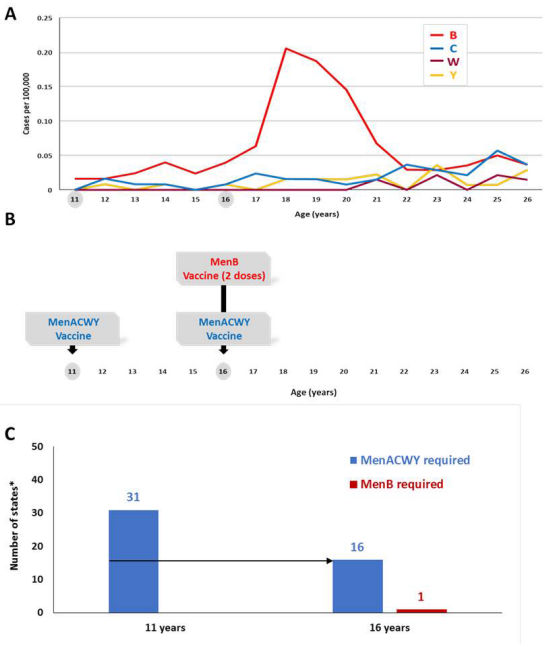
Table 1. School-attendance State Requirements by Vaccine Class

	MenACWY Primary Dose at 11 Years	MenACWY Booster at 16 Years	MenB Vaccination at 16–18 Years
Vaccination + Education	GA, IN, KY, MA, MI, NJ, NY, NC, TX, UT, VT	IN, KY, NY, NC	
Vaccination	AZ, AR, CT, DC, DE, ID, IL, IA, LA, ME, MD, MN, MO, NV, ND, OH, PA, RI, SD, WV	AR, IL, IA, LA, ME, MN, MO, ND, OH, PA, RI, WV	IN
Education Only	OK, TN, WA		

Table 2. College-attendance State Requirements by Vaccine Class

	MenACWY (Proof of Vaccination or Waiver)		MenB Vaccination at 16–18 Years
		(Experienced College MenB Outbreaks)	
Vaccination + Education	CO, CT, DC, DE, FL, IL, IN, LA, MD, MA, MO, NJ, NY, OH, OK, PA, RI, TN, TX, VT, VA	MA, NJ, NY, PA, RI	
Vaccination	KS, NV, ND		IN
Education Only	AK, CA, GA, IA, KY, ME, MN, MS, NE, NC, OR, SC, WA, WI	CA, OR, WI	

Figure 1. Meningococcal disease epidemiology and vaccination platform in the United States: (A) Meningococcal disease incidence by serogroup across ages 11–26 years from 2014–2016; (B) US meningococcal vaccination platform; (C) Number of states* requiring MenACWY and MenB vaccination at ages 11 and 16 years



*Also including the District of Columbia

MenACWY=meningococcal serogroups A, C, W, and Y; MenB=meningococcal serogroup B

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

2722. Effects of Sex, Age, and Race on Immunogenicity of MenB-FHbp, a Bivalent Meningococcal B Vaccine: A Pooled Evaluation of Clinical Trial Data

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Session: 277. Vaccines: Bacterial

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Background: MenB-FHbp (bivalent rLP2086), a meningococcal serogroup B vaccine, is approved in several countries for adolescents and young adults. MenB-FHbp elicited robust immune responses and had an acceptable safety profile during an extensive clinical development program. Because immune responses to vaccines can vary by subject demographics, this subgroup analysis pooled data across 7 randomized MenB-FHbp clinical studies to evaluate potential differences in immunogenicity by sex, age, or race/ethnicity in a larger dataset relative to individual studies.

Methods: Data from subjects who received 120 µg MenB-FHbp at 0, 2, and 6 months and had valid immunogenicity results for 4 vaccine-heterologous test strains were included. Immune responses were evaluated by serum bactericidal assays using human complement (hSBA). Immunogenicity endpoints (assessed 1 month after dose 3) were percentages of subjects achieving ≥ 4-fold rise in hSBA titer against each strain, percentages achieving hSBA titers ≥ the lower limit of quantification (LLOQ) against each strain and against all 4 strains combined (composite response), geometric mean hSBA titers against each strain, and percentages achieving hSBA titers ≥ 1:4 (correlate of protection) against each strain.

Results: This analysis included 8026 subjects aged 10–25 years (51.7% males, 80.7% adolescents aged 10–18 years, 87.0% white, 9.3% black, 0.8% Asian, 3.0% other race). One month after dose 3, percentages of subjects achieving a ≥ 4-fold rise from baseline titer against each strain and achieving a composite response were similar across age and race (table). A marginally greater percentage of males vs. females achieved ≥ 4-fold rise in titer against each strain, but these differences were not considered clinically meaningful because of the high percentages of responders in both groups.

Conclusion: MenB-FHbp immunogenicity was similar across sex, age, and race in this pooled analysis, with high percentages of responders in all evaluated subgroups. The marginally lower response rates among females compared with males were not considered clinically meaningful. These findings support currently recommended MenB-FHbp vaccination practices without modification by sex, age, or race.

