



**Queensland
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Queensland Health

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Update on Human Papillomavirus Vaccine Adverse Events

Advice to Divisions of General Practice

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There has been recent media coverage of adverse events linked with the administration of HPV vaccine. This media coverage is reportedly generating a significant number of calls to general practice from concerned women.

Attached are key messages to assist staff in general practice.

- The rate of reported adverse events, (496 events of a total of over 2 million doses of HPV vaccine administered in Australia), is very low and consistent with other vaccines.
- Most of the adverse events reported are minor and short lasting, including injection site reactions, and fainting.
- There have been post-marketing reports of allergic reactions associated with GARDASIL administration. A thorough investigation into these reports has been undertaken by the Therapeutic Goods Administration and the company (Merck).
- Allergic reactions are possible with any medicine or vaccine and have been reported rarely with GARDASIL. As part of good immunisation practice immunisation providers have appropriate processes and equipment in place to manage this rare event.
- The reported rate and types of side effects seen in Australia are consistent with that observed in clinical trials, which included over 26,000 people.
- The media coverage mentions seven deaths in the US that had apparently been associated with GARDASIL. Detailed analysis of these cases revealed that most were third party reports and/or unverified. There is no evidence to suggest a causal relationship between GARDASIL administration and fatal outcome. In the worldwide clinical trial program involving over 26,000 individuals there were no deaths related to either vaccine or placebo.
- To date over 18 million doses of GARDASIL have been distributed worldwide, with GARDASIL available in over 80 countries.
- As with all medicines and vaccines used in Australia, the Therapeutic Goods Administration in conjunction with state and territory health departments will continue to carefully evaluate all reports of adverse events.
- The benefits of GARDASIL in the prevention of cervical, vaginal and vulvar cancers and pre-cancers, as well as genital warts (due to HPV 6,11,16 or 18) are significant, and should be considered in the context of the low reports of side effects, most of which are minor.

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