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Safety Profile of the 9-Valent HPV Vaccine: A Combined Analysis of 7 Phase III Clinical Trials.

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Abstract

OBJECTIVES: The overall safety profile of the 9-valent human papillomavirus (9vHPV) vaccine was evaluated across 7 Phase III studies, conducted in males and females (nonpregnant at entry), 9 to 26 years of age.

METHODS: Vaccination was administered as a 3-dose regimen at day 1, and months 2 and 6. More than 15 000 subjects received ≥1 dose of 9vHPV vaccine. In 2 of the studies, >7000 control subjects received ≥1 dose of quadrivalent HPV (qHPV) vaccine. Serious and nonserious adverse events (AEs) and new medical conditions were recorded throughout the study. Subjects testing positive for pregnancy at day 1 were not vaccinated; those who became pregnant after day 1 were discontinued from further vaccination until resolution of the pregnancy. Pregnancies detected after study start (n = 2950) were followed to outcome.

RESULTS: The most common AEs (≥5%) experienced by 9vHPV vaccine recipients were injection-site AEs (pain, swelling, erythema) and vaccine-related systemic AEs (headache, pyrexia). Injection-site AEs were more common in 9vHPV vaccine than qHPV vaccine recipients; most were mild-to-moderate in intensity. Discontinuations and vaccine-related serious AEs were rare (0.1% and <0.1%, respectively). Seven deaths were reported; none were considered vaccine related. The proportions of pregnancies with adverse outcome were within ranges reported in the general population.

CONCLUSIONS: The 9vHPV vaccine was generally well tolerated in subjects aged 9 to 26 years with an AE profile similar to that of the qHPV vaccine; injection-site AEs were more common with 9vHPV vaccine. Its additional coverage and safety profile support widespread 9vHPV vaccination.