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Background. The first quadrivalent meningococcal conjugate vaccine (MenACWY-D) was recommended for use in adolescents in 2005. Soon after, case reports of Guillain-Barre syndrome (GBS) following vaccination prompted subsequent studies, with a meta-analysis concluding that the attributable risk of GBS after MenACWY-D is unlikely to exceed 1 case per million vaccinations. We conducted a retrospective cohort study in the Vaccine Safety Datalink to assess the risk of 10 outcomes, including GBS, following MenACWY-D.

Methods. We included adolescents (aged 11–18 years) vaccinated with MenACWY-D during the years 2005–2014. We identified pre-specified outcomes using ICD-9 (International Classification of Disease, version 9) codes. We used automated data only for Bell's palsy, fever, seizure and syncope, and we confirmed incident cases by medical record review for acute disseminated encephalomyelitis (ADEM), acute transverse myelitis (ATM), anaphylaxis, chronic inflammatory demyelinating polyneuropathy (CIDP), GBS and Henoch-Schönlein purpura (HSP). We used a self-controlled risk interval design to estimate relative risk (RR).

Results. Following 1.4 million doses of MenACWY-D, we detected increased risks for fever in the 1–6 days following vaccination (RR 1.5, 95% confidence interval [CI] 1.3–1.7) and syncope on the day of vaccination (RR 5.8, 95% CI 4.1–8.3), but not for seizures (RR 1.1, 95% CI 0.7–1.9) or Bell's palsy (RR 1.1, 95% CI 0.8–1.5). We detected no cases in the post-vaccination risk intervals for CIDP, ADEM or ATM. We detected few cases of the other outcomes resulting in relatively unstable RR estimates: anaphylaxis (RR 1.9, 95% CI 0.5–7.1), GBS (RR 2.5, 95% CI 0.6–10.0) and HSP (RR 1.6, 95% CI 0.7–3.3). We estimated that the attributable risk of GBS was 1.5 cases per million vaccinations (upper bound of one-sided 95% CI, 4.9).

Conclusion. In a large retrospective cohort, we detected increased risks for syncope and fever, but not seizures or Bell's palsy, following vaccination with MenACWY-D. Other outcomes were rare. Our findings, consistent with previous studies, suggest that the increased risk of GBS, if any, is likely small (<5 excess cases of GBS per million vaccinations).

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2462. Immunogenicity and Safety of a Quadrivalent Meningococcal Conjugate Vaccine (MenACYW-TT) Administered in Individuals 56 Years of Age and Older

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Background. The MenACYW-TT conjugate vaccine is a quadrivalent meningococcal vaccine candidate intended for global use in all age groups. This Phase III study evaluated the safety and immunogenicity of the vaccine when compared with a licensed quadrivalent meningococcal polysaccharide vaccine (MPSV4) in adults ≥56 years of age.

Methods. A randomized, modified double-blind, multicenter study (NCT02842866) was conducted in 907 healthy adults in the United States. Participants were randomized to receive a single dose of either MenACYW-TT conjugate vaccine or MPSV4, stratified according to age into 2 subsets: 56 to 64 and ≥65 years. Descriptive analyses were also planned for age subsets 65–74 years and ≥75 years. Serum bactericidal assay with human (hSBA) and baby rabbit (rSBA) complement was used to measure antibodies against serogroups A, C, Y, and W test strains at baseline and 30 days after vaccination. Safety data were collected up to six months post-vaccination.

Results. Non-inferiority of immune responses was demonstrated between MenACYW-TT conjugate vaccine and MPSV4 based on percentages of subjects achieving hSBA vaccine seroresponse for serogroups A, C, Y, and W at Day 30 compared with baseline. The proportions of individuals with hSBA ≥ 1:8 obtained after MenACYW-TT conjugate vaccine were higher than those after MPSV4 for all four serogroups (A: 89.4% vs. 84.2%; C: 90.1% vs. 70.9%; W: 77.4% vs. 63.0%; Y: 91.7% vs. 67.7%). Overall, the results were similar in the three age substrata. Percentages of participants with post vaccination rSBA ≥ 1:128 were numerically higher for all serogroups in subjects vaccinated with MenACYW-TT conjugate vaccine. A difference in the local reactogenicity profiles was observed between the two vaccine groups, possibly influenced by the different routes of administration. Most unsolicited adverse events were of Grade 1 or Grade 2 intensity. No vaccine related serious adverse events were reported.

