

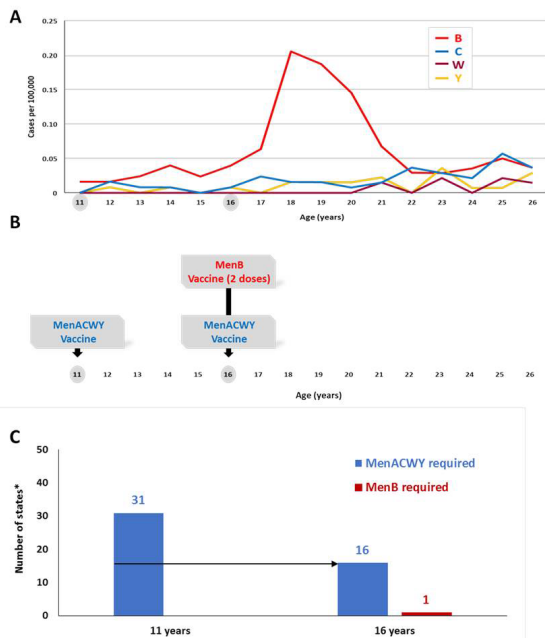
**Table 1. School-attendance State Requirements by Vaccine Class**

	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, MI, MO, NJ, NY, OH, OK, PA, RI, TN, TX, VT, WA	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

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**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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**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)				Composite Response*
		PMB80 (A22)	PMB2001 (A56)	PMB2948 (B24)	PMB2707 (B44)	
<b>Total</b>	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)	
<b>Sex</b>						
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)
<b>Age group, y</b>						
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)
<b>Race</b>						
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

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

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**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<sup>®</sup> [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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**Background:** MenACYW-TT is an investigational quadrivalent meningococcal conjugate vaccine that contains tetanus toxoid as carrier protein. The vaccine is intended for global use in individuals 6 weeks of age and older. We evaluated the safety and immunogenicity of MenACYW-TT compared with a licensed quadrivalent conjugate meningococcal vaccine (MenACWY-CRM [Menveo<sup>®</sup>]) in US children 2–9 years of age.

**Methods:** In a modified double-blind Phase III study (NCT03077438), 1000 children were randomized to receive one dose of either MenACYW-TT vaccine or MenACWY-CRM vaccine. Serum bactericidal assays with human (hSBA) and baby rabbit (rSBA) complement were used to measure antibodies against representative meningococcal serogroup strains at baseline and 30 days after vaccination. Safety data were collected up to 6 months post-vaccination.

**Results:** Non-inferiority of immune responses for all four serogroups, based on percentages of participants achieving hSBA vaccine seroresponse, was demonstrated for MenACYW-TT compared with MenACWY-CRM at Day 30 compared with baseline. The proportions of individuals with hSBA titers  $\geq 1:8$  following MenACYW-TT administration were higher than those after MenACWY-CRM administration for all four serogroups (A: 86.4% vs 79.3%; C: 97.8% vs 67.1%; W: 94.8% vs 86.3%; Y: 98.5% vs 90.8%). Similar results were observed in two age substrata (2 to 5 years and 6 to 9 years). Percentages of participants with post-vaccination rSBA titers  $\geq 1:128$  were comparable between both groups. The safety profiles of MenACYW-TT and MenACWY-CRM were comparable. Reactogenicity at the MenACYW-TT injection site was lower than at the MenACWY-CRM injection site. There were no immediate adverse events (AEs), no AEs leading to study discontinuation, and no vaccine-related serious adverse events reported in the study.

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

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

**2725. Immunogenicity and Safety of a Booster Dose of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) in Adolescents and Adults**

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**Background:** The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine that contains tetanus toxoid as carrier protein. 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 safety and immunogenicity of the vaccine when compared with a licensed quadrivalent meningococcal conjugate vaccine in individuals  $\geq 15$  years of age.

**Methods:** A randomized, modified double-blind study (NCT02752906) was conducted in the United States and Puerto Rico. The study evaluated 810 participants primed with a licensed quadrivalent meningococcal conjugate vaccine (Menactra<sup>®</sup> [MenACWY-D] or MENVEO<sup>®</sup> [MenACWY-CRM]) in the 4 to 10 years prior to enrollment. Participants were randomly assigned to receive either a single booster dose of MenACYW-TT conjugate vaccine or MenACWY-D. Safety data were collected up to 6 months post-vaccination.

**Results:** Non-inferiority of immune response was demonstrated for MenACYW-TT vs. MenACWY-D based on percentages of participants achieving a serum bactericidal assay with human complement (hSBA) seroresponse for serogroups A, C, W, and Y at Day 30 post-vaccination. Post-vaccination hSBA geometric mean titers (GMTs) were higher following administration of MenACYW-TT compared with MenACWY-D for age subgroups  $\geq 15$  to  $< 18$  years and  $\geq 18$  years. Relative to MenACWY-D, post-vaccination hSBA GMTs were higher for all 4 serogroups following administration of MenACYW-TT in participants who received the priming vaccine  $< 7$  years prior to the booster; for participants who received priming vaccine  $\geq 7$  years prior to booster, post-vaccination GMTs were higher for serogroups C, W and Y, and comparable for serogroup A. In MenACWY-CRM-primed subjects, hSBA vaccine seroresponse rates were comparable for all 4 serogroups regardless of the booster vaccine administered. In MenACWY-D-primed subjects, hSBA seroresponse rates following MenACYW-TT booster administration were comparable for serogroups A and Y, and higher for serogroups C and W. Reactogenicity profiles were comparable across study groups.

