statistically significant differences were found for aTIV compared to TIV-HD for prevention of influenza-related hospitalizations/ER visits in the sub-analyses evaluated.

Conclusion: In adjusted analyses, aTIV reduced influenza-related office visits compared to TIV-HD within the two older age groups and HIAP sub-analysis. aTIV and TIV-HD demonstrated comparable reductions in influenza-related hospitalizations/ER visits.

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15. A Novel Approach to Bacterial Vaccines: Haemophilus influenzae as a Paradigm

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Session: P-2. Adult Vaccines

Background: The *H. influenzae* type b vaccines target the type b capsule and therefore have no impact on the nontypable (unencapsulated) *H. influenzae* (NTHi). NTHi has become the most common cause of otitis media and is the most common isolate from patients with exacerbations of Chronic Obstructive Pulmonary Disease (COPD). Therefore, NTHi is an appropriate target for vaccine development.

Methods: To characterize potential vaccine targets, the core outer proteins of NTHi present in the available sequenced genomes were identified through genomic bioinformatics. The structures of the outer proteins were analyzed through comparison with the available structures of homologues characterized by X-ray crystallography. Sequenced conserved outer regions of these proteins were analyzed for their protective capacity in the infant rat model of *H. influenzae* infection.

Results: Nine peptides that were protective in the infant rat model were used in a novel vaccine to immunize chinchillas, the most established animal model of otitis media. Chinchillas (40 vaccinated and 41 controls) were infected with NTHi 86-028NP. The vaccinated group cleared infection more quickly than the control group as indicated by significantly decreased positive findings on video-otoscopy ($p< 0.0001$) and tympanometry ($p=0.0002$) on day 7, and presence of middle ear fluid obtained by aspiration ($p=0.0001$) on day 10 post infection. Similarly, in the mouse model of NTHi pulmonary clearance, the vaccinated group (n=5) reduced infection more rapidly than the control group (n= 5), $p=0.008$.

Conclusion: These data demonstrate the effectiveness of the Bacterial Vaccine Polypeptide methodology in development of a vaccine against NTHi with protection in relevant preclinical models of both otitis media and pulmonary clearance. The methods are applicable to other bacteria, and this approach to a Bacterial Vaccine Polypeptide against NTHi serves as a paradigm for development of similar vaccines to protect against other bacterial infections.

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

16. A Randomized Phase 1 Study of a Novel Pneumococcal Conjugate Vaccine in Healthy Japanese Adults in the United States

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Session: P-2. Adult Vaccines

Background: Because of the number and variability of serotypes causing pneumococcal disease among different geographic regions, age groups, and environmental backgrounds, expanding serotype coverage with pneumococcal conjugate vaccines (PCVs) is a continued unmet need.

Methods: This phase 1, randomized, double-blind study included healthy Japanese adults aged 18–49 years residing in the United States. Subjects were randomized 1:1:1 to receive a single dose of a 20-valent PCV (containing 13-valent PCV [PCV13] serotypes plus 8, 10A, 11A, 12F, 15B, 22F, 33F), a novel pneumococcal polysaccharide conjugate vaccine with extended coverage, or PCV13 (control). Safety was the primary endpoint and included reactogenicity events occurring ≤ 14 days after vaccination, adverse events (AEs) ≤ 1 month after vaccination, and serious AEs (SAEs) ≤ 6 months after vaccination. The secondary endpoint was pneumococcal serotype-specific immunogenicity as determined by opsonophagocytic activity (OPA) titers on sera collected before and 1 month after vaccination.

Results: Overall, 35 subjects received PCV20 and 35 subjects received PCV13. One subject withdrew before the 1-month follow-up. Local reactions and systemic events across groups were generally mild or moderate (**Figure 1**). Two vaccine-related AEs occurred (injection site erythema and swelling in the PCV20 group); no severe AEs, SAEs, or safety-related withdrawals were reported. OPA geometric mean titers increased for all 20 serotypes in the PCV20 group and all 13 serotypes in the PCV13 group 1 month after vaccination; corresponding OPA geometric mean fold rises from baseline to 1 month after vaccination are reported (**Figure 2; Figure 3**).

