



Disease

What are human papillomaviruses (HPVs)?

HPVs are common viruses that can infect the skin and mucous membranes. They are grouped into high-risk and low-risk types based on how likely chronic infection is to cause cancer. About four out of five people are infected with HPV at some time in their lives, usually within the first two years of commencing sexual activity.

Most people infected with a high-risk HPV-type clear the virus around 18 months after being infected, reinfection is possible. Some people will develop a persistent infection that may cause cell changes, which if not detected and treated can cause cancers such as laryngeal, cervical or anal cancer.

Infection with low-risk HPV-types can cause warts such as palmar, plantar or genital warts. Although the virus is never cleared, infection with low-risk HPV-types does not usually lead to cancer.

How are HPVs spread?

HPVs can be spread through skin to skin contact, including orogenital contact, and through sexual intercourse.

How do HPVs cause cancer?

During persistent infection with high-risk HPV-types, virus DNA may integrate with host cell DNA and cause cell changes, which if not detected and treated can become cancer cells.

What type and how much cancer can they cause?

Seven high-risk HPV-types (16, 18, 31, 33, 45, 52, and 58) have been implicated in around 83–90% of anogenital cancers (anal, cervical, vaginal, vulval, and penile), and around 94% of HPV-positive oropharyngeal cancers.

The absolute numbers of HPV-related cancers are low when you consider that most people are infected with HPV within the first two years of sexual activity.

Do vaccinated women still require cervical screening?

Yes. Vaccinated women who have ever had sexual intercourse still need to have cervical screening to check for abnormal cervical cells. The vaccine does not provide protection against every HPV-type that could cause cervical cancer, even vaccinated women may still be at risk for some HPV-related cancers.

How many pre-cancers and cancers in New Zealand could potentially have been prevented by HPV immunisation in 2012?

	Women (n)	Men (n)	% of cases associated with HPV	% of cases associated with HPV types 16, 18, 31, 33, 45, 52, & 58	Cases potentially preventable by HPV immunisation in 2012	
					Women (n)	Men (n)
Cervical cancer	166	-	100%	90%	149	-
Cervical pre-cancer	2213	-	100%	90%	1992	-
Vulval cancer	67	-	40%	86%	23	-
Vaginal cancer	14	-	70%	88%	9	-
Penile cancer	-	15	50%	87%	-	7
Anal cancer	52	20	85%	83%	41	14
Cancer of the base of the tongue and oropharynx	35	8	66%	94%	22	5
Total	2547	43			2236	26

Sources: Ministry of Health. Cancer: New registrations and deaths 2012 & Cancer: New registrations and deaths 2012 – Additional data tables. Wellington: Ministry of Health; 2015. <http://www.health.govt.nz/publication/cancer-new-registrations-and-deaths-2012>.

Vaccines

What HPV vaccines are in New Zealand?

Gardasil® (HPV4) has been in NZ since 2008

Provides protection against the two highest cancer-risk HPV-types (16, 18) and the two highest genital warts-risk HPV-types (6, 11).

Gardasil®9 (HPV9) will be introduced in 2017

Provides protection against the seven highest cancer-risk HPV-types (16, 18, plus 31, 33, 45, 52, 58), and the two highest genital warts-risk HPV-types (6, 11).

Gardasil® and Gardasil®9 are fully interchangeable

- Individuals who begin with Gardasil® (HPV4) can complete their vaccine course with Gardasil®9 (HPV9).
- The number and timing of doses is the same for both vaccines.
- There are no safety concerns with changing vaccine brands during a course of vaccines.

When will Gardasil®9 (HPV9) be available?

Primary care will only begin to receive HPV9 after the national stock of HPV4 has been used up. This means a number of eligible individuals will begin their course of vaccines with HPV4 and finish with HPV9.

- Immunisation with HPV4 provides protection against the two highest cancer-risk HPVs and the two highest genital warts-risk HPVs.
- There is no data as to whether using one or two HPV9 doses to complete a HPV immunisation course started with HPV4 will provide protection against more than the four HPV-types in HPV4.

