findings by assessing post-vaccination timing and medical record reviews. We evaluated and reviewed medical records for all day 0 allergic reaction and syncope events, and all deaths during the study. An independent Safety Review Committee reviewed potential safety signals.

Results: We studied 140,628 9vHPV-vaccinated individuals, including 69,027 (49%) who received 2 doses and 29,901 (21%) 3 doses, totaling 239,556 doses. Eight categories were significantly increased in at least one analysis (Table). On review, most findings were previously known, preceded vaccination, or were better explained by other medical history. Some day 0 allergic reactions and syncope were potentially related to vaccination. None of the 20 deaths were considered related to 9vHPV.

Table. Elevated diagnosis categories comparing risk and self-comparison intervals.

Diagnosis Categories	ORs (95% CI)
Diabetes mellitus	1.66 (1.01, 2.74)
Delirium	NE (1.11, NE)
Nervous system disorders^{+2}	1.33 (1.02, 1.72)
Digestive disorders^{+4}	1.21 (1.03, 1.41)
Male genital disease	1.60 (1.04, 2.46)
Skin disorders^{+1}	1.88 (1.00, 3.53)
Congenital anomalies, nervous system	5.01 (1.10, 22.83)
Symptoms, ill-defined^{+1}	1.36 (1.13, 1.64)

$^{+n}$ indicates number of elevated sub-categories, for a total of 16 categories. NE: not estimable.

Conclusion: This large study of individuals who received only 9vHPV vaccine did not identify any new safety events related to 9vHPV administration and provides reassuring evidence of the favorable safety profile of the 9vHPV vaccine.

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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

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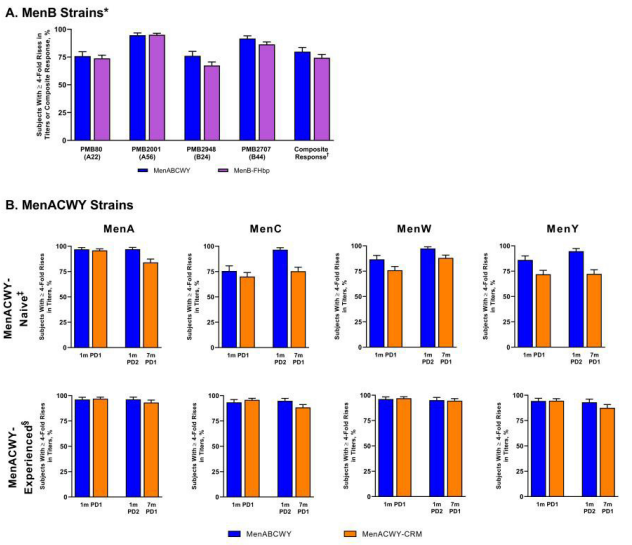
Background: Meningococcal serogroups A, B, C, W and Y cause nearly all meningococcal disease globally. Vaccination is complicated by different dosing recommendations for serogroup B (MenB) and quadrivalent (MenACWY) vaccines, which could be solved with a single pentavalent vaccine. This study in adolescents and young adults evaluated a new pentavalent MenABCWY vaccine that combines 2 licensed vaccines, MenB-FHbp (Trumenba®; bivalent rLP2086) and MenACWY-TT (Nimenrix®), into a single vaccine.

Methods: In this ongoing, randomized, controlled, observer-blinded, multicenter study (NCT03135834), MenB vaccine-naive and MenACWY-naive or -experienced 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 A, C, W and Y strains and 4 diverse, vaccine-heterologous MenB strains. Endpoints included percentages of subjects achieving ≥ 4-fold rises in titers from baseline. Noninferiority of immune responses was assessed at the 10% margin (95% CI lower limit > −10%). Safety was assessed.

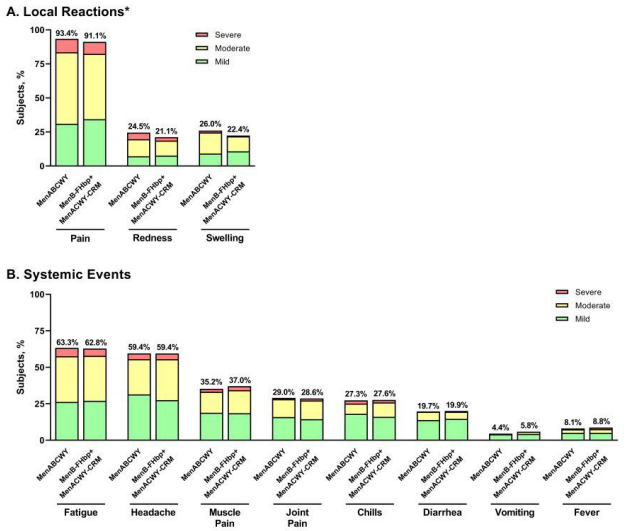
Results: Following dose 2, high percentages of MenABCWY (n=543) and MenB-FHbp (n=1057) recipients achieved ≥ 4-fold rises against each of the 4 MenB strains (75.8–94.7% vs 67.4–95.0%) and titers reaching at least the lower limit of quantification against all 4 strains combined (79.9% vs 74.3%; **Figure 1A**). MenABCWY was noninferior to MenB-FHbp for all 5 endpoints. MenABCWY was also noninferior to a single MenACWY-CRM dose with 75.5–96.9% and 93.0–97.4% of MenABCWY 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 MenABCWY or MenB-FHbp were similarly frequent, mostly mild/moderate in severity (**Figure 2**), and unaffected by MenACWY experience.

Figure 1. Immune Responses as Measured in hSBA to (A) MenB Test Strains at 1 Month After Dose 2 and (B) MenA, MenC, MenW, and MenY Test Strains at 1 Month After Doses 1 and 2



Error bars represent 95% CIs. MenB strains note FHbp variants in parentheses.
*MenABCWY, n=418–432; MenB-FHbp, n=814–850.
†Composite response=hSBA titer ≥LLOQ for all 4 MenB test strains.
‡MenABCWY, n=227–262; MenACWY-CRM, n=446–506.
§MenABCWY, n=187–257; MenACWY-CRM, n=370–495.
hSBA=serum bactericidal activity with human complement; MenA=meningococcal serogroup A; LLOQ=lower limit of quantitation; m=month; MenABCWY=pentavalent serogroups A, B, C, W, Y vaccine; MenACWY-CRM=Menveo®, quadrivalent meningococcal CRM vaccine; MenB=meningococcal serogroup B; MenB-FHbp=Trumenba®, bivalent rLP2086; MenC=meningococcal serogroup C; MenW=meningococcal serogroup W; MenY=meningococcal serogroup Y; PD=postdose.

Figure 2. (A) Local Reactions and (B) Systemic Events Reported Within 7 Days After Any Dose



MenABCWY, n=542; MenB-FHbp+MenACWY-CRM, n=1050.
*At the MenABCWY/MenB-FHbp injection site.
MenABCWY=pentavalent serogroups A, B, C, W, Y vaccine; MenACWY-CRM=Menveo®, quadrivalent meningococcal CRM vaccine; MenB-FHbp=Trumenba®, bivalent rLP2086.

Conclusion: MenABCWY 4-fold immune responses from baseline were robust and noninferior to MenB-FHbp and MenACWY-CRM administered separately. Vaccination was safe and well tolerated. The favorable benefit-risk profile supports further MenABCWY development as a simplified alternative to current meningococcal vaccination practices. Funded by Pfizer.

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