

# immunisation newsletter

## Human Papillomavirus vaccination Frequently asked questions

### **In this issue:**

---

About the National HPV Program in Victoria

---

About the HPV National Register

---

About human papillomavirus (HPV)

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About the HPV vaccine

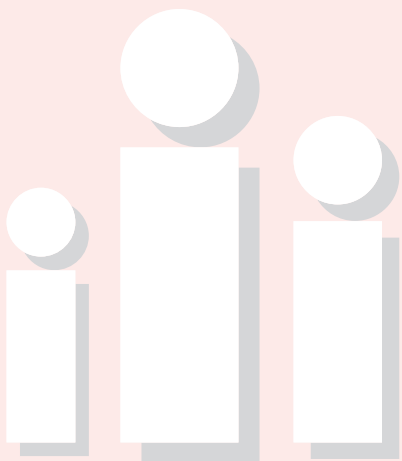
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General questions

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HPV resources

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# About the National HPV Immunisation Program in Victoria

## When does the National HPV vaccination program start in Victoria?

The National Human Papillomavirus (HPV) Vaccination Program will commence from April 2007 for all females aged 12 to 18 years and from July 2007 for females aged 18 to 26 years.

## Who is eligible for free HPV vaccine?

Females aged between 12 and 26 years are eligible for free HPV vaccine.

## What is the rollout plan for school girls?

From April 2007, Councils will deliver free HPV vaccine through school-based programs to girls. The rollout schedule is as follows:

<b>2007</b>	Year 7 Year 10 Year 11 Year 12	Secondary School
<b>2008</b>	Year 7 Year 9 Year 10	Secondary School
<b>2009 and ongoing</b>	Year 7	Secondary School

## What is the rollout plan for women aged 18 to 26 years?

From July 2007 until June 2009, free HPV vaccine will be available through general practice and

other immunisation providers for women aged 18 to 26 years. The full course of 3 doses must be completed before the end of June 2009 and/or before the woman reaches age 27 years of age.

## If parents wish to vaccinate their daughters who are in Years 8 & 9 do they need to pay for the vaccine?

Yes. Parents of girls in Year 8 & 9 should be advised that the vaccine is funded for females in this age group in 2008. If parents of females in Years 8 and 9 wish to have their daughter vaccinated in 2007 they must obtain a prescription from their doctor. They are not to be vaccinated using the nationally funded stock until 2008.

## What if a parent does not wish to have their child vaccinated at school, but rather by their local doctor?

Females eligible for the HPV vaccine as part of the 2007 school immunisation program must wait until July 2007 before they can access the HPV vaccine from their doctor.

## About the HPV National Register

### What is the HPV Register?

A National HPV Vaccination Program Register (HPV Register) is being developed by the Australian Government to collect data about the Program. Information will be collected to evaluate:

- the impact of the Program on cervical cancer rates
- to issue reminders if the course is incomplete
- to issue confirmation the course is complete
- to contact vaccine recipients if booster doses are required.

### Who is reported to the HPV National Register?

The details of girls vaccinated between the ages of 12-18 years must be reported to the HPV Register. It is also recommended that immunisation providers report details of females aged 18-26 years age.

The details and manner in which GPs are to report this information to the HPV Register will be confirmed at a later date.

# About human papillomavirus

## What is HPV (human papillomavirus)?

Human papillomaviruses (HPV) are small, non-enveloped DNA viruses that can affect cutaneous and mucosal epithelial tissues. Over 100 different types of HPV can be linked to cervical, anal, vaginal, vulval, penile, head and neck cancers. HPV can be transmitted by direct, skin-to-skin contact during all types of sexual activity.

Up to 40 of these HPV types can infect the anogenital epithelium. These HPV types are classified as high risk (oncogenic) or low risk (non-oncogenic). Some low risk HPV types can cause genital warts. HPV types 6 and 11 are linked to approximately 90 per cent of genital warts cases.

## What is the link between HPV and cervical cancer?

High-risk HPV types 16 and 18 are linked to 70% of cervical cancers in Australia.

It usually takes more than 10 years for cervical cancer to develop. During this time, cervical cell lesions can be detected through regular Pap smear screening, enabling treatment to be given before the development of cancer.

Most women who have HPV slowly clear the virus naturally and do NOT develop cervical cancer.

## Can HPV infection be treated?

No. There is no treatment for HPV infection. Treatments are available for the effects of the virus, such as abnormal changes to cells in the cervix and genital warts.

