

**Minutes of the**  
**Adverse Drug Reactions**  
**Advisory Committee**

**303<sup>rd</sup> Meeting**

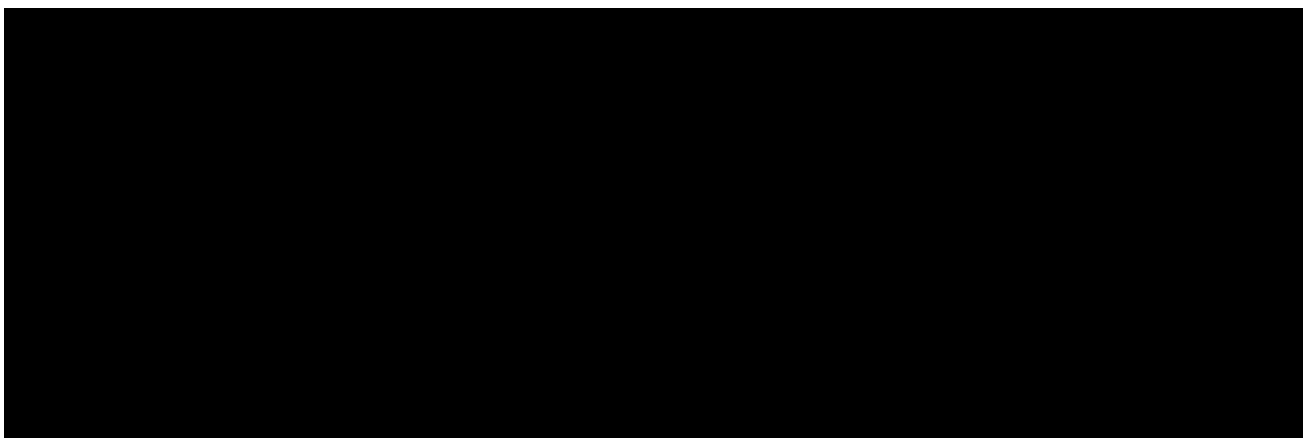
**21 September 2007**

## **10 Vaccines**

### **10.1 Vaccine issues and published articles**

- National Vaccine Information Center. Human Papilloma Virus Vaccine Safety. Analysis of Vaccine Adverse Events Reporting System Reports: Part III August 14, 2007 (revised 08/15/07)

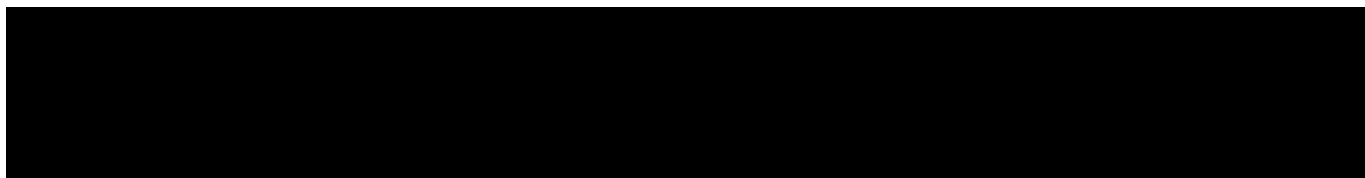
This paper discusses adverse events associated with human papilloma virus (HPV) vaccine in the USA. The situation is not of direct relevance to Australia because in the US HPV vaccine is administered together with other vaccines (some of which are not registered in Australia) while in Australia HPV vaccine is virtually always administered as a single vaccination.



### **10.2 Vaccine reports**

During the 6-week period from 1 July to 15 August 2007, about 185 reports of vaccine adverse reactions were lodged. This represents about 13% of the reports lodged for the period.

83 of the reports related to HPV vaccine (Gardasil). Virtually all of the Gardasil reports are for teenaged girls given the vaccine via school-based programs. The number of reports received from each State or Territory are: VIC: 23; NSW: 37; QLD: 4; SA: 2; WA: 9; ACT: 0; NT: 1; TAS: 3. The majority of the reports are from State Governments, but 1 was from the AMEL, 3 were from sponsors and 20 were from private doctors (7 from VIC, 4 from NSW, 4 from WA, 3 from TAS, and 2 from SA).



There were no vaccine-associated deaths. Details of reactions associated with individual vaccines are shown in the Table, below.

The case reports for all vaccines received during the period were provided.

