POSTER ABSTRACTS

1. The Impact of Behavioral Nudges, Communication Training and Assessment and Feedback on Adolescent Vaccination Rates and Parent Satisfaction

Andrea Bradley-Ewing, MPA, MA[1]; Kathy Goggin, PhD[2]; Georgann Meredith, BSN, BS[1]; Brian R. Lee, MPH, PhD[1]; Susan Li, NA[3]; Jason Doctor, PhD[4]; Angela Myers, MD, MPH[5]; [1]Children's Mercy Kansas City, Kansas City, MO; [2]University of Missouri - Kansas City, Kansas City, MO; [3]Vanderbilt University, Nashville, Tennessee; [4]University of Southern California, Calabasas, CA; [5]Children's Mercy Hospital, Kansas City, MO

Abstracts

Session: P-1. Adolescent Vaccines

Background: Effective prevention of HPV is possible, but < 50% of adolescents in the Midwest complete the recommended vaccine series. Strategies to increase HPV vaccination rates have demonstrated efficacy, however widespread implementation of these interventions has not been realized. Behavioral nudges have demonstrated efficacy in increasing uptake of desired heath behaviors among providers (e.g. hand hygiene, judicious antibiotic prescribing). This trial assessed the impact of an assessment and feedback, communication training, and behavioral nudge (i.e. poster-sized vaccine commitment statements) intervention (T^3) on adolescent vaccination rates and parental satisfaction at four Midwestern pediatric practices.

Methods: Practices were randomly assigned to receive either 1) assessment and feedback or 2) T^3 intervention. Providers (n=16) completed surveys regarding vaccine polices and parents of vaccine eligible adolescents (n=230) reported their child's vaccine history and satisfaction with the consultation. Practice- level vaccination rates for Tdap, Meningococcal, and HPV were calculated through billing data queries from an integrated pediatric health network. Vaccination rates and provider/ parental responses were compared by intervention arm.

Results: All practices evidenced increased adolescent vaccine rates, ranging from 0.8% to 3.4% for Meningococcal and 1.3% to 12.1% for Tdap. Three of the four practices had increased HPV vaccination rates (1% to 10%), however there was no statistically significant difference by study arm. Most parents (*M* age 41.34; *SD* 8.05; 85% female, 68% White) indicated their child had previously initiated the HPV vaccine series (61%) and 72% indicated receipt of an HPV vaccine during the study visit. Concerns among HPV vaccine hesitant parents (n=60) included concerns about vaccine safety and necessity. Most (97%) of parents were satisfied with their consultation.

Conclusion: Practices in both intervention groups evidenced an increase in adolescent vaccination rates. While some parents had concerns about HPV vaccine safety and necessity, parents welcomed discussions about HPV vaccine and were satisfied with their provider's communication regardless of their vaccine decisions.

Disclosures: **Brian R. Lee, MPH, PhD**, **Merck** (Grant/Research Support)

2. Understanding Patient Preferences for Meningococcal Serogroup B Vaccines in the United States

Reed Johnson, PhD[1]; Angelyn Fairchild, BA[2]; Dale Whittington, PhD[2]; Jessica Presa, MD[3]; Amit Srivastava, PhD[3]; Liping Huang, MD, MA, MS[3]; [1]Duke University School of Medicine, Durham, North Carolina [2]University of North Carolina at Chapel Hill, Chapel Hill, North Carolina; [3]Pfizer, Inc., Collegeville, Pennsylvania

Session: P-1. Adolescent Vaccines

Background: Among US adolescents, meningococcal disease serogroup B (MenB) causes more cases (62% in 2018) than other 4 serogroups (A, C, W, Y). ACIP's recommendation for shared clinical decision-making calls for individuals to be given the choice of vaccination after consultation with their health care provider. No data are available to-date that formally quantify values and preferences for MenB vaccines. Our objective is to quantify such values.

Methods: Following best-practice standards for stated-preference research, a survey employed a discrete choice experiment (DCE) and contingent-valuation (CV) questions to quantify respondents' trade-off preferences for vaccines that protect against diseases with various levels of severity and incidence, and to estimate the monetary value of receiving additional consultation regarding MenB vaccination with healthcare providers. A total of 2162 respondents (1203 young adults and 1185 parents) completed on-line surveys between August - October 2019.

