Protection of anogenital warts conferred by HPV vaccination in immunocompetent girls

Population : Immunocompetent girls
Intervention: HPV vaccination
Comparison: Placebo/ no vaccination
Outcome : Anogenital warts

What is the scientific evidence to support administration of the currently licensed quadrivalent HPV vaccine to immunocompetent girls to substantially reduce their risk of developing anogenital warts later in life?*

			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		4/ RCT 1/ observational[1]	4
	Factors decreasing confidence	Limitation in study design	None serious	0
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	None serious	0
		Publication bias	None serious	0
	Factors increasing confidence	Large effect	Not applicable	0
		Dose-response	Not applicable	0
		Antagonistic bias and confounding	Not applicable	0
	Final numerical rating of quality of evidence			**4**
Summary of Findings	**Statement on quality of evidence**			**We are very confident that the true effect lies close to that of the estimate of effect on health outcome**
	Conclusion			**We are highly confident that administration of quadrivalent HPV vaccine to immunocompetent girls to prevents the development of anogenital warts later in life.**

*The bivalent HPV vaccine is not designed to protect against anogenital warts

[1] *Garland SM et al* evaluated quadrivalent vaccine efficacy against anogenital warts in 2261 females and 2279 controls aged 16-24 years at enrolment. Among females naive to HPV 6 or HPV 11 through to 1 month following the 3rd vaccine dose, protection against such lesions due to the HPV type or types for which the subject was naive at enrolment was 100% (95% CI 94-100%) after a mean follow-up of 3 years. In an analysis of two international RCTs including a study population of 17,622 females aged 16-26, *Dillner J et al* estimated 99% (96% CI 95-100%) vaccine efficacy against HPV 6/11/16/18-related anogenital warts in the per protocol group who had received 3 doses of the vaccine and were tested HPV negative when initiating the vaccination series, *Munoz et al* confirmed these findings in a subset of participants from these trials and estimated 96.4% (95%CI 92.14-98.8%) vaccine efficacy in preventing anogenital warts. Evidence of protection against genital warts was confirmed by large postlicensure studies. The findings from these RCTs were confirmed in an observational study: *Ali et al.* observed large declines in the proportions of under 21 year old (92.6%) and 21-30 year old (72.6%) women diagnosed as having genital warts in the vaccination period, from 11.5% in 2007 to 0.85% in 2011 (P<0.001) and from 11.3% in 2007 to 3.1% in 2011 (P<0.001), respectively. *Ferris et al.* demonstrated persisting long-term anti-HPV6/11/16/18 responses for at least 8 years post-vaccination. Among 429 subjects who received HPV4 vaccine at a mean age of 12, none developed HPV6/11/16/18-related disease or persistent infection of ≥12 months' duration

References

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