Vaccine	No. reports	Inject. site reaction	Convulsion seizure	Fever/pyrexia	Dyspnoea/apnoea	HHE	Other notable reports/important reactions / comments
Human papilloma virus (Gardasil)	83	17	s22	9	8		4 x anaphylaxis: s22 (and s22 ?); 10 x swelling/oedema; 28 rash/urticaria/pruritus; 5 syncope/vasovagal; 12 x dizziness;

### 10.2.1 Allergic reactions with HPV vaccine

Members' attention was drawn to cases of allergic reactions and/or anaphylaxis with Gardasil vaccine. Some of these reports had been discussed previously at the ADRAC teleconference on Gardasil, held 4 July 2007 (identified as 'discussed previously' below).

Report s22

This report was received from a sponsor but there was no information to determine whether it had also been submitted by another source (eg, vaccine administrator, treating doctor, parent). It described a 16 year old girl with a history of asthma who experienced a severe asthma attack (wheeze, shortness of breath) and rash (urticaria) over 6-10 hours after administration of Gardasil. The girl was treated with adrenaline and steroids and developed similar symptoms 2 days later. Although the onset of symptoms was somewhat delayed, Members considered this was probably a case anaphylaxis in response to Gardasil.

Report s22 (discussed previously; NSW case 46)

This case involved a girl who *"returned to clinic 10 mins post vaccine (dose 2) with throat tightness and slight dizziness. Urticarial blotchy rash across face and upper chest noted. Anxiety noted. 0.5 mL adrenaline given. Transferred to hospital."* The case had been discussed previously at the ADRAC teleconference on Gardasil. Members confirmed the view that there was a Level 2 degree of certainty (according to criteria defined by the Brighton Collaboration) this was a case of anaphylaxis.

Report s22

This report from a GP described a patient who experienced dyspnoea (shortness of breath), erythema (red face, skin red and blotchy), hyperhidrosis and 'feeling hot' following vaccination with Gardasil. It was unclear if the reaction was allergic in nature since there was no indication whether the change in skin colour was due to rash or vasodilatation. ADRAC agreed this was a difficult case to interpret and could not confidently be categorized as anaphylaxis.

Report s22

This case, reported by a GP, may have been a case of anaphylaxis as it described urticarial rash lasting for 2 days and difficulty breathing, both within 30 minutes of vaccination with Gardasil. However, the respiratory symptoms were ill-defined and therefore it was not certain if this was anaphylaxis.

Report s22

Two days following administration of Gardasil, a girl experienced "widespread urticarial lesions, itchy wheals, raised hot to the touch, very uncomfortable (full body rash)". The report also listed vomiting and respiratory symptoms but there was some indication in the report that these occurred following treatment for the initial urticarial reaction and therefore may not have been associated with the vaccine. Members requested the reactions experienced in this case should be clarified. Based on the information provided, it appeared to be a case of urticaria in response to Gardasil.

Report s22

The reporter for this case (from WA) described the reaction in a girl given Gardasil as "anaphylactic reaction after 1<sup>st</sup> Gardasil injection - developed flushing, tight chest, difficulty in breathing". The

girl was treated with adrenaline and hydrocortisone at the scene and again after admission to hospital where she was also given oral steroids.

The description of symptoms, in particular the skin reaction, was not entirely consistent with anaphylaxis although it was noted that treatment with adrenaline and steroids had continued after admission to hospital. Members agreed it was possible this was a case of anaphylaxis, but the level of certainty was not high.

Report s22

This report was from NSW and had not been considered previously by the Committee. It described a girl who 15 minutes after receiving Gardasil vaccine felt dizzy, experienced tongue swelling, throat tightening, shortness of breath, palpitations and sweating. Members considered there was a level 2 degree of certainty that this was a case of anaphylaxis.

### **10.2.2 Other reactions with HPV vaccine**

Members' attention was also drawn to 2 reports of syncope s22 and s22 that were treated with adrenaline. The Committee s22 it was wise to err on the side of caution in situations such as this. Members also noted case s22 which described grand mal seizures in a female who had been vaccinated with Gardasil 2 days previously. Members were not convinced there was an association with the vaccine in this case. Fifteen additional reports of skin rash in response to Gardasil were also noted at the Meeting.

The Committee was advised that ADRU were currently reviewing reactions reported with Gardasil and a report would be presented to the Committee at a future date.