Serogroup B (MenB) is the leading cause of invasive meningococcal disease (IMD) in the United States, including 69% of cases among individuals 16- to 23-year-olds. College students have 3.5 times greater MenB risk vs noncollege individuals, and MenB caused all college IMD outbreaks between 2011 and 2019. For healthy adolescents, the Advisory Committee on Immunization Practices (ACIP) recommends routine MenACWY vaccination at 11 and 16 years and MenB vaccination based on individual clinical decision-making, preferably at 16-18 years (Figure 1A, B). Given the recent shift in disease epidemiology, we investigated whether current state policies also shifted to help protect adolescents against all 5 meningococcal serogroups.

Methods: We researched requirements for meningococcal vaccination using state public health websites and national stakeholder materials (e.g., Immunization Action Coalition and their state chapters). Data as of November 2018 were compiled by vaccinenow.net and state policies were assessed from the CDC's National Immunization Survey-Teen (NIS-Teen) database on state vaccination requirements. State vaccination requirements have helped catalyze MenACWY vaccination and/or vaccine education for school attendance (grades 6–12) and for college individuals, and MenB caused all college IMD outbreaks between 2011 and 2019.

Results: Forty-five states and Washington DC require either meningococcal vaccination and/or vaccine education for school attendance (grades 6–12) and for college attendance. Thirty-one states require a MenACYW primary dose (at 11 years), of which 16 states also require the booster dose at 16 years (Table 1, Figure 1C). One state requires MenB vaccination at 16-18 years. Of the 8 states that experienced college MenB outbreaks between 2013 and February 2019, all require vaccination or education for MenACWY but not MenB (Table 2). These differences in state requirements may undermine the reported adolescent vaccination coverage rates for MenACWY (85% for ≥1 dose, 44% for ≥2 doses) and MenB (14.5% for ≥1 dose of multidose series) vaccines, and additional reasons may be the efficiency of school-based vaccination programs, strength of the 11-year immunization platform, the more recent availability of MenB vs MenACYW vaccines, and disparate ACIP recommendations for these vaccines.

Conclusion: State vaccination requirements have helped catalyze MenACWY vaccine impact. Tailoring new requirements to the current epidemiology can help quell MenB disease and ensure that US adolescents are fully protected against meningococcal disease.

Funding: Pfizer

2721. US States’ Policies for Meningococcal Vaccination vs. Disease Epidemiology
Amit Srivastava, PhD1; Justine Alderfer, PharmD2; 1Vaccine Medical Development, Scientific & Clinical Affairs, Pfizer, Inc. Cambridge Massachusetts; 2Vaccine Medical Development, Scientific & Clinical Affairs, Pfizer, Inc. Collegville Pennsylvania
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Background: Serogroup B (MenB) is the leading cause of invasive meningococcal disease (IMD) cases in the United States, including 69% of cases among individuals 16- to 23-year-olds. College students have 3.5 times greater MenB risk vs noncollege individuals, and MenB caused all college IMD outbreaks between 2011 and 2019. For healthy adolescents, the Advisory Committee on Immunization Practices (ACIP) recommends routine MenACWY vaccination at 11 and 16 years and MenB vaccination based on individual clinical decision-making, preferably at 16-18 years (Figure 1A, B). Given the recent shift in disease epidemiology, we investigated whether current state policies also shifted to help protect adolescents against all 5 meningococcal serogroups.

Methods: We researched requirements for meningococcal vaccination using state public health websites and national stakeholder materials (e.g., Immunization Action Coalition and their state chapters). Data as of November 2018 were compiled by vaccinenow.net and state policies were assessed from the CDC's National Immunization Survey-Teen (NIS-Teen) database on state vaccination requirements. State vaccination requirements have helped catalyze MenACWY vaccination and/or vaccine education for school attendance (grades 6–12) and for college attendance. Thirty-one states require a MenACYW primary dose (at 11 years), of which 16 states also require the booster dose at 16 years (Table 1, Figure 1C). One state requires MenB vaccination at 16-18 years. Of the 8 states that experienced college MenB outbreaks between 2013 and February 2019, all require vaccination or education for MenACWY but not MenB (Table 2). These differences in state requirements may undermine the reported adolescent vaccination coverage rates for MenACWY (85% for ≥1 dose, 44% for ≥2 doses) and MenB (14.5% for ≥1 dose of multidose series) vaccines, and additional reasons may be the efficiency of school-based vaccination programs, strength of the 11-year immunization platform, the more recent availability of MenB vs MenACYW vaccines, and disparate ACIP recommendations for these vaccines.

Conclusion: State vaccination requirements have helped catalyze MenACWY vaccine impact. Tailoring new requirements to the current epidemiology can help quell MenB disease and ensure that US adolescents are fully protected against meningococcal disease.