Results: DCE analysis identified 3 classes of respondents for parents (table 1) and young adults, respectively. Overall, half of the respondents considered vaccines for low-incidence, high-severity diseases such as MenB to be at least as important as vaccines for high-incidence, low- severity diseases.

Respondents were asked to react to a hypothetical situation in which the health care provider did not discuss MenB vaccines with them and found out later. Approximately 70% of respondents expressed reactions ranging from 'Concerned' to 'Angry or Disgusted' (Figure 1). The majority of young adults and parents wanted physician-provided information about protection against low-incidence but serious diseases such as MenB.

The CV analysis estimated that willingness to pay for the MenB vaccine was about US$300 for young adults and over US$400 for parents. However, they often felt entitled to the consultation with their health care provider about the MenB vaccines and were not willing to pay much for it (Figure 2).

Table 1. Parent Class Results (n=1185)

	Class 1	Class 2	Class 3
Class Membership Probability	0.47	0.39	0.13
Attribute Preferences	• Disease outcome is the most important attribute • Duration and cost of a vaccine are least important • Respondents traded logically between Incidence and Outcome	• Disease Incidence is most important • Disease outcome levels are illogically ordered and estimates are imprecise	• Vaccine cost more important than in other classes • Disease incidence and outcome are about equally important • Respondents traded logically between Incidence and Outcome
Significant Covariates	• Not Likely to be older than 55, but not likely to have child age less than 18 • Likely to accept CV vaccine bid • Likely to be concerned about not receiving information from doctor • Likely to say need doctor to help make vaccine decision	• Likely to complete survey in less than 10 minutes • Likely to have child age less than 18 • Likely to be older than 55 with high school education or less • Likely to have had a vaccine discussion with doctor • Likely to accept CV more-time bid	• Likely to reject CV bids for both time and vaccine • Not likely to be concerned about getting information from doctor)

Figure 1. Respondents' Reactions to Health Care Provider Choosing Not to Discuss the MenB Vaccine with Them

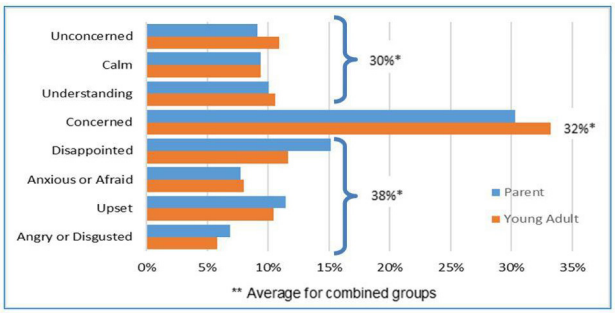
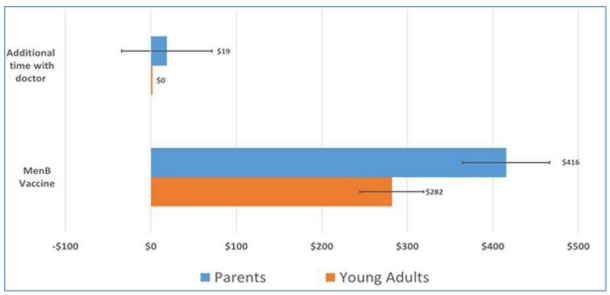


Figure 2. Mean Willingness to Pay for Additional Time with Doctor for Discussing MenB Vaccine and Willingness to Pay for MenB Vaccine



Conclusion: The study found that parents of adolescents and young adults placed significant value on obtaining information about and protection against low-incidence diseases such as MenB that can result in severe long-term disabilities and death.

