

result indicated a very high safety profile for the vaccine. A recent safety review by the FDA and the Centers for Disease Control and Prevention (CDC) examined events related to Gardasil that had been reported to the Vaccine Adverse Events Reporting System (VAERS). The adverse events were consistent with what was seen in previous safety studies of the vaccine. Of note, rates of syncope and venous thrombotic events were higher with Gardasil than those usually observed with other vaccines.

The quadrivalent HPV vaccine is approved for (1) vaccination of females ages 9–26 years of age to prevent genital warts and cervical cancer caused by HPV types 6, 11, 16, and 18; (2) vaccination of the same population to prevent precancerous or dysplastic lesions, including cervical AIS, CIN 2/3, VIN 2/3, VaIN 2/3, and CIN 1; (3) vaccination of males 9–26 years of age to prevent genital warts caused by HPV types 6 and 11; and (4) vaccination of people ages 9–26 years to prevent anal cancer and associated precancerous lesions due to HPV types 6, 11, 16, and 18. While the duration of protection has not been established, no evidence of waning protection has been found after a three-dose series of the quadrivalent HPV vaccine, even after 10 years of follow-up from clinical trials. The quadrivalent HPV vaccine is no longer available in the United States but is still available in many other countries, although production is not likely to continue in the future.

NINE-VALENT VACCINE (GARDASIL-9) In 2014, the FDA approved a new nine-valent L1 VLP vaccine. The nine-valent vaccine is marketed under the name Gardasil-9 (Merck). It is administered intramuscularly three times (months 0, 2, and 6). The nine-valent vaccine targets HPV types 6, 11, 16, and 18 (the types also targeted by the quadrivalent HPV vaccine) as well as five additional oncogenic HPV types (31, 33, 45, 52, and 58). HPV types 16 and 18 together cause up to 80% of all cervical cancers worldwide, and worldwide data show that HPV types 31, 33, 35, 45, 52, and 58 are the next most frequently detected types in invasive cervical cancers. Mathematical models estimate that the level of protection conferred by the nine-valent HPV vaccine against all HPV-associated squamous cell cancers worldwide could be raised to 90%.