HPV Vaccines The development of HPV vaccines effective in preventing infection and HPV-associated disease represents a major development in the past decade. The vaccines use virus-like particles (VLPs) that consist of the HPV L1 major capsid protein. The L1 protein self-assembles into VLPs when expressed in eukaryotic cells (i.e., yeast or insect cells). These VLPs contain the same epitopes as actual HPV virions. However, they do not contain genetic material and therefore cannot transmit infection. The immunogenicity of the HPV vaccines relies on development of conformational neutralizing antibodies directed toward epitopes displayed on viral capsids.

Several large vaccine trials have been completed and demonstrate the high degree of safety and efficacy of HPV vaccines. There have been three HPV vaccines developed, tested, and U.S. Food and Drug Administration (FDA) approved, as described below.

BIVALENT VACCINE (CERVARIX) The bivalent HPV vaccine contains L1 VLPs of HPV types 16 and 18 and is marketed under the name of Cervarix (GlaxoSmithKline). This vaccine was tested in 18,644 women 15−25 years of age residing in the United States, South America, Europe, and Asia. It is administered by intramuscular injection three times (months 0, 1, and 6). The primary endpoints of the study included vaccine efficacy against persistent infections with HPV types 16 and 18. Investigators also assessed vaccine efficacy against CIN grade 2 or higher due to HPV 16 and 18 in women who had no evidence of HPV 16 or 18 infection at baseline. Vaccine efficacy related to HPV 16 or HPV 18 was 94.9% (95% confidence interval [CI], 87.7–98.4%) against CIN 2 or worse; 91.7% (95% CI, 66.6–99.1%) against CIN 3 or worse; and 100% (95% CI, –8.6–100%) against adenocarcinoma in situ (AIS). Adverse events associated with the bivalent vaccine were evaluated in phase 3 trials in a subset of 3077 women who received vaccine and 3080 women who received hepatitis A vaccine. Injection-site adverse events (pain, redness, and swelling) and systemic adverse events (fatigue, headache, and myalgia) were reported more frequently in the HPV vaccine group than in the control group. Serious adverse events, new-onset chronic disease, or medically significant conditions