Figure 1

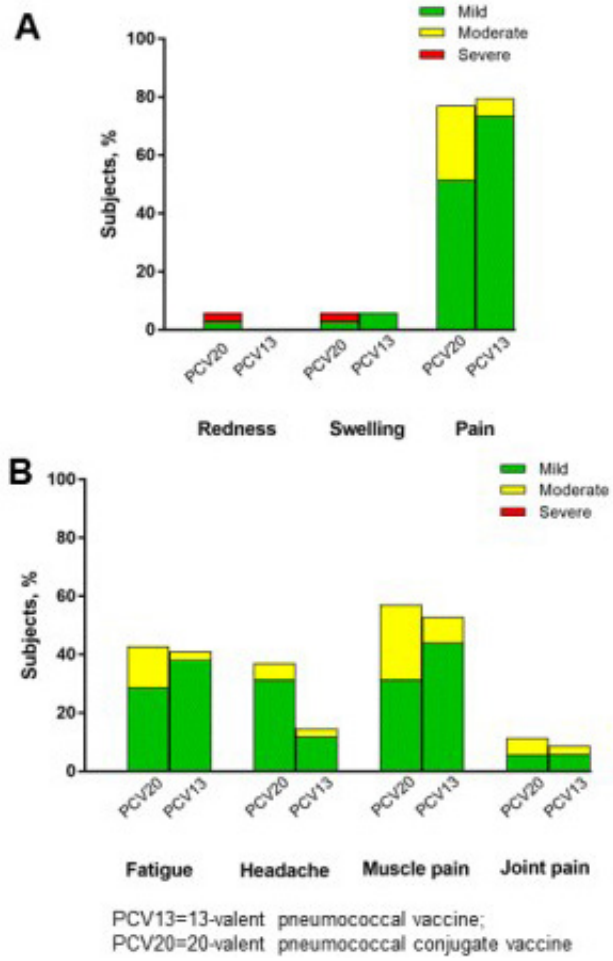
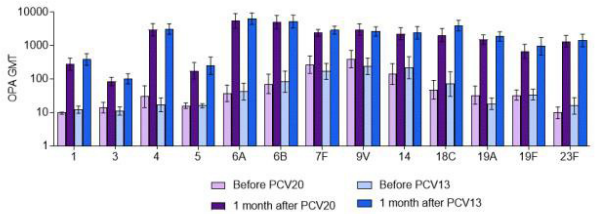


Figure 2

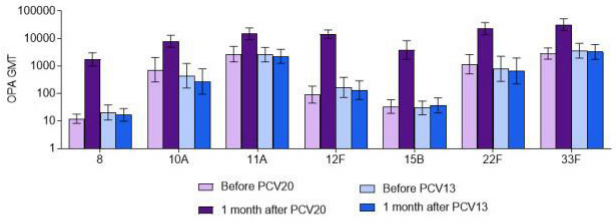


Serotype		1	3	4	5	6A	6B	7F	9V	14	18C	19A	19F	23F
PCV20	GMFR	29.1	6.1	96.3	11.0	144.7	65.0	8.4	7.5	11.9	38.8	46.3	20.3	136.9
	95% CI	18.9, 44.8	4.4, 8.5	40.5, 228.9	6.0, 20.0	70.7, 296.4	31.4, 134.2	4.4, 15.8	4.3, 13.1	5.8, 24.3	19.1, 78.8	24.3, 88.3	11.6, 35.7	79.2, 236.6
PCV13	GMFR	31.8	9.2	177.6	15.7	152.7	46.7	18.1	11.3	11.2	53.7	98.9	27.4	90.9
	95% CI	21.4, 47.2	6.4, 13.3	97.6, 323.3	8.5, 28.7	77.0, 302.6	22.2, 98.2	10.6, 30.8	6.8, 18.9	5.1, 24.5	24.0, 120.0	60.4, 162.1	14.5, 51.6	51.6, 160.1

GMFR=geometric mean fold rise; GMT=geometric mean titer; LLOQ=lower limit of quantitation; OPA=opsonophagocytic activity; PCV13=13-valent pneumococcal conjugate vaccine; PCV20=20-valent pneumococcal conjugate vaccine.

Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

Figure 3



Serotype		8	10A	11A	12F	15B	22F	33F
PCV20	GMFR	150.7	10.6	6.1	149.1	101.6	19.6	10.0
	95% CI	72.5, 313.3	4.5, 25.3	3.2, 11.6	68.0, 327.2	35.5, 291.0	8.4, 45.7	6.3, 15.6
PCV13	GMFR	0.9	0.7	0.7	1.0	1.3	1.3	0.9
	95% CI	0.6, 1.4	0.5, 1.1	0.6, 1.0	0.9, 1.0	0.9, 1.9	0.8, 2.1	0.7, 1.1

GMFR=geometric mean fold rise; GMT=geometric mean titer; LLOQ=lower limit of quantitation; OPA=opsonophagocytic activity; PCV13=13-valent pneumococcal conjugate vaccine; PCV20=20-valent pneumococcal conjugate vaccine.

Assay results below the LLOQ were set to 0.5 × LLOQ in the analysis.

Conclusion: PCV20 was well tolerated and induced serotype-specific functional OPA immune responses that are anticipated to be associated with protection in Japanese adults. ClinicalTrials.gov: NCT03642847. Funding: Pfizer Inc.

Disclosures: David Fitz-Patrick, MD, Pfizer Inc (Grant/Research Support) Mariano Young Jr., MD, Pfizer Inc (Employee, Shareholder) Daniel Scott, MD, Pfizer (Employee, Shareholder) Ingrid L. Scully, PhD, Pfizer Inc (Employee, Shareholder) Gary Baugher, PharmD, Pfizer Inc (Employee, Shareholder) Yahong Peng, PhD, Pfizer (Employee, Shareholder) Kathrin U. Jansen, PhD, Pfizer (Employee, Shareholder) William C. Gruber, MD, Pfizer (Employee, Shareholder) Wendy Watson, MD, Pfizer (Employee, Shareholder)

17. Assessment of Recombinant Zoster Vaccine Second Dose Completion in the United States

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Session: P-2. Adult Vaccines

Background: Recombinant Zoster Vaccine (RZV) was licensed in the United States (US) in October 2017 for the prevention of herpes zoster in adults ≥ 50 years of age (YOA). The vaccine is administered in a two-dose sequence with a 2- to 6-month interval; however, the Center for Disease Control & Prevention has advised against restarting a series after the prescribed window. This study describes an assessment of 2nd dose completion and compliance of RZV in the US.

Methods: Primary analysis was conducted on a cohort ≥ 50 YOA who received an initial RZV dose between October 2017 and September 2018 as indicated in the IQVIA longitudinal prescription claims or medical claims databases. Subjects were required to have ≥ 1 year of observable time post initial dose. A sensitivity analysis was conducted using all eligible subjects regardless of observable time post initial dose. Endpoints of analyses were monthly and cumulative 2nd dose label-compliant proportions at 6 months and completers by 12-month intervals and time to completion from initial RZV vaccine administration with stratifications by age, sex, claim source and payer type.

Results: The primary sample included 1,225,088 subjects, while the sensitivity analysis included 7,097,441 (Table 1). Overall, 2nd RZV dose completion was 70.4% within 6 months and 81.8% within 12 months. Minimal variation for 12-month completion was demonstrated across age (77.2–84.5%), sex (81.7–81.9%), and Commercial vs. Medicare (80.9–83.0%). However, larger variations were seen across claim sources and other payer type, with medical claims (64.9%), Medicaid patients (72.8%) and Cash patients (74.7%) having lower rates at 12 months (Table 2). Overall, the average time to completion was around 4 months regardless of stratification except by claims source, with medical claims taking 5 months on average to complete. The sensitivity analysis of the variable follow-up cohort demonstrated findings consistent with that of the primary sample.

