

---

**FACT SHEET**  
**NATIONAL IMMUNISATION PROGRAM –**  
**HPV VACCINATION FOR BOYS**

---

Human papillomavirus (HPV) is a highly contagious virus which is transmitted via sexual contact. Most people become infected upon becoming sexually active. Around 80% of people are infected with at least one genital type of HPV at some stage in their life. HPV can cause genital warts and certain cancers (and their precursors) in both women and men.

**Human papillomavirus (HPV)**

There are 40 distinct HPV genotypes that affect the genital tract; of these 15 genotypes are designated as 'high risk'. High-risk genital HPV genotypes are causally associated with the development of cervical cancer, a spectrum of other anogenital diseases, including vulva, vaginal, penile, and anal cancers, and their precursors (anal intraepithelial neoplasia (AIN) and cervical intraepithelial neoplasia (CIN)) and with extragenital diseases, including squamous cell carcinomas of the head and neck. HPV genotypes 16 and 18 are the causative agents in 70-80% of all cervical cancers.

HPV genotypes 6 and 11 are among the HPV genotypes designated as 'low-risk' (for cancer) and are associated with 90% of genital warts and 100% of recurrent respiratory papillomatosis (RRP) cases (wart-like growths in the upper airway which may cause significant airway obstruction or voice change).

Source: Australian Immunisation Handbook 9th edition 2008

The HPV vaccine, Gardasil® is highly efficacious in providing protection against four HPV genotypes (6, 11, 16 and 18) associated with genital warts; precancerous lesions (anal intraepithelial neoplasia (AIN)); and cervical, anal, oropharyngeal, penile, and perineal cancers.

Vaccinating boys against HPV infection will complement the current vaccination program for girls that was introduced in 2007; extending the program to boys will increase herd immunity and provide indirect protection to the 28% of girls who are estimated to be not fully vaccinated<sup>1</sup>.

HPV 16 is the predominant HPV type seen in male cancers; HPV 18 has a lesser role. Together, these types account for around 90% of all HPV attributable cancers in males.

The vaccine is most effective when the primary course is completed before a person's first sexual contact and exposure to HPV. Long-term follow up studies have demonstrated that at 8.5 years the vaccine remains highly immunogenic and efficacious with no disease reported in the vaccinated group<sup>2</sup>.

**Herd immunity**

High immunisation coverage rates limit the spread of a disease among a population, reducing the risk that non immune people (ie, those people who have not been vaccinated and those who were vaccinated but whose immune systems did not respond to the vaccine) will become infected.

The program will complement the Gardasil vaccination program for girls, increasing herd immunity and provide indirect protection to unvaccinated girls against HPV. It has been estimated that an

---

<sup>1</sup> Unpublished data – HPV register, data at January 2011: Immunisation coverage of girls turning 15 years of age in 2010.

<sup>2</sup> Olsson SE, Vila LL, Costa RL et al. Induction of immune memory following administration of a prophylactic quadrivalent human papillomavirus (HPV) types 6/11/16/18 L1 virus-like particle (VPL). *Vaccine* 2007; (25): 4931-7.

additional 24% of new HPV infections will be avoided with a male vaccination program that achieves similar coverage in men to that achieved in women<sup>3</sup>.

This approach is consistent with the provision of funding to vaccinate boys against rubella (German measles) as well as girls to prevent congenital rubella syndrome (which can include severe heart disorders, blindness, deafness, or other life threatening organ disorders and spontaneous abortion).

In the early 1940s, an Australian ophthalmologist, Norman Gregg, discovered the association between rubella infection in pregnancy and a pattern of congenital birth defects. In the early 1990s there were rubella epidemics through Australia with more than 5,000 notifications during 1995. The introduction of the measles-mumps-rubella (MMR) vaccine in 1993 ensured that boys as well as girls received the vaccine. Between 1999 and 2009 there were 10 notifications of congenital rubella syndrome reported in Australia, with the last case reported in 2007.

A recent analysis of national sentinel surveillance data<sup>4</sup> collected during the period January 2004 (prior to the introduction of the HPV vaccination program for girls which commenced in 2007) and December 2009 has shown a decrease of around 59% in frequency of genital warts in young Australian women and 28% decrease in heterosexual men, more pronounced in younger men indicating HPV vaccination is providing protective effects in heterosexual men through herd immunity. These results are very promising given that surveillance was undertaken only 2 years following the introduction of the HPV immunisation program. Further significant reduction in warts prevalence could be expected if more boys were vaccinated.

In the absence of a HPV vaccination program for males, men who exclusively have sex with men (MSM) would not be protected as they are exposed to other unvaccinated men.

### **HPV infection and disease in women**

The peak prevalence of HPV infection in women is seen in adults younger than 25 years of age, in general after sexual activity begins<sup>2</sup>.

There is no screening test to check for overall 'HPV' status. The only available screening for HPV related cancer is the Pap test which is available to women through the National Cervical Screening Program which screens for cervical lesions that can lead to cervical cancer.