Disclosures: Reed Johnson, PhD, Pfizer (Research Grant or Support) Angelyn Fairchild, BA, Pfizer (Research Grant or Support) Dale Whittington, PhD, Pfizer (Research Grant or Support) Jessica Presa, MD, Pfizer (Employee) Amit Srivastava, PhD, Pfizer (Employee) Liping Huang, MD, MA, MS, Pfizer (Employee)

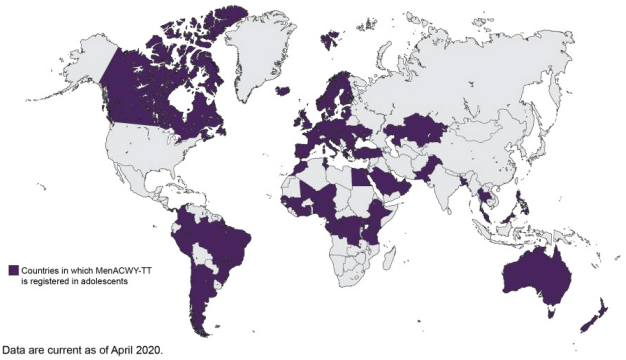
3. A Review of the Clinical Development of MenACWY-TT, a Quadrivalent Meningococcal Vaccine Conjugated to Tetanus Toxoid, in Adolescents

Paula Peyrani, MD[1]; Chris Webber, MD[2]; Cindy Burman, PharmD[1]; Paul Balmer, PhD[1]; John L. Perez, MD, MA[1]; [1]Pfizer Inc, Collegeville, Pennsylvania; [2]Pfizer, Ltd. Hurley UK, Hurley, England, United Kingdom

Session: P-1. Adolescent Vaccines

Background: As a peak in meningococcal disease often occurs during adolescence, meningococcal vaccination programs are available for this age group in various regions across the globe. Quadrivalent meningococcal (MenACWY) conjugate vaccines are being incorporated in an increasing number of programs in response to changing meningococcal serogroup epidemiology. MenACWY-TT (Nimenrix®) is a MenACWY conjugate vaccine available in the European Union and 50 other countries for preventive vaccination of serogroup A, C, W, and Y disease (**Figure 1**). MenACWY-TT is licensed in some countries as a 2-dose primary series in individuals as young as 6 weeks of age, while a single dose may be given to previously unvaccinated individuals ≥ 6 months of age, adolescents, and adults. Here, we provide an overview of the 3 primary and 5 extension studies evaluating the clinical development of MenACWY-TT in adolescents (**Table 1**).

Figure 1. Global Registration Status of MenACWY-TT (Nimenrix®) in Adolescents



Data are current as of April 2020.

Table 1. Pivotal Clinical Studies of MenACWY-TT (Nimenrix®) Supporting Licensure in Adolescents

Phase	Type (identifier)	Design	Subjects		Immunogenicity, %[f] (rSBA titer ≥ 1:8)		Location
			Age, y	n[a]	MenACWY-TT	MenACWY-DT/PS	
2	Primary (NCT01165242)	MenACWY-TT vs MenACWY-DT	10–25	1011	51.0–82.5[g]	39.0–76.3[g]	United States, Canada
	Extension (NCT00715910)	Antibody persistence ≤ 5 y postprimary		312[b]	48.9–94.4	44.4–90.9	United States
2	Primary (NCT00356369)	MenACWY-TT vs MenACWY-PS	11–17[c]	301	99.6–100	100	Saudi Arabia, Philippines
	Extension (NCT00356369	Antibody persistence ≤ 5 y postprimary		284	74.0–92.8	23.7–80.3	Saudi Arabia, Philippines
	Extension (NCT01934140)	Antibody persistence ≤ 10 y postprimary; MenACWY-TT booster		182[d,e]	69.3–91.2; 100	24.4–88.9; 97.7–100	Philippines
3	Primary (NCT00464815)	MenACWY-TT vs MenACWY-PS	11–17	1025	99.7–100	99.6–100	India, Philippines, Taiwan
	Extension (NCT00974363)	Antibody persistence 5 y postprimary		478	86.0–97.5	34.9–93.0	India, Philippines
	Extension (EudraCT 2013-001512-29)	Antibody persistence ≤ 10 y postprimary; MenACWY-TT booster		229	71.6–90.7; 100	43.1–82.4; 98.0–100	Philippines

MenACWY-D=quadrivalent meningococcal vaccine conjugated to diptheria toxin; MenACWY-PS=quadrivalent meningococcal polysaccharide vaccine; MenACWY-TT=quadrivalent meningococcal vaccine conjugated to tetanus toxoid.
[a]The number of subjects who received vaccination unless otherwise specified.
[b]The number of subjects with the longest follow-up period.
[c]Study included subjects aged 11–55 y, but only data for those aged 11–17 y are presented.
[d]Values at year 10 are shown.
[e]207 subjects had immunogenicity assessments for 1 mo postbooster.
[f]Percentage of subjects.
[g]Vaccine response was defined as a serum bactericidal titer of ≥ 1:8 in subjects initially seronegative (titer < 1:4) and as a 4-fold increase in titer in subjects initially seropositive (titer ≥ 1:4).

