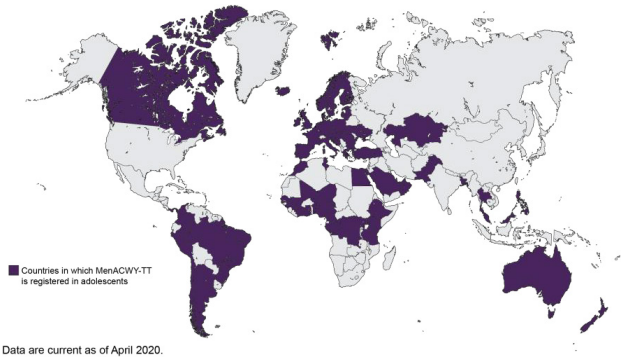
Figure 1. Global Registration Status of MenACWY-TT (Nimenrix®) in Adolescents



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

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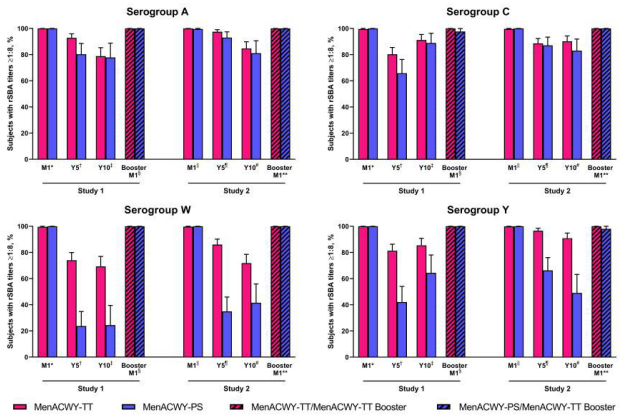
Session: P-1. Adolescent Vaccines

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

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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