Funding: Pfizer

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Table 1. School-attendance State Requirements by Vaccine Class

| Vaccine Class | Primary Dose | Dose at 10 Years | Dose at 16 Years |
|---------------|--------------|-----------------|-----------------|
| Teen/College  | 12th Grade   | 11th Grade      | 12th Grade      |
| Elementary    | 8th Grade    | 7th Grade       | 8th Grade       |


table: School-attendance State Requirements by Vaccine Class

| Vaccine Class | Primary Dose | Dose at 10 Years | Dose at 16 Years |
|---------------|--------------|-----------------|-----------------|
| Teen/College  | 12th Grade   | 11th Grade      | 12th Grade      |
| Elementary    | 8th Grade    | 7th Grade       | 8th Grade       |


table: School-attendance State Requirements by Vaccine Class

Table 2. College-attendance State Requirements by Vaccine Class

| Vaccine Class | Pre-school | Kindergarten | Grade 1 | Grade 2 |
|---------------|------------|-------------|---------|---------|
| Elementary    | 7th Grade  | 6th Grade   | 5th Grade| 4th Grade|
| College       | 10th Grade | 9th Grade   | 8th Grade| 7th Grade|


table: College-attendance State Requirements by Vaccine Class

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) 14 meningococcal vaccination platform; (C) Number of states requiring MenACYW and MenB vaccination at ages 11 and 16 years

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

Johannes Beelaar, MD, Paula Pyrani, MD, Jason Maguire, MD, Joseph Eiden, MD, PhD, Paul Palmer, PhD; Roger Amanon, MS, Graham Crowther, MD; John L. Perez, MD; Pfizer Vaccines Clinical Research and Development, New York, New York; Pfizer Vaccines Clinical Research and Development, Pearl River, New York; Pfizer Vaccines Clinical Research and Development, Collegeville, Pennsylvania; Pfizer Vaccines Clinical Research and Development, Collegeville, Pennsylvania; Pfizer Vaccines Clinical Research and Development, Collegeville, Pennsylvania; Pfizer Vaccines Clinical Research and Development, Collegeville, Pennsylvania

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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 ages 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 naive 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 a single dose of Menactra® [MenACWY-D]. Serum bactericidal assay with human complement (hSBA) and 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.

Results: This analysis included 8026 subjects aged 10–25 years (51.7% males, 80.7% Caucasians aged 10–18 years, 87.0% white, 9.3% black, 0.8% Asian, 3.0% other race/stage). One month after dose 3, percentages of subjects achieving ≥ 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 a ≥ 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 marginal 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.

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Disclosures: All authors: No reported disclosures.

Table: Percentage of Subjects in the Pooled Immunogenicity Population Achieving a ≥4-fold Rise in hSBA Titer and Composite Response vs. 1 Month After Dose 3 Funging According to Age and Sex

| Number of Subjects Achieving ≥4-fold Rise in hSBA Titer and Composite Response vs. 1 Month After Dose 3 | Percentage Achieving hSBA Titers ≥ 4-fold Rise vs. Baseline |
|-------------------------------------------------|-------------------------------------------------|
| Sex                                             |                                   |
| Male                                            | 89.3% vs. 89.1%                     |
| Female                                          | 87.6% vs. 87.5%                     |
| Age group                                       |                                   |
| 10–18                                           | 89.3% vs. 89.0%                     |
| 10–24                                           | 89.1% vs. 89.0%                     |
| 15–55                                           | 89.2% vs. 89.0%                     |
| Ethnicity                                       |                                   |
| White                                           | 87.6% vs. 87.5%                     |
| Hispanic                                        | 89.2% vs. 89.0%                     |
| Asian                                           | 87.6% vs. 87.5%                     |

Triphasic: For <4-fold rise, multiple-factor analysis was performed comparing hSBA titer at each level of quantification.

References: All authors: No reported disclosures.

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

James Peterson, MD; James Hedrick, MD; June Pan, PhD; David Neveu, MPH, Emil Jordanov, MD; Mandeep S. Dhingra, MD; J. Lewis Research, Inc., Salt Lake City, Utah; Kentucky Pediatric Adult Research, Bardstown, Kentucky; Sanofi Pasteur, Swiftwater, Pennsylvania

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Background: The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine containing tetanus toxoid as carrier protein. The vaccine is intended for general 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 ages 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 naive 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 a single dose of Menactra® [MenACWY-D]. Serum bactericidal assay with human complement (hSBA) and 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.

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 MenACYW-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 MenACYW-D administration for all four serogroups (A: 96.2% vs. 89.0%; C: 98.5% vs. 93.7%; 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 MenACYW-D vaccine when administered as a single dose to meningococcal vaccine naive 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 5–17 Years of Age

Michael W Simon, MD, Donald Brandon, MD, Shane Christensen, MD; Carmen Baccarini, MD, Emil Jordanov, MD; Mandeep S. Dhingra, MD; Pediatrics, Nicholasville, Kentucky; California Research Foundation, San Diego, California; Lewis Research, Inc., Foothill Family Clinic South, Salt Lake City, Utah.