There is a risk of exposure to these HPV-types and infection if HPV immunisation is due to be commenced or completed with HPV4, but is delayed until HPV9 is distributed to primary care.



Eligibility

Up to and including 31 December 2016	From 1 January 2017
<p>Females aged 9 years to under 20 years.</p> <ul style="list-style-type: none"> HPV immunisation course is funded from 9 years in primary healthcare. <ul style="list-style-type: none"> The School-based Immunisation Programme deliver the vaccine to female school students in year 8. Non-residents must be aged under 18 years to receive funded vaccine doses. Males and females aged under 26 years who are HIV-positive. Males and females who have received a solid organ or stem cell transplantation. Males and females aged under 26 years who completed a course of three HPV vaccine doses before having chemotherapy – one additional dose post-chemotherapy. Catch-up eligibility for NZ female residents: if at least one dose was given before 20 years of age, there is no upper age limit to receive funded catch-up doses. 	<p>Males and females aged 9 years to under 27 years.</p> <ul style="list-style-type: none"> HPV immunisation course is funded from 9 years in primary healthcare. <ul style="list-style-type: none"> The School-based Immunisation Programme deliver the vaccine to school students in year 8. Non-residents must be aged under 18 years to receive funded vaccine doses. Males and females aged under 27 years who are HIV-positive, or who have received a solid organ or stem cell transplantation <ul style="list-style-type: none"> A course of three HPV vaccine doses for all ages including those aged 9–14 years inclusively. Males and females aged under 27 years who completed a course of three HPV vaccine doses before having chemotherapy – one additional dose post-chemotherapy. Catch-up eligibility for NZ residents: if at least one dose was given before 27 years of age, there is no upper age limit to receive funded catch-up doses.

Catch-up planning

There will not be a formal HPV vaccine catch-up programme. Primary care will need to identify and recall eligible individuals who will not be offered HPV immunisation through a school-based vaccination programme (students in year 8).

It is suggested that primary care extend existing query builders and processes used to identify girls who have not received any HPV vaccine doses, or who have not completed their HPV vaccine course through a school-based vaccination programme. From 1 January 2017, for NZ residents: if one dose is given before 27 years of age, there is no upper age limit to complete the vaccine course with funded catch-up doses.

Recall recommendations	
Areas with school-based vaccination programmes	Areas without school-based vaccination programmes
<p>Up to and including 31 December 2016</p> <ul style="list-style-type: none"> Females aged 14–19 years (under 20 years) <p>From 1 January 2017</p> <ul style="list-style-type: none"> Males and females aged 14–26 years (under 27 years) 	<p>Up to and including 31 December 2016</p> <ul style="list-style-type: none"> Females aged 12–19 years (under 20 years) <p>From 1 January 2017</p> <ul style="list-style-type: none"> Males and females aged 12–26 years (under 27 years)
<ul style="list-style-type: none"> Who have not had any HPV vaccine doses, or Who have not received three HPV vaccine doses <p>Note: Non-residents must be aged under 18 years to receive funded vaccine doses.</p>	

Vaccine administration (from 1 January 2017)

Gardasil® (HPV4) and Gardasil® 9 (HPV9) are fully interchangeable

Males and females aged 9–14 years inclusively	
<p>Not HIV-positive, or post-solid organ or stem cell transplantation</p> <ul style="list-style-type: none"> Two HPV vaccine doses The standard schedule is 0 and 6–12 months with a minimum interval of 5 months between doses one and two. <ul style="list-style-type: none"> If doses one and two are given at least 5 months apart, no further doses are required. If doses one and two are given less than 5 months apart, a third HPV vaccine dose is required. If dose two is not given until the child is aged 15 years or older, a third HPV vaccine dose is required. 	<p>HIV-positive, or post-solid organ or stem cell transplantation</p> <ul style="list-style-type: none"> Three HPV vaccine doses The standard schedule is 0, 2, 6 months, i.e. an interval of 2 months between doses one and two, and an interval of 4 months between doses two and three. <ul style="list-style-type: none"> An alternate schedule can be followed, 0, 1, 4 months, on specialist advice.
Males and females aged 15–26 years inclusively	
<ul style="list-style-type: none"> Three HPV vaccine doses The standard schedule is 0, 2, 6 months, i.e. an interval of 2 months between doses one and two, and an interval of 4 months between doses two and three. <ul style="list-style-type: none"> An alternate schedule can be followed, 0, 1, 4 months, i.e. a minimum interval of 1 month between doses one and two, and a minimum interval of 3 months between doses two and three. 	



