[4]Sanofi Pasteur, Swiftwater, Pennsylvania

Session: 277. Vaccines: Bacterial
Saturday, October 5, 2019: 12:15 PM

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®]) 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 ≥ 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 ≥ 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

James Hedrick, MD[1]; Michael W Simon, MD[2]; Shane Christensen, MD[3]; German Anez, MD[4]; Judy Pan, PhD[4]; Emilia Jordanov, MD[4]; Mandeep S. Dhingra, MD[4]; [1]Kentucky Pediatric / Adult Research, Bardstown, Kentucky; [2]Pediatrics, Nicholasville, Kentucky; [3]J. Lewis Research, Inc. / Foothill Family Clinic South, Salt Lake City, Utah; [4]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. 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 ≥ 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® [MenACWY-D] or MENVEO® [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 an 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 ≥15 to < 18 years and ≥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 ≥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 ≥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

Lindsay Bengtson, PhD, MPH[1]; Gary S. Marshall, MD[2]; Ami R. Buikema, MPH[1]; Eleena Koep, MS[1]; Patricia Novy, PhD[3]; Cosmina Hogea, PhD[4]; [1]Optum, Minnesota; [2]University of Louisville, Louisville, Kentucky; [3]GlaxoSmithKline, Philadelphia, Pennsylvania; [4]GlaxoSmithKline Vaccines, Philadelphia, Pennsylvania

Session: 277. Vaccines: Bacterial
Saturday, October 5, 2019: 12:15 PM

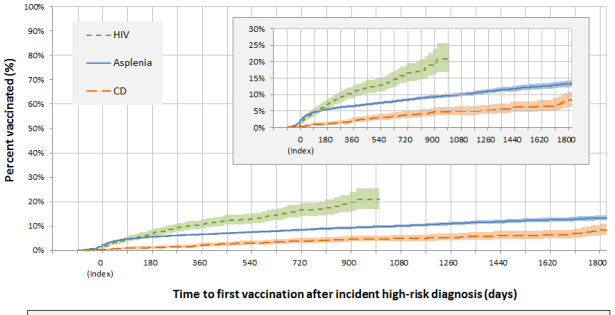
Background: Quadrivalent conjugate and polysaccharide meningococcal vaccines (MenACWY) have been recommended in the United States for patients at high-risk due to functional or anatomic asplenia, complement component deficiency (CD) and human immunodeficiency virus (HIV) infection. Serogroup B vaccines (MenB) are recommended for patients ≥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 ≥2 outpatient medical claims with evidence of the condition ≥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 ≥12 months before and ≥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 ≥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 ≥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 ≥1 dose of each vaccine for 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 ≥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 ≥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).

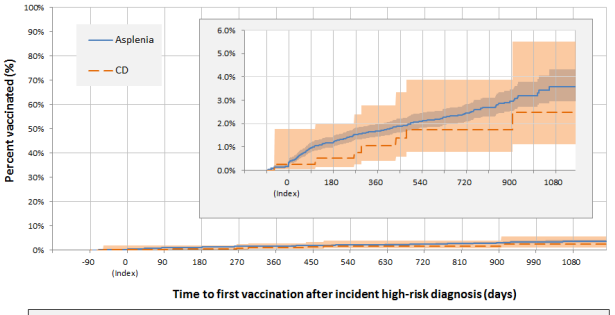
Conclusion: Uptake of meningococcal vaccines in patients newly diagnosed with high-risk conditions is very low and the time to vaccination is long, leaving patients vulnerable to invasive meningococcal disease for extended periods of time.

Figure 1. Kaplan-Meier Curves of Meningococcal Quadrivalent (MenACWY) Vaccine Uptake[1] by Condition



[1] Receipt of ≥1 dose of MenACWY-D, MenACWY-CRM or MPSV4 during a minimum 6-month post-index period, including vaccination within 90 days prior to the index date, among patients with an incident high-risk diagnosis
A total of 15,349 asplenia, 1,470 CD and 1,208 HIV patients met the study inclusion criteria
Maximum duration of post-index observation time for patients in the HIV cohort is 1,002 days
Index = Incident high-risk diagnosis date
95% confidence intervals calculated using the pointwise estimate method are shown in colored bands around each curve

Figure 2. Kaplan-Meier Curves of MenB Vaccine Uptake[1] by Condition



[1] Receipt of ≥1 dose of MenB-FHbp or MenB-4C during a minimum 6-month post-index period, including vaccination within 90 days prior to the index date, among patients with an incident high-risk diagnosis
A total of 9,081 asplenia and 396 CD patients met the study inclusion criteria
Index = Incident high-risk diagnosis date
95% confidence intervals calculated using the pointwise estimate method are shown in colored bands around each curve

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