2719. Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Adults 18–55 Years of Age

James Peterson, MD[1]; James Hedrick, MD[2]; Judy Pan, PhD[3]; David Neveu, MPharm[3]; Emilia Jordanov, MD[3]; Mandeep S. Dhingra, MD[3]; [1]J. Lewis Research, Inc., Salt Lake City, Utah; [2]Kentucky Pediatric/Adult Research, Bardstown, Kentucky; [3]Sanofi Pasteur, Swiftwater, Pennsylvania

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 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 adults 18 through 55 years of age (*n* = 1,807).

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 (18–55 years) with hSBA ≥ 1:8 following MenACYW-TT administration were higher than those after MenACWY-D administration for all four serogroups (A: 93.5% vs. 88.1%; C: 93.5% vs. 77.8%; W: 94.5% vs. 80.2%; Y: 98.6% vs. 81.2%). A similar trend was observed for post vaccination GMTs in adult 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 adults.

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

2720. Potential Public Health Impact of a Pentavalent vaccine targeting *Neisseria meningitidis* Serogroups A, B, C, W, and Y

Sonya J. Snedecor, PhD[1]; Amit K. Sirvastava, PhD[2]; Paul Palmer, PhD[3]; Liping Huang, MD, MA, MS[4]; [1]Pharmerit International, Bethesda, Maryland; [2]Pfizer, Inc., Cambridge, Massachusetts; [3]Pfizer Vaccine Medical Development, Scientific & Clinical Affairs, Collegeville Pennsylvania; [4]Pfizer, Inc., Collegeville, Pennsylvania

Session: 277. Vaccines: Bacterial

Saturday, October 5, 2019: 12:15 PM

Background: In the United States, most invasive meningococcal disease (IMD) is caused by serogroup B, followed by C, W, and Y. ACIP recommends universal vaccination against MenACWY (Category A) and MenB based on individual clinical decision-making (Category B) (Figure 1). In 2017, MenACWY vaccine uptake among adolescents was 44.3% for ≥2 doses and MenB uptake was 14.5% for ≥1 dose of a multi-dose series. A pentavalent vaccine (MenABCWY or Penta) has the potential to simplify immunization schedules and improve uptake to achieve further reductions in IMD. Our objective was to estimate the potential public health impact of Penta.

Methods: Using CDC's enhanced meningococcal disease surveillance data (2015–2017 average), a dynamic transmission model was constructed to estimate the reduction in IMD over 10 years resulting from various implementation strategies including Penta within the existing United States meningococcal vaccination platform. The model assumed that 2-doses of Penta could provide 95% and 85% direct and 25.5% and 0% indirect protection, respectively, against serogroups ACWY and B for 5 years, with 10% relative waning per year. For partial compliance (1 dose Penta only), we assumed protection against ACWY equal to 2-doses but partial protection against B. Future uptake of Penta was assumed higher than 2017 uptake, and sensitivity analyses with lower uptake were conducted.

Results: Based on 2015–2017 epidemiology, the current schedule and uptake of MenACWY and MenB vaccines (total 4 doses) was estimated to avert 149 IMD cases over 10 years. Replacing MenACWY and/or MenB doses with Penta at 11 and/or 16 years could avert more cases, ranging from 172 to 243 (Figure 2). The most beneficial schedule was 2-doses of Penta at 11 years and 1-dose Penta at 16 years. Additional sensitivity analyses indicated that, even assuming current uptake rates, more cases could be prevented by utilizing Penta.

Conclusion: Replacing one or more MenACWY/MenB vaccine doses with Penta could improve prevention of IMD caused by all 5 meningococcal serogroups among the US adolescent population and provide substantial public health benefit while reducing the recommended number of vaccine administrations.

Figure 1. Meningococcal Vaccination Platform – United States

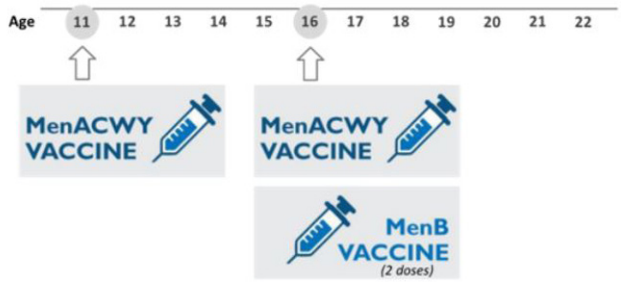
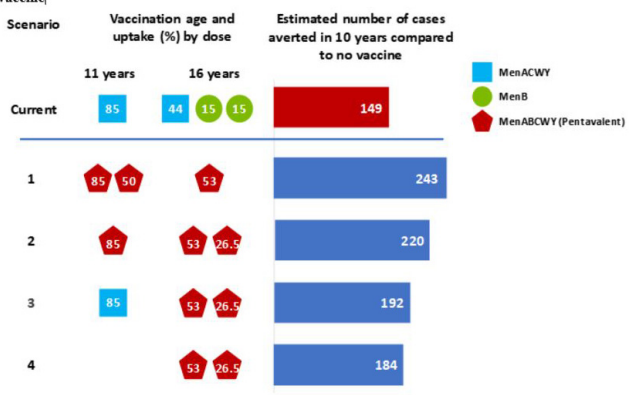


Figure. Estimated number of IMD cases averted over 10 years relative to no vaccination, in scenarios replacing one or more doses of MenACWY with Pentavalent MenABCWY vaccine



Notes:
Assumed uptake rates are based on 2017 Adolescent Vaccination Coverage Report (2017 NIS-Teen Survey) published by CDC: MenACWY ≥1 dose = 85%, assumed uptake at age 11 years; MenACWY ≥2 doses = 44%; MenB ≥1 dose of multidose series = 14.5%, assumed 15% uptake at age 16 years; HPV ≥2 doses = 53%, assumed uptake of 1st dose at age 16 years
At age 11 years, the 2nd of 2-dose series is assumed 70% of 1st dose uptake
At age 16 years, the 2nd of 2-dose series is assumed 50% of 1st dose uptake

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

2721. US States' Policies for Meningococcal Vaccination vs. Disease Epidemiology

Amit Srivastava, PhD[1]; Justine Alderfer, PharmD[2]; [1]Vaccine Medical Development, Scientific & Clinical Affairs, Pfizer, Inc. Cambridge Massachusetts; [2]Vaccine Medical Development, Scientific & Clinical Affairs, Pfizer, Inc. Collegeville Pennsylvania

Session: 277. Vaccines: Bacterial

Saturday, October 5, 2019: 12:15 PM

Background: Serogroup B (MenB) is the leading cause of invasive meningococcal disease (IMD) cases in the United States, including 69% of cases among 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 vaccine type, age, and school/college requirements.

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 MenACWY 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 underlie 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 MenACWY 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