

Grading of scientific evidence (HIV)

Question: Is there evidence to support administration of the currently licensed quadrivalent and bivalent HPV vaccines to HIV-infected young adolescent girls to prevent cervical cancer later in life?

Settings: Global

Conclusion: Very low quality of scientific evidence to support vaccination of HIV-infected young adolescent girls to prevent cervical cancer later in life.

Quality assessment							Quality	Importance
No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision	Other considerations		
Efficacy of HPV vaccines against cervical cancer in HIV- positive young adolescent girls								
1 ¹	RCT	serious ²	no serious	serious ³	very serious ⁴	With and without anti-HIV therapy	⊕⊕OO VERY LOW	CRITICAL
Risk of serious adverse events following HPV vaccines in HIV- positive young adolescent girls								
1 ⁵	RCT	serious ²	no serious	no serious	very serious ⁴		⊕⊕OO VERY LOW	CRITICAL

¹Only a poster presentation by Weinberg A et al is available. This was a study of North American HIV-infected girls and boys vaccinated with the quadrivalent HPV vaccine. The study included a placebo group of HIV-infected children and the immune responses of HIV-infected vaccine recipients were compared with those of HIV-uninfected historic controls, most of whom were older. The report shows that the quadrivalent HPV vaccine was immunogenic and safe in 120 HIV infected children aged 7-11 years, some of whom were on antiretroviral therapy. Following 3 doses of the quadrivalent HPV vaccine ≥ 99.5% seroconverted to HPV types 16 and 18. However, geometric mean titres for all the four types included in the vaccine were lower for HIV-infected children than for non-HIV-infected historical controls of similar age, but differences were statistically significant only for HPV type 6 and 18.

² Only one small study available. Presentation in the form of a poster limits the assessment of study quality.

³ Weinberg A et al investigated immunogenicity and did not present data on vaccine efficacy. The immunological correlates of protection are as yet unknown. Historic controls were older than HIV-infected children; other studies indicate that age influences immune response to this vaccine. Study included only North American children, some of whom were on antiretroviral therapy and may not be representative of other HIV-infected children with more substantial immune compromise due to HIV infection or other factors. Data is lacking on sustained immune response that may be a marker of long-term protection which will be essential to protect against sexually-acquired infection acquired years after vaccination.

Data on the immunogenicity and safety of bivalent vaccine in HIV-infected persons are not available.

⁴ The study included only North American children, some of whom were on antiretroviral therapy, and may not be representative of other HIV-infected children with more substantial immune compromise due to HIV infection or other factors. In terms of adverse events, the period of observation is short (weeks) and thus no data are available with regard to possible long-term effects.

⁵ No serious safety concerns were detected in this study. The plasma HIV ribonucleic acid (RNA) and CD4 cell per cent fluctuations were similar in HIV-infected vaccinees and placebo recipients and the profile of local adverse events in vaccinees did not differ by HIV infection status.

Bibliography

Weinberg A, et al. Safety and immunogenicity of a quadrivalent vaccine to prevent human papillomavirus (HPV) in HIV-infected children: IMPAACT P1047. Poster 619a presented at the 15th Conference on Retroviral and Opportunistic Infections, Boston, USA, February 3-6, 2008.