Vaccine administration (continued)

Gardasil® (HPV4) and Gardasil® 9 (HPV9) are fully interchangeable

Who cannot have HPV vaccine?

The only contraindication to Gardasil® (HPV4) or Gardasil®9 (HPV9) is anaphylaxis to a previous dose or any component of either vaccine.

Can HPV vaccine be given at the same time as other vaccines?

Yes. Administration of a different inactivated or live vaccine, either at the same visit or at any time before or after HPV vaccine, is acceptable because HPV is not a live vaccine.

Who should start HPV immunisation from 9 years of age?

There are some medical conditions where a clinician may recommend to start the immunisation programme before treatment begins, e.g. prior to long-term immunosuppressive or pre-solid organ transplantation.

Who immunises a student in year 8 if they miss HPV vaccine doses through school programme?

Students need to complete their course of vaccines through primary care. Providers should do an NIR status query to check when the vaccine was due and recall the individual.

What about individuals aged 27 years or older who have not had any HPV vaccine doses?

In certain situations, clinicians may recommend a course of HPV vaccines for individuals aged 27 years or older. The vaccine doses need to be prescribed by a doctor and purchased from Healthcare Logistics.

Do we have to restart the course of HPV vaccines when doses have been delayed?

No. It is not necessary to repeat doses/restart course of Gardasil® (HPV4) or Gardasil®9 (HPV9) after a delay in administration, even if the course of vaccines exceeds 12 months.

Resume the vaccine schedule without repeating prior doses with the available HPV vaccine.

However, if dose one is given to a child aged 9–14 years inclusively but dose two is not given until the child is aged 15 years or older, a third vaccine dose is required 4 months after the second.

Who can have the HPV vaccine?

The individual has a penicillin or sulfur/sulfonamide antibiotic allergy

Neither Gardasil® (HPV4) nor Gardasil®9 (HPV9) contain preservative or antibiotics.

The individual has a chronic medical condition

Individuals with a history of febrile seizures or history of epilepsy, or with a current diagnosis of epilepsy, ovarian cysts, a cardiac condition or any other chronic medical condition, can have Gardasil® (HPV4) or Gardasil®9 (HPV9).

The individual is on long-term medication

Individuals on IM penicillin for rheumatic fever prevention, cardiac medications, warfarin, thyroid hormone replacement medication, or any other long-term medication can have Gardasil® (HPV4) or Gardasil®9 (HPV9).

When the vaccine is administered to an individual who is taking anticoagulant medication or has a bleeding condition, it is recommended to apply firm pressure over the injection site without rubbing for at least 10 minutes.

The individual is immune compromised

Immune compromised individual's can have Gardasil® (HPV4) or Gardasil®9 (HPV9). However, they may not respond as well as they would have if they were not immunosuppressed.

If immunosuppressive therapy is planned (except stem cell transplantation), it is better to immunise before starting the treatment. If the immunosuppressive therapy is temporary, it may be worth considering delaying HPV immunisation.

The individual isn't ready to become sexually active

Starting HPV immunisation before the start of any kind of sexual activity provides the best protection possible. It is standard practice to vaccinate people before they are exposed to an infection, as is the case with hepatitis B and the other recommended childhood vaccines. Similarly, we want to vaccinate children before they get exposed to HPV.

Younger adolescents respond better to the vaccine than older adolescents and young adults.

There is no evidence that receipt of HPV vaccine increases the chance that a child will become sexually active.