Table 1. Subject Demographics

Characteristic	Primary Sample (n = 1,225,088)		Sensitivity Analysis Sample (n = 7,097,441)	
Age group (years)	n	%	n	%
50-59	172,668	14.09%	1,164,962	16.41%
60-64	204,183	16.67%	1,259,672	17.75%
65-69	237,523	19.39%	1,476,553	20.80%
70-79	424,023	34.61%	2,292,433	32.30%
80+	186,691	15.24%	903,821	12.73%
Sex				
Male	501,612	40.94%	2,989,561	42.12%
Female	723,476	59.06%	4,107,880	57.88%
Payer type				
Medicare	611,700	49.93%	3,369,348	47.47%
Commercial	589,488	48.12%	3,553,487	50.07%
Cash	20,594	1.68%	146,680	2.07%
Medicaid	3,306	0.27%	27,926	0.39%
Claim Source				
Pharmacy claims	1,082,468	88.36%	6,503,532	91.63%
Medical claims	142,620	11.64%	593,909	8.37%

Table 2. Primary Analysis RZV Completion by 6 and 12 Months Post Initial Vaccination

Stratification	n	6-month Completion Rate (95%CI)		12-month Completion Rate (95%CI)	
Overall	1,225,088	70.41% (70.26%-70.56%)		81.80%	(81.64%-81.96%)
Age group (years)					
50-59	172,668	64.76%	(64.38%-65.14%)	77.15%	(76.74%-77.57%)
60-64	204,183	68.03%	(67.67%-68.39%)	80.06%	(79.67%-80.45%)
65-69	237,523	71.02%	(70.68%-71.36%)	82.28%	(81.92%-82.65%)
70-79	424,023	73.51%	(73.25%-73.77%)	84.45%	(84.17%-84.72%)
80+	186,691	70.40%	(70.02%-70.78%)	81.35%	(80.95%-81.76%)
Sex					
Male	501,612	70.43%	(70.20%-70.66%)	81.70%	(81.45%-81.95%)
Female	723,476	70.39%	(70.20%-70.58%)	81.86%	(81.65%-82.07%)
Payer type					
Medicare	611,700	72.13%	(71.92%-72.34%)	82.99%	(82.76%-83.21%)
Commercial	589,488	68.91%	(68.69%-69.12%)	80.86%	(80.63%-81.09%)
Cash	20,594	63.73%	(62.65%-64.83%)	74.66%	(73.49%-75.85%)
Medicaid	3,306	61.07%	(58.46%-63.79%)	72.75%	(69.90%-75.71%)
Claim Source					
Pharmacy claims	1,082,468	73.23%	(73.07%-73.39%)	84.02%	(83.85%-84.19%)
Medical claims	142,620	48.98%	(48.62%-49.35%)	64.90%	(64.48%-65.32%)

Conclusion: Assessment of RZV suggests high levels of completion across age, sex, payer type and claim sources. More effort is needed to understand barriers to completion rates in Medicaid patients and settings where vaccination claims are processed outside of the vaccine recipient's pharmacy benefit.

Disclosures: Brandon J. Patterson, PharmD, PhD, GSK (Employee, Shareholder) Chi-Chang Chen, PhD, MSPharm, GSK (Research Grant or Support) Catherine B. McGuiness, MA, MS, GSK (Research Grant or Support)Pfizer (Shareholder) Lisa I. Glasser, MD, GSK (Employee, Shareholder) Kainan Sun, MS, PhD, GSK (Research Grant or Support) Philip O. Buck, PhD, MPH, ORCID: 0000-0002-3898-3669, GSK (Employee, Shareholder)

18. Association Between State-level Voting Patterns and Prior Receipt of the HPV Vaccine, an Analysis Using Data from the Behavioral Risk Factor Surveillance System 2016 – 2018

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Session: P-2. Adult Vaccines

Background: Human papillomavirus (HPV) is the main cause of cervical, anal and oro-pharyngeal cancer worldwide. The HPV vaccine can prevent over 90% of HPV-related malignancies but vaccination rates in the United State (US) vary significantly by region. In this study, we assessed whether state-level politics is associated with receipt of HPV vaccination in the US, and if the association is modified by sex and age.