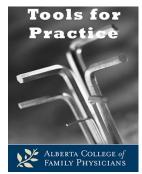
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HPV Vaccine: Shot of Cancer (and Wart) Prevention

<u>Clinical Question</u>: How effective is the Human Papillomavirus (HPV) vaccine in preventing cervical lesions or genital warts (condyloma)?

Bottom-line: HPV vaccine is effective in preventing advanced cervical lesions (CIN≥2) in one in 60-125 women and condyloma in one in 40-50 men and women over 3-4 years.

Evidence:

- Focusing on three largest, international, randomized, placebo-controlled trials (RCTs) in women aged 15-26 using modified intention-to-treat analysis (including patients who were HPV positive at baseline), for all HPV lesions. 1-4
 - o Quadrivalent (HPV 6, 11, 16, 18) vaccine (Gardasil®):
 - FUTURE 1: 1 5,455 women followed four years. Decreased:
 - External genital lesions (most commonly condyloma): 3.8% vs. 5.7% (placebo), number needed to vaccinate (NNV)=50.
 - Cervical intra-epithelial lesions (CIN)≥2: 6.6% vs. 7.1% (placebo), not statistically significant.
 - FUTURE 2: 2 12,167 women followed three years. Decreased:
 - CIN≥2: 3.6% vs. 4.4% (placebo), NNV=125.
 - FUTURE 1/2 Combination: Followed four years. Decreased:
 - External genital lesions (most commonly condyloma): 1.5% vs. 4% (placebo), NNV=40.
 - CIN≥2 not reported.
 - Bivalent (HPV 16, 18 vaccine) (Cervarix[®]):⁴ 18,644 women followed four years.
 Decreased CIN≥2: 3.3% vs. 4.9% (placebo), NNV=60.
 - o Smaller studies showed similar effects. 5,6 All studies:
 - Excluded those pregnant, with previous abnormal pap results or genital warts, or with >4-6 lifetime sexual partners.
 - Funded by vaccine manufacturers.
- Similar relative efficacy seen in males aged 16-26 (for condyloma).⁷

Context:

 Worldwide cervical cancer affects >500,000 women/year, most commonly in developing countries,^{8,9} while in Canada ~1500 women/year are diagnosed.¹⁰

- ~90% of women with cervical cancer have HPV.^{8,9} Women have ~50% chance of becoming HPV positive after three years of sexual activity.¹¹
- Safety: serious adverse event rate similar to placebo. 1,2,4-7
- Future longer-term studies will delineate true impact on cervical cancer and whether booster needed.
- Current Canadian recommendations: 12
 - o Gardasil[®]: Girls 9-45 years, boys 9-26 years.
 - o Cervarix[®]: Girls 10-25 years.

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Disclosure:

Authors do not have any conflicts to disclose.

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