The progression from HPV infection to cervical cancer is well understood due to the availability of cervical screening. While a HPV infection may result in low grade changes to the cervix and may resolve itself, some infections of high risk HPV genotypes go on to become high grade lesions and over many years can develop into cervical cancer. Cervical screening aims to identify high grade lesions and remove them prior to cancer developing.

While women have access to Pap tests to detect early changes which may lead to cervical cancer, similar screening tests are not available for the detection of other HPV cancers.

The incidence of cervical cancer is three times higher in Aboriginal and Torres Strait Islander women than non-Indigenous women and the mortality rate is five times higher than in non-Indigenous women<sup>5</sup>. The proportion of Aboriginal and Torres Strait Islander women who are fully immunised against HPV disease is likely to be less than non-Indigenous women.

There is early evidence with the implementation of HPV vaccination in women that the rate of high grade cervical lesions in women in the vaccinated age cohort has reduced.

---

<sup>3</sup> Georgousakis M et al. Population-wide vaccination against human papillomavirus in adolescent boys: Australia as a case study. *The Lancet* March 23, 2012.

<sup>4</sup> Donovan B, Franklin N, Guy R et al. Quadrivalent human papillomavirus vaccination and trends in genital warts in Australia: analysis of national sentinel surveillance data. *Lancet* 2011;11: 39-44.

<sup>5</sup> Australian Institute of Health and Welfare 2012. Cervical screening in Australia 2009–2010. Cancer series 67. Cat. no. CAN 63. Canberra: AIHW.

## HPV infection and disease in men

Knowledge of the natural history of HPV infection and associated diseases in men is increasing, but remains less extensive than that for women. As in women, most HPV infections in men are transient, asymptomatic, and resolve spontaneously. The progression from AIN to anal cancer in men (and women) is expected to be similar to the progression from HPV infection to CIN to cervical cancer. In men HPV infection is evident at all ages and the risk of acquiring new infections remains stable over time<sup>2</sup>.

Cancer of the anus is rare. Australian data indicate that there were around 234 new cases in men and women per year in the period 1998-2002; 40% of cases were in men. The incidence of anal cancer has been increasing in both men and women over the last 4 decades. Over the same period, there were 347 new cases of penile cancer (around 69 new cases per year). In 2008, there were 2,076 new cases of oral cavity cancer (65%: 1344 in men). Of 390 deaths, 64% (250) were among men<sup>6</sup>.

### *At risk groups*

- **Men who have sex with men (MSM)** are likely to have the greatest benefit from the vaccine. An incidence of anal cancer of cancer in MSM is more than 30 times that that in other men. The incidence is particularly high with similar rates to that of cervical cancer prior to screening<sup>2</sup>.
- **Unvaccinated women** – an estimated 28% of women have not completed the full course of three doses of HPV vaccine. Coverage of 72% is considered good both in international comparisons and for a program delivered to adolescents in high schools given three doses are required.
- **Women not participating in cervical screening** – around 30% of women do not participate regularly in cervical screening in Australia.
- **Aboriginal and Torres Strait Islander women** have a higher incidence of cervical cancer than non-Indigenous women and lower participation in cervical screening.

### **Safety of Gardasil**

HPV vaccines have a good safety record. The US Institutes of Medicine has reviewed the evidence for adverse events to common vaccines, including HPV vaccines. This report *Adverse Effects of Vaccines: evidence and Causality*, published on 25 August 2011, identified that the only adverse event for which there is evidence of a causal relationship with HPV vaccine is anaphylaxis.

In September 2008, the *Journal Multiple Sclerosis* published electronically an article by a group of neurologists at St Vincent's Hospital, Sydney, describing five patients who presented with multifocal or atypical symptoms of multiple sclerosis (MS) within 21 days of immunisation with Gardasil. Following these reports the Therapeutic Goods Administration established a Gardasil Expert Panel (GEP), chaired by Nobel Laureate Professor Peter Doherty, to evaluate the safety of Gardasil vaccine. The GEP found that the rate of anaphylaxis to be similar to that associated with other vaccines. The panel also found the incidence of demyelinating disorders including MS, following Gardasil to be no higher than would be expected by chance.

An analysis of several clinical trials (cumulative enrolment of more than 29,000 men and women) identified that 40 deaths were reported in 29,323 individuals. The death rates were comparable to those expected in healthy adolescent and adult populations and they were the same in the vaccine the control arm<sup>7</sup>.

In the UK a 14 year old girl died within hours of receiving an HPV vaccine. An autopsy later attributed the death to an undiagnosed malignant tumour.

Given the serious nature of these adverse events the program includes the establishment of an enhanced adverse event surveillance system in the program's initial implementation so that the expected high safety profile of the vaccine can be confirmed in practice.

---

<sup>6</sup> WHO/ICO Information Centre on HPV and Cervical Cancer (HPV Information Centre). Human papillomavirus and related cancers. Summary report 2010 Australia.

<sup>7</sup> Omer SB. Safety of quadrivalent human papillomavirus vaccine. *J Int Med* 2011; 271:177-8