Conclusion. MenACYW conjugate vaccine was immunogenic and well tolerated when administered to individuals ≥56 years of age. Such a vaccine will offer an alternative for the prevention of invasive meningococcal disease in areas of the world where only polysaccharide vaccines are currently available for immunization of older adults.

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2463. Post-licensure Surveillance of 9-Valent Human Papillomavirus Vaccine (9vHPV) in the Vaccine Adverse Event Reporting System (VAERS), United States, 2014–2017

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Background. 9-valent human papillomavirus vaccine (9vHPV) was licensed in December 2014 and recommended by the Advisory Committee on Immunization Practices (ACIP) in February 2015. 9vHPV is FDA-approved for females and males aged 9–26 years; ACIP recommends routine vaccination at 11–12 years and through age 26 for women and 21 for males. About 29 million doses of 9vHPV were distributed in the United States through the end of 2017. We analyzed the first 3 years of US post-licensure safety data in the Vaccine Adverse Event Reporting System (VAERS).

Methods. We searched VAERS, a spontaneous reporting system, for US reports of adverse events (AEs) following 9vHPV from December 1, 2014 to December 31, 2017. We conducted descriptive analysis of reports and assessed the most common signs and symptoms of AEs. Physicians reviewed reports and available medical records for reports classified as serious (death, life-threatening illness, hospitalization, prolongation of hospitalization and permanent disability) and for selected pre-specified conditions of interest.

Results. VAERS received 7,244 reports following 9vHPV; 186 (2.6%) were classified as serious. In 5,411 (74.7%), 9vHPV was administered alone. The most frequently reported symptoms were dizziness (579; 8.0%), syncope (517; 7.1%), headache (418; 5.8%), nausea (361; 5.0%), and injection site pain (324; 4.5%). Median time from vaccination to symptom onset was <1 day (range 0–751 days). There were 7 (0.1%) death reports; 2 verified from autopsy report, death certificate, and/or medical records (causes of death were cardiac arrest and cerebellar aneurysm) and 5 "hearsay" reports with no verifiable medical information. Reports of selected pre-specified conditions of interest included anaphylaxis (9; 0.1%), Guillain–Barré syndrome (8; 0.1%), postural orthostatic tachycardia syndrome (17; 0.2%), primary ovarian insufficiency (3; <0.1%), and complex regional pain syndrome (1; <0.1%). No unusual clustering around onset interval was observed.

Conclusion. In our VAERS review, the safety profile of 9vHPV was consistent with that observed from pre-licensure clinical trials and from post-licensure safety monitoring of other HPV vaccines. We did not observe any new safety signals or unexpected patterns of AEs.

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2464. A Significant Portion of College Students Are Not Aware of HPV Disease and HPV Vaccine Recommendations

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Background. Although HPV vaccination has been shown to be very effective in preventing genital warts and cancers caused by the vaccine strains, immunization rates are low, especially among males and certain ethnic groups. ACIP has recommended that the HPV vaccine be administered to females through age 26 and males through age 21 (26 in MSM). Therefore, there is a significant amount of time for catch up. We assessed college students' awareness of HPV disease and ACIP-HPV vaccine recommendations in Los Angeles County.

Methods. A 31-question survey was developed and IRB approved (WIRB No 1920852-43973015). CSULB Health Sciences students were trained on HPV disease and prevention, and they administered the survey in-person to other students at various locations on campus and recorded the data.

Results. One hundred eighty individuals were surveyed from February to April 2018. The average age of the respondents was 21 ± 2 years. The majority (110 out of 180; 61.1%) of the respondents were female. 75 out of 180 (41.7%) respondents were Latino/Hispanic, 62 out of 180 (34.4%) were Caucasian, 30 out of 180 (16.7%) were Asian