Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Human papillomavirus vaccine (GARDASIL)

Advice from the Therapeutic Goods Administration

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- Australia was one of the first countries to roll out a national cervical cancer immunisation campaign using Gardasil. Gardasil is a vaccine that protects young women from the strains of human papillomavirus (HPV) that cause 70% of cervical cancers.
- Vaccination with Gardasil is most effective when given to females before they are likely to be exposed to HPV. Four out of five people will be exposed to HPV during their lifetime and exposure to HPV from a single lifetime partner can still be enough to result in an infection that can lead to cervical cancer. Over 700 new cases of cervical cancer are reported each year in Australia, and in 2005 cervical cancer led to the deaths of 216 women.
- To date approximately 4.7 million doses of Gardasil have been distributed in Australia. The overall number of suspected adverse events reported following Gardasil administration is very low, and consistent with other new vaccines and adverse event rates reported in other countries. Worldwide, over 43.8 million doses have been distributed. With this number of people receiving the vaccine, even if all are healthy and young, some serious events can be expected within days or hours of vaccination by chance alone and unrelated to vaccination.
- No vaccine is completely without side-effects, and so adverse events following immunisation are carefully monitored in Australia and regularly reviewed by expert advisory groups. A significant volume of reporting of adverse events is often seen shortly after the introduction of a new, widely-used vaccine because of the higher degree of vigilance and lack of familiarity with the new product. Many of the reported events (such as headache, feeling dizzy or unwell) may be equally common in people of the same age who have not received the vaccine.
- As at 1 April 2009 a total of 1,304 suspected adverse reactions had been reported in Australia following vaccination with Gardasil. The great majority have been mild and common problems such as soreness, swelling, or redness at the injection site. Most of the adverse reactions that have been reported are well recognised and listed in the Gardasil Product Information. Common adverse events reported to date are listed below:

Suspected adverse reaction	Number of reports (% of total reports for Gardasil)
Injection site reaction	267 (20.4%)
Headache	270 (21%)
Dizziness	180 (14%)
Nausea	208 (16%)
Fatigue and lethargy	128 (10%)

Fever	127 (10%)
Fainting	116 (9%)
General feeling of being unwell	111 (8.5%)
Vomiting	104 (8%)

- 'Psychogenic' events comprise approximately 20% of all adverse reaction reports for Gardasil. These events include dizziness, fainting and panic attacks, which are well recognised reactions associated with administration of vaccines or other injection procedures in general.
- An important category of possible reactions to any vaccine is allergy. Severe allergic reactions, such as anaphylaxis, may require adrenaline injections or other treatment, which is the reason why all persons providing vaccines must have the necessary drugs and equipment available. As at 1 April 2009, there had been 13 reports of anaphylaxis and 115 reports of urticarial reactions (hives) in Australia following Gardasil injection. All cases reported to the TGA to date have either been treated appropriately or have resolved without treatment. The current estimated rate of anaphylaxis based on doses distributed in Australia is 2.8 cases per million doses. The rates for other vaccines given to children and adolescents range from 0 to 3.5 per million doses in international studies.[1]
- All reports of suspected anaphylaxis following HPV vaccination have been assessed by the Adverse Drug Reactions Advisory Committee (ADRAC) using the Brighton Collaboration definition, a relatively new set of criteria for defining anaphylaxis.[2] Anaphylaxis is a rare event but healthcare professionals and patients should be aware of its possible occurrence. The occurrence of anaphylaxis and allergic reactions is not predictable and can occur in anyone regardless of whether they have a previous history of allergy or not. The rare occurrence of allergic reactions with Gardasil does not change any recommendations regarding the vaccine, but it is important that such reactions are reported promptly by the treating doctor to the relevant State or Territory Health Department or directly to the TGA, as set out in the Immunisation Handbook.
- The TGA is also aware of a small number of cases in which neurological symptoms, similar to those experienced in patients with a demyelinating disorder such as multiple sclerosis, have been reported shortly after HPV vaccination. In some of these cases symptoms were present prior to the vaccination. These reports have been actively investigated by an independent panel of clinical and scientific experts in immunology, neurology, epidemiology and paediatrics. Based on the available reported cases, the incidence of demyelinating disorders amongst recipients of Gardasil is not demonstrably higher than would be expected to occur by chance.
- No deaths occurring after Gardasil have been reported in Australia and no deaths directly linked to the vaccine have been reported in the USA or Europe.
- In Australia, all adverse events reported following Gardasil vaccination are reviewed by an expert committee, ADRAC, which advises the TGA. Every six months, detailed reports of adverse events are published in *Communicable Diseases Intelligence*, a quarterly publication of the Department of Health and Ageing.
- In addition to assessing Australian adverse event data, the TGA continues to evaluate all available safety information on Gardasil, including analyses from the United States Vaccine Adverse Event Reporting System and studies from the Vaccine Safety Datalink project. Worldwide reports of rare adverse events such as pancreatitis and neurological adverse events will continue to be monitored closely. Through ongoing contact with overseas regulatory agencies the TGA will continue to monitor the occurrence of any serious events related to the use of Gardasil anywhere in the world.

- In addition to the TGA, both the US Food and Drug Administration (FDA) and the European Medicines Agency (EMEA) have assessed Gardasil as safe and effective.

1. Bohlke K, Davis RL, Marcy SM. Braun MM et al., Risk of anaphylaxis after vaccination of children and adolescents. *Pediatrics* 2003;112: 815-820.
2. Rüggeberg JU, Gold MS, Bayas J-M, Blum MD et al. Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine* 2007; 25: 5675-5684.

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