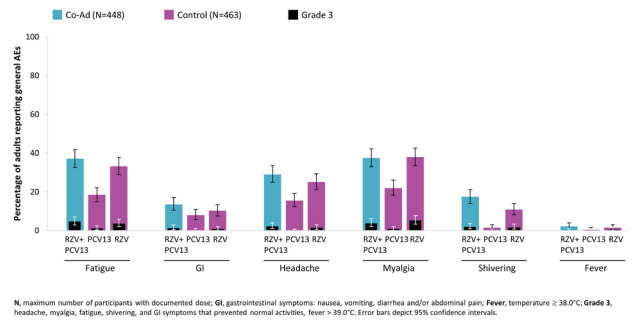


Figure 2. The incidence of solicited general adverse events (AEs) post-dose 1 occurring within 7 days post-vaccination (exposed set)



N, maximum number of participants with documented dose; GI, gastrointestinal symptoms: nausea, vomiting, diarrhea and/or abdominal pain; Fever, temperature  $\geq 38.0^\circ\text{C}$ ; Grade 3, headache, myalgia, fatigue, shivering, and GI symptoms that prevented normal activities, fever  $> 39.0^\circ\text{C}$ . Error bars depict 95% confidence intervals.

**Conclusion.** Co-administration of the 1st RZV dose with PCV13 showed non-inferior immune responses to sequential administration. The reactogenicity and safety of RZV in the Co-Ad group were within the range of the established safety profile of RZV. Co-administration of RZV with PCV13 may improve vaccination rates in  $\geq 50$  YOA population.

**Funding.** GlaxoSmithKline Biologicals SA

**Disclosures.** Ji-Young Min, PhD, GSK group of companies (Employee) Agnes Mwakingwe-Omar, MD, PhD, GSK group of companies (Employee) Megan Riley, PhD, GSK group of companies (Employee, Shareholder) Lifeter Yenwo Molo, BSc(hons) MSc(hons), GSK group of companies (Employee) Jyoti Soni, MA, GSK group of companies (Employee) Ginette Girard, MD, Diex Recherche Inc. Sherbrooke (Scientific Research Study Investigator) Jasur Danier, MD, GSK group of companies (Employee, Shareholder)

## 10. Quadrivalent M2SR (M2-deficient Single Replication) Live Influenza Vaccine Provides Better Protection Than Inactivated Vaccine Against Drifted Influenza B Virus Challenge in Ferrets

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Session: P-02. Adult Vaccines

**Background.** Quadrivalent inactivated influenza vaccines (QIV) induce neutralizing antibodies (Abs) against the viral hemagglutinin (HA). Despite annual update of HA vaccine antigens to match circulating strains, current vaccines provide  $\sim 60\%$  vaccine effectiveness (VE). QIV VE can be as low as 10% when circulating strains do not match vaccine HA. The live M2SR (M2-deficient single replication) influenza vaccine candidate has previously shown broad humoral, mucosal and cellular immune responses and protection against multiple influenza A subtypes. Here we show similar properties with the Quadrivalent M2SR (Quad M2SR) against drifted influenza B challenge in comparison to QIV.

**Methods.** Ferrets pre-infected with influenza H1N1 and B/Yamagata viruses, were immunized intranasally (IN) with PBS (Mock) or Quad M2SR, or intramuscularly with Fluzone QIV. Serum collected post-vaccination was evaluated for Ab responses. Forty-two days after vaccination, ferrets were challenged IN with  $10^6$  pfu of B/Brisbane/60/2008 (Victoria lineage) influenza virus. Nasal washes were taken for 7 days post-challenge and evaluated for challenge virus by TCID<sub>50</sub> assay. Nasal turbinates, trachea and lungs were also evaluated for virus.

**Results.** Quad M2SR and QIV elicited high serum Abs against the vaccine strain B/Colorado/06/2017 (Fig. 1A) and against the drifted influenza B challenge strain B/Brisbane/60/2008 (Fig. 1B) in ferrets with preexisting immunity. Like Mock, ferrets who received QIV displayed both weight loss (6.2%, Fig. 2A) and a rise in temperature ( $1.1^\circ\text{C}$ , Fig. 2B) after challenge. In contrast, the Quad M2SR group did not exhibit any significant weight or temperature changes after challenge. Quad M2SR controlled the drifted challenge virus better than QIV as evidenced by significantly lower or absent post-challenge virus titer in nasal washes (Fig. 3A) and nasal turbinates (Fig. 3B).