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Gardasil® virus like particle vaccine: Is its safety research adequate?

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A high level of safety evidence is required for population vaccines for well individuals. New vaccine designs arguably require more research than their forbears to ascertain the safety of the multiple new factors being introduced. The design, size, reporting process, internal validity and generalizability of their safety trials must meet rigorous standards. Recent controversies over quadrivalent human papillomavirus vaccine (QHPV) safety bring attention to these benchmarks. Concern about idiopathic premature ovarian insufficiency has arisen following a 13 fold increase in notifications of prolonged amenorrhoea following a vaccine after the introduction of QHPV vaccine in 2006 and in association with it. Two published case series of very young women with premature ovarian failure present possible toxicology and autoimmune mechanisms of ovarian demise and two observational studies report new onset menstrual cycle irregularity in 45% and 48% of young women following QHPV vaccination. Review of safety trials finds phase III studies excluded the vaccine's target group; vaccination of placebo cohorts precluded long term safety observation; post marketing studies were incapable of reporting ongoing menstrual function; up to 83% of safety trial participants were using hormonal contraception masking ovarian performance; and no placebo was used that did not contain vaccine excipients or excipients and adjuvant. All placebos are misrepresented. The design, process, internal validity and generalizability of this virus-like particle vaccine's safety studies are analyzed in the context of this vaccine's ovarian concerns and suggest further research is required for public vaccine confidence and ongoing reproductive health.