## Should females be vaccinated if they have had sexual contact?

Yes. Females, who have had sexual contact, may still benefit from the vaccine. Vaccination with HPV vaccine is most effective when it is given to females before they are exposed to HPV.

## Should a female be vaccinated if they have had genital warts or an abnormal Pap smear?

Yes. Females may benefit from HPV vaccine even if they have had genital warts and/or an abnormal Pap smear result. However, the HPV vaccine may be less effective depending on which HPV type caused the infection.

No reliable tests are available to check for past and current infections with the specific HPV types covered in the vaccine.

# About the HPV vaccine

## What vaccine is available for HPV protection?

GARDASIL® (CSL Biotherapies/Merck) is a quadrivalent vaccine registered for use in females aged 9 to 26 years and males aged 9 to 15 years.

## What is the recommended vaccine schedule?

GARDASIL® is given as a series of three intramuscular injections, usually within a six-month period:

- first dose: at a chosen date;
- second dose: 1 - 2 months after the first dose; and
- third dose: 4 - 6 months after the first dose.

The vaccine has been shown to be effective if all three doses are given within 12 months.

If a shorter vaccination schedule is necessary, a compressed schedule of 0,1 and 4 months can be followed. Because of the April start date, shorter vaccination schedules are likely to be used in the school-based program during 2007.

## When can immunisation providers, other than Councils, order the HPV vaccine?

New vaccine order forms will be distributed to all immunisation providers in June. These will also be posted on the immunisation website ([www.health.vic.gov.au/immunisation/forms](http://www.health.vic.gov.au/immunisation/forms)).

It is likely to be mid to late July before clinics will take receipt of their order. It is not recommended to take bookings until clinics have the vaccine in stock.

## What are the storage and handling requirements of the vaccine?

GARDASIL® should be refrigerated at 2° to 8°C and administered soon after being removed from refrigeration. Shake well before administration.

## Can GARDASIL® be given on the same day as other vaccines?

Yes. It is recommended to give all scheduled vaccines at the one time. The National Centre for Immunisation Research and Surveillance (NCIRS) fact sheet states, 'there is no reason to believe that HPV vaccine cannot be administered on the same occasion as other vaccines such as varicella or dTpa'.

## What are the contraindications to GARDASIL®?

GARDASIL® should not be given to any person who:

- is pregnant
- has a history of severe immediate hypersensitivity to yeast or any of the vaccine components (aluminium phosphate, sodium chloride, L-histidine, polysorbate and sodium borate), or who has had a severe allergic reaction to a previous dose of the vaccine.
- has a moderate to severe febrile illness.

## Who is the vaccine not recommended for?

The safety and efficacy of GARDASIL® has not been tested in children younger than 9 years, males over 15 years, females over 26 years and HIV-positive people.

## What are the common side effects of the vaccine?

Few serious adverse events were reported during clinical trials. Common side effects include:

Mild to moderate pain, redness or swelling at the injection site

- Headache
- Fever
- Nausea

For more information refer to the product information.

## In what form will the vaccine be supplied?

GARDASIL® will be supplied in a single use vial and will need to be drawn up for each dose. Shake vial well before use. Pre-filled syringes will be available in the future.



## Where were the HPV vaccine trials conducted?

HPV vaccine trials were conducted in Australia, North America and Europe.

## How many people were involved in the HPV vaccine trials?

Over 20,000 people aged between 9 and 26 years of age participated in the vaccine trials around the world.

Since 2006 approximately two million doses of GARDASIL® have been administered after being licensed in the USA.

## How long has the HPV vaccine been researched?

GARDASIL® has been trialed for five years. Research has shown the vaccine to be safe and effective with minimal side effects. Ongoing research will determine if booster doses are required.

## Please explain the components of GARDASIL®?

- Aluminium Phosphate – adjuvant (helper) for localising the vaccine at the injection site to promote an immune response
- L-histidine – amino acid, used to stabilise vaccine in adverse conditions and prevent vaccine components adhering to the side of the vial
- Polysorbate – emulsifier
- Sodium borate – antimicrobial to act as a preservative
- Sodium chloride – salty solution to support the other components for injection.

## If the spacing between the vaccines is longer than recommended in the product information (0,2 & 6m) does the person need to start the course again?

No. Where there has been a delay between doses of GARDASIL® it is expected that the course continue as recommended. There is no need to re-start.