Methods: Immunogenicity and safety data from these 8 clinical studies are summarized.

Results: Across studies, MenACWY-TT antibody responses against all vaccine serogroups were comparable to those of other MenACWY vaccines 1 month post vaccination (**Table 1**). Antibody responses to MenACWY-TT persisted for up to 10 years in those vaccinated during adolescence. A MenACWY-TT booster given 10 years after primary meningococcal vaccination in early childhood or adolescence elicited robust antibody responses. MenACWY-TT had an acceptable safety profile, with reactogenicity events most commonly reported. Reactogenicity profiles with MenACWY-TT booster were similar to those seen after primary MenACWY-TT.

Conclusion: The MenACWY-TT clinical study program demonstrated the immunogenicity and safety of primary and booster dosing in adolescents. Immune responses persisted through 10 years after primary vaccination.

Funding: Pfizer.

Disclosures: Paula Peyrani, MD, Pfizer Inc (Employee, Shareholder) Chris Webber, MD, Pfizer Inc (Employee, Shareholder) Cindy Burman, PharmD, Pfizer Inc (Employee, Shareholder) Paul Balmer, PhD, Pfizer Inc (Employee, Shareholder) John L. Perez, MD, MA, Pfizer Inc (Employee, Shareholder)

4. MenACWY-TT Long-Term Antibody Persistence Following Adolescent Vaccination and Evaluation of a Booster Dose: A Review of Clinical Data

Paula Peyrani, MD[1]; Chris Webber, MD[2]; Cindy Burman, PharmD[1]; Paul Balmer, PhD[1]; John L. Perez, MD, MA[1]; [1]Pfizer Inc, Collegeville, Pennsylvania; [2]Pfizer, Ltd. Hurley UK, Hurley, England, United Kingdom

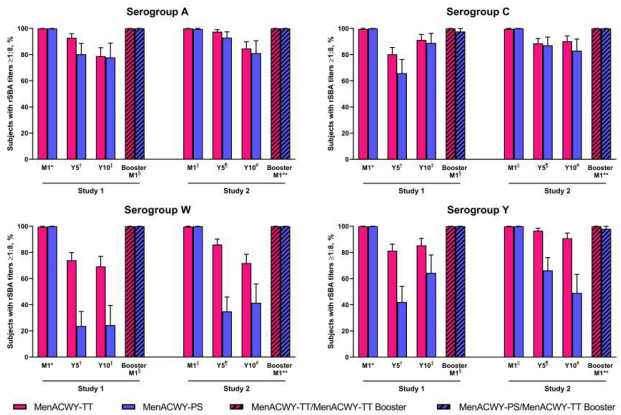
Session: P-1. Adolescent Vaccines

Background: A peak in meningococcal carriage and invasive meningococcal disease (IMD) occurs during adolescence and young adulthood. In the United States, preventive vaccination with a quadrivalent meningococcal (MenACWY) conjugate vaccine is recommended at age 11–12 years, with a booster dose given at age 16 years. MenACWY-TT (Nimenrix®), a MenACWY tetanus toxoid conjugate vaccine, was first licensed in 2012 and is available in the European Union and 50 other countries. Immune responses to other MenACWY conjugate vaccines decline over several years following vaccination. Here, we review 2 recent studies evaluating the long-term persistence of MenACWY-TT immune responses in adolescents as well as safety and immunogenicity of a booster dose given 10 years after primary vaccination.

Methods: Both studies (ClinicalTrials.gov NCT01934140, NCT03189745) were extensions of phase 2 or 3 studies of subjects 11–17 years of age given a single dose of MenACWY-TT or MenACWY polysaccharide vaccine (MenACWY-PS). Immune responses through 10 years after primary vaccination and after a Year 10 MenACWY-TT booster dose were measured by serum bactericidal antibody assays using baby rabbit complement (rSBA). Specific endpoints included percentages of subjects with rSBA titers ≥1:8 and ≥1:128 and geometric mean titers (GMTs). Booster dose safety and tolerability were also evaluated.

