Quadrivalent and nonavalent HPV vaccine: Ovarian safety research

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Human papillomavirus (HPV) vaccination may prevent up to 90% of oncogenic HPV infection. Quadrivalent and 9-valent vaccines and HPV testing are replacing the Papanicolaou cervical screening programme to reduce cervical cancer in Australia, which is now mostly confined to women not accessing regular screening. HPV vaccine marketing, licensing and advisory body statements of ovarian safety have followed case series of premature ovarian insufficiency (POI) in vaccine recipients. What evidence supports these statements? Adolescent ovarian safety research post quadrivalent and nonavalent vaccines were reviewed up to 2018. Controlled adolescent safety studies, studies reporting on menstrual function and studies addressing fertility concerns were analysed for design, internal validity, generalizability and outcome. No research has established ovarian safety post HPV vaccination. Two observational studies report 48% and 45% of young women experience irregular menses post vaccine. Research claiming to evidence reproductive safety in response to public concern about fertility effects of HPV vaccination was invalidated by correction for irregular menses, the most frequent presenting sign in POI. Existing vaccine ovarian safety statements are unevended. Possible autoimmune and toxicological vaccine effects have been postulated. Currently available post-marketing experience indicates a pressing need to investigate ovarian health after HPV vaccination. In the context of currently advocated long-acting reversible and other hormonal contraception, detection of an ovarian safety problem will be delayed until seeking pregnancy. HPV vaccine ovarian safety statements may confound vaccine adverse event reporting efficiency, reduce vaccine safety datalink effectiveness, delay ovarian safety research and contribute to reduced public vaccine confidence.

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