

Epidemiologic Evidence of HPV Vaccine Effectiveness and Safety

What's Known

High-quality studies have shown that HPV vaccination prevents precancers and genital warts and is safe. Clinical trials established the efficacy and safety evidence of HPV vaccination, leading to recommendation for routine provision of HPV vaccine to adolescents ages 11-12,¹⁻⁴ recommendation of 9-valent HPV vaccine,⁵ and a reduced dosing schedule for younger adolescents.⁶ Post-licensure safety studies with millions of patients across at least 6 countries continue to document no increased risk of autoimmune or neurologic conditions following HPV vaccination.^{7,8}

What's New

Long-term observational studies continue to confirm the effectiveness and safety of HPV vaccine.

HPV vaccine effectiveness

- Vaccine-type HPV infections have decreased by 78% for US women ages 20-24 and 38% for ages 25-29.¹¹ These declines also occurred in unvaccinated women, offering evidence of community protection (i.e., herd immunity) from HPV vaccination.
- Trials show long-term prevention of HPV pre-cancers and cancers, with only 1 breakthrough case (low-grade CIN1) over 12 years in a cohort of over 2,000 women,¹² and 0 breakthrough cases of HPV-related cancers over 65,656 person-years of follow-up for 9,529 vaccinated females compared to 10 cases of HPV-related cancers among 124,245 person-years of follow-up for 17,838 non-vaccinated females.¹³
- The average annual decrease in high-grade cervical pre-cancers was 24% for women ages 18-20 and 10% for women ages 21-24 who received cervical screening in an active surveillance area in the US between 2008 and 2013.¹⁴
- Population-level cervical cancer incidence, estimated from the Surveillance, Epidemiology, and End Results (SEER) registry, decreased in young women by 29% (ages 15-24) and 13% (ages 25-34) between 2003-2006 (before the vaccine was available) and 2011-2014 (after US licensure).¹⁵
- Preliminary estimates from population-based observational studies¹⁶ and post-hoc analyses of clinical trial data^{17,18} indicate that a single dose of HPV vaccine may be effective for prevention of cervical cancer.
- Systematic reviews^{9,10} of HPV vaccine effectiveness have highlighted protection against HPV-related pre-cancers and cancers, with a recent meta-analysis¹⁰ estimating 83% reduction in HPV-16 and -18 infection in 13-19-year-olds and 66% reduction in 20-24-year-olds, with 51% reduction in CIN2+ among 15-19-year-olds and 31% reduction among 20-24-year-olds.

HPV vaccine safety

- A Cochrane Review of randomized trials and a general narrative review of 109 studies documented no significant increases in adverse events following HPV vaccine receipt.^{9,19}
- Multiple large studies in several countries have substantiated the lack of increased risk of autoimmune or neurologic conditions in adolescents²⁰ and adult women²¹ following HPV vaccination.
- A large cohort study documented no increase in primary ovarian insufficiency (POI) after HPV vaccination nor other adolescent vaccinations.²²

What's Next

In the next 5-7 years, research studies will demonstrate more clearly the impact of HPV vaccination on cancer outcomes. Of particular interest is whether these studies will show decreases in oropharyngeal cancer, an important outcome given that no screening test exists for this HPV cancer. Studies will also document protection against HPV pre-cancers beyond 12 years, reduction of HPV infections and HPV pre-cancers among 27-45-year-olds following updated vaccine licensure, the long-term effectiveness of a two-dose HPV vaccine regimen, and the effectiveness of a 1-dose regimen.

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The HPV Vaccination Roundtable convenes, communicates with, and catalyzes member organizations to increase HPV vaccination rates and prevent HPV cancers.

Learn more at hpvroundtable.org.