

HPV vaccine for cancer and wart prevention

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Clinical question

Is the human papillomavirus (HPV) vaccine effective in preventing cervical lesions or genital warts (condyloma)?

Bottom line

The HPV vaccine prevents advanced cervical lesions (cervical intraepithelial neoplasia [CIN] grades 2 or 3) in 1 in 60 to 125 women and condyloma in 1 in 40 to 50 men and women over 3 to 4 years.

Evidence

Three large international RCTs in females aged 15 to 26 used modified intention-to-treat analysis (including patients with positive test results for HPV at baseline) for all HPV lesions.¹⁻⁴

- Quadrivalent vaccine (HPV 6, 11, 16, and 18):
 - FUTURE 1 trial¹ following 5455 women for 4 years found decreased external genital lesions (3.8% vs 5.7% [placebo]; number needed to vaccinate [NNV]=53) and CIN of grade 2 or 3 (6.6% vs 7.1% [placebo]; not statistically significant).
 - FUTURE 2 trial² following 12 167 women for 3 years found decreased CIN of grade 2 or 3 (3.6% vs 4.4% [placebo]; NNV=125).
 - FUTURE 1 and 2 combination³ trial following women for 4 years found decreased external genital lesions (1.5% vs 4% [placebo]; NNV=40); CIN of grade 2 or 3 was not reported.
- Bivalent vaccine (HPV 16 and 18 vaccine)⁴:
 - Trial following 18644 women for 4 years found decreased CIN of 2 or 3 (3.3% vs 4.9% [placebo]; NNV=63).
- Smaller studies showed similar effects.^{5,6}
 - All studies excluded those who were pregnant, had previous abnormal Papanicolaou test results or genital warts, or had more than 4 to 6 lifetime sexual partners. All studies were funded by vaccine manufacturers.

Similar relative efficacy was seen for condyloma in males aged 16 to 26.⁷

Context

- Worldwide, cervical cancer affects more than 500 000 women per year, mostly in developing countries,^{8,9} while in Canada about 1500 women per year are diagnosed.¹⁰
- About 90% of women with cervical cancer have HPV.^{8,9} Women have about a 50% chance of having positive test results for HPV after 3 years of sexual activity.¹¹
- Vaccine serious adverse event rate is similar to placebo.^{1,2,4-7}
- Future longer-term studies will delineate true effect on cervical cancer and whether a booster is needed.
- In Canada, the quadrivalent vaccine is recommended for females aged 9 to 45 and males aged 9 to 26, and the bivalent vaccine is recommended for females aged 10 to 25.¹²

Implementation

Primary care clinicians must educate patients and parents about the efficacy and safety of the HPV vaccine. As of May 2013, 111 million doses had been given worldwide.¹³ Based on postmarketing surveillance (including 700 000 doses in Ontario¹³), the risk of syncope is 8 per 100 000¹⁴ and the risk of anaphylaxis is 0.3 to 3 per 100 000.¹³⁻¹⁵ Co-administering the HPV and hepatitis B vaccines in schools should improve logistics and uptake,¹² although some provinces are using only 2 doses. The larger trials did not find an overall increase in spontaneous abortion or congenital abnormalities,^{2,4} but the vaccine is not recommended for pregnant women. 🌿

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