**Conclusion:** MenACYW-TT conjugate vaccine was immunogenic and well tolerated when administered as a booster dose to individuals  $\geq 15$  years of age.

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

**2726. Meningococcal Vaccination Among Patients Newly Diagnosed at High-Risk for Meningococcal Disease in the United States**

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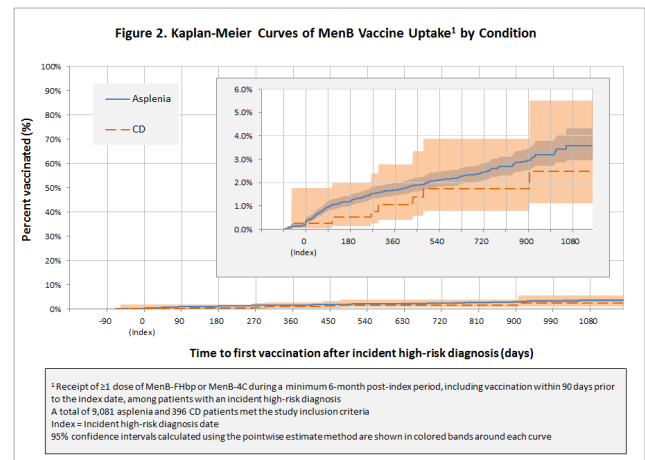
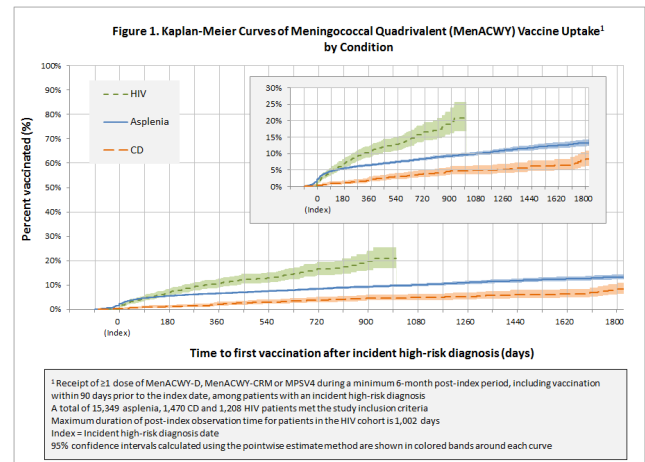
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**Background:** Quadrivalent conjugate and polysaccharide meningococcal vaccines (MenACWY) have been recommended in the United States for patients at high-risk due to functional or anatomic asplenia, complement component deficiency (CD) and human immunodeficiency virus (HIV) infection. Serogroup B vaccines (MenB) are recommended for patients  $\geq 10$  years of age with asplenia or CD. Little is currently known about meningococcal vaccine uptake and time to vaccination among patients with incident high-risk diagnoses.

**Methods:** Patients newly diagnosed (1 inpatient or  $\geq 2$  outpatient medical claims with evidence of the condition  $\geq 30$  days apart) with functional or anatomic asplenia (excluding sickle cell disease), CD or HIV infection were identified in the Optum Research Database. Continuous enrollment for  $\geq 12$  months before and  $\geq 6$  months after the diagnosis date (index date) was required. Patients with evidence of pre-existing conditions were excluded. MenACWY uptake was assessed among patients  $\geq 2$  years of age at index date from January 1, 2010 for asplenia and CD, and January 1, 2016 for HIV infection, through March 31, 2018; and MenB uptake among patients  $\geq 10$  years of age at index date from January 1, 2015 through March 31, 2018. Current Procedural Terminology and National Drug Codes on medical claims were used to capture vaccinations. For each condition, Kaplan-Meier analysis was used to estimate uptake and time to receipt of  $\geq 1$  dose of each vaccine up to 5 years post-index date; vaccinations within 90 days before the index date were also included in calculations.

**Results:** Among asplenia patients, the percentage with receipt of  $\geq 1$  dose of MenACWY at 1, 2.5, and 5 years post-index date was 6.6%, 9.4%, and 13.3%, respectively; for CD patients the corresponding percentages were 2.2%, 4.8%, and 8.3%; and for HIV patients at 1 and 2.5 years post-index date the percentages were 10.8% and 19.8% (Figure 1). Receipt of  $\geq 1$  dose of MenB at 1 and 2.5 years post-index date was 1.7% and 3.1%, respectively, for asplenia patients and 1.1% and 2.5%, respectively, for CD patients (Figure 2).

**Conclusion:** Uptake of meningococcal vaccines in patients newly diagnosed with high-risk conditions is very low and the time to vaccination is long, leaving patients vulnerable to invasive meningococcal disease for extended periods of time.



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