The individual is already sexually active

HPV vaccine should be offered to all eligible individuals whether they have been sexually active or not. Ideally, individuals would be immunised before onset of sexual activity. However, those who have already been infected with one or more HPV vaccine-types could still be protected from the other HPV vaccine-types.

The individual's sexual orientation is same-sex

Yes. HPV vaccine is recommended for males and females regardless of their sexual orientation.

The individual already has genital warts or abnormal cervical smears

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, people with this history might not have been infected with both HPV 6 and 11 or with the other HPV-types included in Gardasil® (HPV4) and Gardasil®9 (HPV9). Immunisation can provide protection against infection with HPV vaccine-types the individual has not already acquired.

Providers should explain that the vaccine will not have a therapeutic effect on existing HPV infection, but it is still important the individual completes the vaccine course.

The woman could be or is pregnant

It is not recommended to do a routine pregnancy test before administration of Gardasil® (HPV4) or Gardasil®9 (HPV9).

If a woman is known to be pregnant during her course of HPV vaccines, it is recommended that the remaining HPV vaccine doses are delayed until completion of pregnancy. However, as inactive vaccines can be safely administered to pregnant women no intervention is needed if a HPV vaccine dose is inadvertently administered during pregnancy.

The woman is breast feeding

A woman who is breast feeding can be safely immunised with Gardasil® (HPV4) or Gardasil®9 (HPV9).



Consent

When can a child consent for themselves?

In primary care, a child aged under 16 years has the right to give consent for minor treatment, including immunisation, providing he or she understands fully the benefits and risks involved. Refer to *Section 2.2.6 Consent and children* in the Immunisation Handbook 2014 (2nd Edition).

Within the School-based Immunisation Programme, the consent requirements are different to those primary care. For children aged under 16 years who are being immunised at school, written consent must be obtained from the parent/guardian. Individuals who are aged 16 years or older may self-consent. Refer to *Section 2.2.5 Immunisation consent in other settings (e.g. schools)* in the Immunisation Handbook 2014 (2nd Edition).

A child who requests HPV immunisation at the School-based Programme but does not have a completed and signed consent form, should be referred to their usual healthcare provider.

Who can consent for a foreign exchange student?

Emailing the consent form to the student's legal guardian and printing the returned, signed consent form is preferred for exchange students. However, it is possible that the consent form could be signed by the exchange student's homestay parents after they have obtained consent from the student's legal guardian.

What does a parent do with a school consent form when their child has started/has had HPV vaccine through primary care?

Parents are requested to return the consent form to school having ticked the option *My child has already received the HPV immunisations* in Section B.

Efficacy

How well and for how long does HPV vaccine work?

HPV9 vaccine targets the types of HPV responsible for 90% of cervical cancer, 83% of anal cancer, 94% of oropharynx cancer, and 90% of genital warts.

Clinical trials show it is highly effective in preventing infection with these types of HPV in young people who have not previously been exposed to them.

Ongoing clinical studies show the vaccine protects against HPV infection for at least ten years after immunisation, and clinical antibody studies suggest protection will be long lasting, similar to the case with the hepatitis B vaccine. There is no evidence that a booster HPV vaccine dose will be required.

Safety

What are the common HPV vaccine responses?

Fainting after immunisation is a known response to the immunisation process, especially in adolescents.

After immunisation, individuals may experience local responses of mild pain, redness and swelling around injection site, or systemic responses including mild fever less than 39°C, irritability, mild headache, malaise and tiredness.

How do we respond to safety concerns after media stories about HPV vaccines?

The Gardasil®9 (HPV9) safety data is consistent with the Gardasil® (HPV4) safety studies that include over 1 million individuals.

No relationship between Gardasil® (HPV4) and chronic regional pain syndromes (CRPS), postural orthostatic tachycardia syndrome (POTS), fibromyalgia syndrome, paralysis, fatigue, ovarian failure, or sterility have been found, despite extensive ongoing research. The types of events described above occur in girls who are not vaccinated as well as those who are.

There has been a dramatic reduction in genital warts, pre-cancerous lesions and dysplasia in countries who have included the Gardasil® (HPV4) vaccine on their immunisation schedules.

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