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.

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.

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

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

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Background: Nine-valent human papillomavirus (HPV) vaccine (9vHPV vaccine, Gardasil®) 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 vaccine safety following routine administration.

Methods: We included KPNC members 9 years or older who received 9vHPV vaccine 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
6. Pentavalent Meningococcal (MenABCWY) Vaccine is Safe and Well Tolerated With Immunogenicity Noninferior to Coadministered MenB-FHbp and MenACWY-CRM in a Phase 2 Study of Healthy Adolescents and Young Adults

Methods:
In this ongoing, randomized, controlled, observer-blinded, multi-center study (NCT03135834), MenB vaccine-naive and MenACY-NAF-vaccinated healthy 10–25-year-olds were randomized 1:2 to MenABCWY (Month 0.6) or MenB-FHbp (Month 0.6) and MenACWY-CRM (Month 0). Immune responses were measured by serum bactericidal activity assays with human complement (hsBA) against serogroup B A, C, W and Y strains and 4 diverse, vaccine-heterologous MenB strains. Endpoints included percentages of subjects achieving ≥4-fold rises against each of the 4 MenB strains (75.8–94.7% vs 67.4–95.0%) and titters reaching at least the lower limit of quantification against all 4 strains combined (79.9% vs 74.3%; Figure 1A). MenACWY was noninferior to MenB-FHbp for all 5 endpoints. MenACWY was also noninferior to a single MenACWY-CRM dose with 75.5–96.9% and 93.0–97.4% of MenACWY recipients after dose 1 or 2, respectively, achieving ≥4-fold rises against serogroup A, C, W and Y depending on prior MenACWY experience (Figure 1B). Local reactions and systemic events after MenACWY or MenB-FHbp were similarly frequent, mostly mild/moderate in severity (Figure 2), and unaffected by MenACY experience.