Funding: Pfizer

Table. Percentage of Subjects in the Evaluable Immunogenicity Population Achieving ≥4-fold Rise in hSBA Titer and Composite Response* 1 Month After Dose 3 According to Subgroup

	Number of Subjects, n	Percentage of Subjects Achieving ≥4-fold Rise (95% CI)				
		PMB80 (A22)	PMB2001 (A56)	PMB2948 (B24)	PMB2707 (B44)	Composite Response*
Total		84.1 (83.3, 85.0)	92.1 (91.3, 92.8)	81.4 (80.5, 82.3)	81.1 (79.9, 82.1)	83.6 (82.5, 84.7)
Sex						
Male	4153	85.7 (84.5, 86.7)	94.3 (93.3, 95.2)	83.4 (82.2, 84.6)	85.1 (83.6, 86.4)	87.3 (85.9, 88.6)
Female	3873	82.5 (81.2, 83.7)	89.7 (88.3, 90.9)	79.2 (77.8, 80.5)	76.8 (75.1, 78.5)	79.7 (77.9, 81.3)
Age group, y						
10–18	6474	85.0 (84.0, 85.9)	93.0 (92.1, 93.8)	81.9 (80.9, 82.8)	81.6 (80.3, 82.9)	82.7 (81.4, 84.0)
10–14	4290	86.8 (85.7, 87.9)	93.7 (92.5, 94.8)	83.3 (82.1, 84.4)	82.3 (80.6, 84.0)	83.5 (81.8, 85.2)
15–18	2184	81.2 (79.4, 82.9)	92.0 (90.5, 93.4)	79.0 (77.1, 80.8)	80.6 (78.5, 82.6)	81.6 (79.5, 83.6)
19–25	1552	80.9 (78.8, 82.8)	90.0 (88.4, 91.5)	79.5 (77.4, 81.5)	79.9 (77.8, 81.9)	85.5 (83.6, 87.3)
Race						
White	6982	84.2 (83.3, 85.1)	91.7 (90.8, 92.6)	80.6 (79.6, 81.6)	80.7 (79.5, 81.9)	83.9 (82.7, 85.0)
Black	745	82.5 (79.6, 85.2)	95.0 (92.8, 96.8)	85.3 (82.5, 87.8)	82.8 (79.3, 85.9)	80.0 (76.3, 83.4)
Asian	61	91.4 (81.0, 97.1)	90.5 (77.4, 97.3)	93.0 (83.0, 98.1)	76.7 (61.4, 88.2)	82.9 (67.9, 92.8)
Other	238	85.8 (80.6, 90.0)	91.6 (85.5, 95.7)	87.1 (81.9, 91.2)	86.1 (79.2, 91.4)	88.1 (81.3, 93.0)

*Composite response defined as the percentage of subjects achieving an hSBA titer ≥LLOQ for all 4 primary FHbp test strains combined.
FHbp=factor H binding protein; hSBA=serum bactericidal assay using human complement; LLOQ=lower limit of quantification

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

2723. Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Adolescents 10–17 Years of Age

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Session: 277. Vaccines: Bacterial

Saturday, October 5, 2019: 12:15 PM

Background: The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine that contains tetanus toxoid as carrier protein. The vaccine is intended for global use in all age groups (i.e., individuals 6 weeks of age and older). This Phase III study evaluated the immune lot consistency, and safety and immunogenicity of the vaccine when compared with a licensed quadrivalent meningococcal conjugate vaccine in individuals 10–55 years of age.

Methods: A randomized, modified double-blind, multi-center study (NCT02842853) was conducted in the United States. The study evaluated 3344 meningococcal vaccine naïve adolescents and adults, who were randomly assigned to receive either a single dose of one of the three lots of MenACYW-TT conjugate vaccine or single dose of Menactra® [MenACWY-D]. Serum bactericidal assay with human complement (hSBA) and baby rabbit complement (rSBA) was used to measure antibodies against serogroups A, C, W and Y at baseline before vaccination (Day 0) and 30 days post-vaccination. Safety data were collected up to 6 months post-vaccination. Herein we report the performance of MenACYW-TT in adolescents 10 through 17 years of age (n = 1504).

Results: Immune equivalence was demonstrated across all 3 lots of MenACYW-TT conjugate vaccine based on geometric mean titers (GMTs) for all serogroups. Non-inferiority of immune responses, based on percentages of participants achieving hSBA vaccine seroresponse, was demonstrated between MenACYW-TT and MenACWY-D for all four serogroups at Day 30 compared with baseline. The proportions of individuals (10–17 years) with hSBA ≥ 1:8 following MenACYW-TT administration were higher than those after MenACWY-D administration for all four serogroups (A: 96.2% vs. 89.0%; C: 98.5% vs. 74.7%; W: 98.3% vs. 93.7%; Y: 99.1% vs. 94.3%). A similar trend was observed for post vaccination GMTs in adolescent participants. Reactogenicity profiles were comparable across study groups. Most unsolicited adverse events were of grade 1 or grade 2 intensity. No vaccine-related serious adverse events were reported.

Conclusion: MenACYW-TT vaccine was well tolerated and demonstrated a non-inferior immune response compared with the licensed MenACWY-D vaccine when administered as a single dose to meningococcal vaccine naïve adolescents.

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

2724. Safety and Immunogenicity of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Healthy Meningococcal Vaccine-Naïve Children (2–9 Years)

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