Results: In both studies, the percentages of subjects with rSBA titers ≥1:8 through 10 years postvaccination were generally higher or similar among MenACWY-TT (69.3%–91.2% at Year 10; n=137–163) compared with MenACWY-PS (24.4%–88.9%; n=45–53) recipients for all 4 serogroups (**Figure**); similar results were observed for GMTs (146.0–446.9 vs 12.9–191.0 at Year 10). One month after a MenACWY-TT booster dose, 97.7%–100% of subjects across groups had titers ≥1:8 (**Figure**), and GMTs were markedly higher than prebooster values. No new safety signals were identified following the booster dose.

Figure 1. Subjects in each of the 2 studies with rSBA titers ≥1:8 before and at 1 month, 5 years, and 10 years after primary vaccination with MenACWY-TT or MenACWY-PS at 11–17 years of age and 1 month after booster vaccination with MenACWY-TT at 10 years following primary vaccination.



95% CIs are indicated by error bars.
*MenACWY-TT, n=214–224; MenACWY-PS, n=74–76; [†]MenACWY-TT, n=208; MenACWY-PS, n=76; [‡]MenACWY-TT, n=137; MenACWY-PS, n=45; [§]MenACWY-TT, n=133; MenACWY-PS, n=44; [‖]MenACWY-TT, n=752–759; MenACWY-PS, n=252; [¶]MenACWY-TT, n=236; MenACWY-PS, n=85–86; [#]MenACWY-TT, n=163; MenACWY-PS, n=53; **MenACWY-TT, n=162; MenACWY-PS, n=51.
MenACWY-PS=quadrivalent meningococcal polysaccharide vaccine; MenACWY-TT=quadrivalent meningococcal tetanus toxoid conjugate vaccine; rSBA=serum bactericidal antibody assay using baby rabbit complement.

Conclusion: Functional antibodies for all 4 serogroups persisted through 10 years after MenACWY-TT adolescent vaccination, suggesting that this vaccine may help prevent IMD throughout the lengthy risk period in this group. A MenACWY-TT booster dose may further extend protection regardless of the primary vaccine received.

Funded by Pfizer.

Disclosures: Paula Peyrani, MD, Pfizer Inc (Employee, Shareholder) Chris Webber, MD, Pfizer Inc (Employee, Shareholder) Cindy Burman, PharmD, Pfizer Inc (Employee, Shareholder) Paul Balmer, PhD, Pfizer Inc (Employee, Shareholder) John L. Perez, MD, MA, Pfizer Inc (Employee, Shareholder)

5. Observational Study of Routine Use of 9-Valent Human Papillomavirus Vaccine: Safe in More Than 140,000 Individuals

John Hansen, MPH[1]; Arnold Yee, MBA[1]; Ned Lewis, MPH[1]; Se Li, PhD[2]; Christine Velicer, PhD[2]; Patricia Saddier, MD, PhD[2]; Nicola P. Klein, MD, PhD[3]; [1]Kaiser Permanente Northern California, Oakland, CA; [2]Merck & Co., Inc., Kenilworth, New Jersey [3]Kaiser Permanente Vaccine Study Center, Oakland, California, United States, Oakland, California

Session: P-1. Adolescent Vaccines

Background: Nine-valent human papillomavirus (HPV) vaccine (9vHPV vaccine, Gardasil®9) was licensed in the US in Dec-2014. Using a self-controlled risk interval design, we conducted a post-licensure retrospective cohort study within Kaiser Permanente in Northern California (KPNC) to assess 9vHPV safety following routine administration.

Methods: We included KPNC members 9-years or older who received 9vHPV as their first dose of HPV vaccine between Oct-2015 and Sep-2017. Post-vaccination emergency and hospitalization events were compared during risk intervals (days 1–60 and 0–14) with later self-comparison intervals using conditional logistic regression, following all 9vHPV vaccine doses combined, and by dose. We investigated significant