## Can women who are breastfeeding have the HPV vaccine?

Yes. Breastfeeding is not a contraindication to GARDASIL® however pregnancy is.

# General questions

## What advice do you give to women who want the GARDASIL® vaccine but are planning to become pregnant?

It is recommended for females to complete the course (three doses) prior to planning pregnancy. HPV vaccine should not be given during pregnancy. Where vaccine has inadvertently been administered during pregnancy, further doses should be deferred until after delivery.

## What if a person is exposed to HPV between doses?

Exposure to any of the four HPV types covered by the vaccine before the three doses are completed may lessen the effect of the vaccine.

## Are booster doses of HPV vaccine required?

Not at this point in time. Research to date has demonstrated

protective immunity for at least five years and there is no indication currently that boosters are needed. Clinical trials are continuing and the results will be monitored to determine whether booster doses will be needed in the future.

## Is HPV vaccine available for women older than 26 years?

Not at this time. Older females are likely to have had more exposure to HPV, so the benefits of HPV vaccine may be reduced. Clinical trials into the benefits of the vaccine for women older than 26 years continue.

## Can councils immunise females who are aged 18-26 years?

Yes, after July 2007. Councils would be able to administer the vaccine to 18 - 26 year old females if they wish to do so.

## Are Pap smears required after vaccination against HPV?

Yes. The HPV vaccine does not protect against all HPV types that can cause cervical cancer. All females aged 18–69 who have ever been sexually active, whether vaccinated against HPV or not, should have regular Pap smears as recommended. Pap smears detect abnormal changes to cells in the cervix so treatment can start before cancer develops.

### Sources:

- National Centre for Immunisation Research and Surveillance (NCIRS)
- Immunise Australia Program, Department of Health & Ageing, Australian Government
- Cancer Council, Victoria

## HPV Resources

### Where can I get further information?

Information on HPV is available on the following websites:

- Immunise Australia Program - [www.immunise.health.gov.au](http://www.immunise.health.gov.au) or [www.health.gov.au/cervicalcancer](http://www.health.gov.au/cervicalcancer)
- NCIRS - [www.ncirs.usyd.edu.au](http://www.ncirs.usyd.edu.au)
- Information about the National Cervical Screening Program is available on the Cancer Screening website at [www.cancerscreening.gov.au](http://www.cancerscreening.gov.au)

You can also telephone the National Immunisation Infoline on 1800 671 811 or the Immunisation Program (Victoria) on 1300 882 008.

### When will translated materials be available?

Translated facts sheets for the HPV program are planned. DHS will make available fact sheets translated into other languages via the website. These resources are not likely to be available until prior to the start of the 18-26 year program.



## Who is eligible for HPV vaccine?

April 2007	Year 7 Year 10 Year 11 Year 12	Secondary School
July 2007	18 to 26 year olds	
2008	Year 7 Year 9 Year 10  18 to 26 year olds	Secondary School
2009	Year 7  18 to 26 year olds	Secondary School (ongoing)  (Program ends June 2009)



## Is this the end of cervical cancer?

### The impact of vaccination and HPV DNA testing

- All you need to know about HPV DNA testing in clinical practice and
- The latest update on cervical cancer/HPV vaccines.

Have your questions answered by our panel of experts from around australia and including Professor Jack Cuzick, London, UK.

**Date:** 23 June 2007

**Venue:** The Royal Women's Hospital, Melbourne  
[www.aogin.com](http://www.aogin.com)

The conference will focus on two highly relevant issues (vaccines to prevent cervical cancer and the latest on HPV DNA in clinical practice) and will be aimed at Australian Health Professionals, particularly, General Practitioners, Immunisation Nurses, Obstetricians, Gynaecologists, Sexual Health Workers, Adolescent Health Specialists, Public Health Doctors, Pathologists, Cytologists, Microbiologists etc.

- All conference attendees will have the opportunities to have their questions answered by a panel of experts, composed of speakers.
- An entire session is being devoted to questions from the audience as well as discussion of clinical case scenarios.

## Contact

For further information on the Immunisation Program please contact:

**Immunisation Program, Department of Human Services**

50 Lonsdale Street,  
Melbourne 3000

**Phone:** 1300 882 008

**Fax:** 1300 768 088

**Email:** [immunisation@dhs.vic.gov.au](mailto:immunisation@dhs.vic.gov.au)

[www.health.vic.gov.au/immunisation](http://www.health.vic.gov.au/immunisation)

