Changes to the recommended use of human papillomavirus (HPV) vaccines

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## Plain-language summary

HPV (human papillomavirus) is a common virus that spreads through sexual contact. HPV usually does not cause symptoms, but in some people, it can cause genital warts or skin warts. HPV can also cause cancer, including:

cervical cancer – almost every case of cervical cancer is caused by HPV

anal cancer

vaginal cancer

cancer of the vulva

cancer of the penis

cancer of the back of the mouth and throat (called oropharyngeal cancer).

Before the HPV vaccine was introduced, around 90% of people would be infected with HPV at some point in their life.1

The HPV vaccine has been part of Australia’s National Immunisation Program since 2007. Adolescents aged 12–13 years can get the vaccine for free at their school or at their GP office. The vaccine is very good at stopping HPV infection. This means that vaccinated people are much less likely to develop the diseases that are associated with HPV infection, including cancer.

The recommendations for HPV vaccination are changing. Instead of 2 doses of HPV vaccine, most people will now have only 1 dose. This is because evidence shows that 1 dose is just as effective as 2 or 3 doses, and the protection lasts for a long time.

The age range of people recommended to receive HPV vaccination is also changing, with the previous upper limit of 19 years old being removed. All adolescents and young adults aged 9–25 years are now recommended to receive HPV vaccination. People who might have missed their HPV vaccination when they were at school can still have the vaccine for free up to the age of 25 years. The recommendation that adults aged ≥26 years are not routinely recommended to receive HPV vaccine, but may receive it under some circumstances, is unchanged.

## Summary of revised recommendations

The key changes to HPV vaccine recommendations are:

the recommended vaccination schedule has changed from 2 doses to 1 dose for all immunocompetent people aged 9–25 years

the age range for funded vaccination has changed from 9–18 years to 9–25 years.

Updated recommendation

* Adolescents and young adults are recommended to receive 9vHPV vaccine from 9 years of age.
*People aged 9–25 years are now recommended to receive 1 dose of 9vHPV vaccine.*

Recommendations with minor changes to updated information or to align with the updated recommendation

* Adults aged ≥26 years are not recommended to receive HPV vaccine.
*Changed to increase the age threshold for vaccination from 18 years to 25 years.*
* People with severely immunocompromising conditions are recommended to receive 3 doses of HPV vaccine.
*Supporting information changed to align the recommended vaccination schedule*
* Men who have sex with men ~~of any age~~ are recommended to receive HPV vaccine at any age.
*Supporting information changed to clarify that men who have sex with men can be vaccinated at any age.*

Deleted recommendation

* Women who have received HPV vaccine are recommended to undergo cervical screening according to current guidelines.
*Information incorporated into the updated recommendation.*

## Background and rationale

The Australian Technical Advisory Group on Immunisation (ATAGI) advises the Australian Government on clinical recommendations for vaccinations. ATAGI is proposing changes to the recommendations for the use of HPV vaccines.

The proposed changes reflect the current best clinical practice to prevent HPV-associated disease, including cervical cancer and other anogenital and oropharyngeal cancers caused by HPV. The revised recommendations are published online in the [Australian Immunisation Handbook](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/human-papillomavirus-hpv) (the Handbook). Information relating to the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) assessment is published on the National Centre for Immunisation Research and Surveillance (NCIRS) website.

Important note about this public consultation

The [HPV chapter in the Handbook](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/human-papillomavirus-hpv) was updated on 30 January 2023 to incorporate the changes in this document. This was to enable a 1-dose schedule for HPV vaccination to be implemented in time for the 2023 school year. Comments received during this public consultation will still be considered, and any relevant changes will be made to the published version of the HPV chapter.

### HPV and associated disease

HPV infection is often subclinical, but it can cause genital warts, cutaneous warts and respiratory papillomatosis. People with persistent HPV infection are at risk of developing HPV-associated cancer, including a range of anogenital cancers and oropharyngeal cancer.

### HPV vaccines and the National Immunisation Program

Three HPV vaccines have been available in Australia:

2vHPV vaccine (Cervarix)

4vHPV vaccine (Gardasil)

9vHPV vaccine (Gardasil 9).

Australia’s National Immunisation Program (NIP) now uses Gardasil 9. In 2007, 4vHPV vaccine was introduced to the NIP in a 3-dose schedule for females aged 12–13 years through a school-based program. In 2013, this program was extended to include males of the same age. In 2018, 4vHPV vaccine was replaced by 9vHPV vaccine in a 2-dose schedule, as it provides protection against the four HPV types in the 4vHPV vaccine and an additional five HPV types.

HPV vaccine has high uptake in Australia. In 2021, 86% of girls and 84% of boys had received 1 dose of HPV vaccine by 15 years of age.2

HPV vaccines are safe – in 2020, 91% of adolescents who received their first dose of HPV vaccine at the same time as their diphtheria, tetanus and pertussis vaccine in Australia reported no adverse events.3 The most common adverse events are pain, swelling or redness at the injection site, as well as tiredness, headache and fever.3

### Rationale for updating the recommendations

Results from long-term studies show that a single dose of HPV vaccine has similar effectiveness to 2 or 3 doses, and that this protection is long lasting. In April 2022, the World Health Organization Strategic Advisory Group of Experts on Immunization (WHO SAGE) completed a comprehensive assessment of the evidence for a single dose of HPV vaccine.4,5 As a result of the large body of evidence supporting a 1-dose schedule and the WHO SAGE assessment, a reduced-dose schedule was recommended. ATAGI has therefore also reviewed the evidence in the Australian context and proposed changes to the recommendations in the Handbook.

## GRADE methods

Evidence on benefits and harms of HPV vaccine was assessed using GRADE (Grading of Recommendations, Assessment, Development and Evaluations) methods. This assessment built on a comprehensive GRADE assessment conducted by the WHO SAGE in April 2022.4,5 The PICO (population, intervention, comparator, outcomes) questions used by the WHO SAGE were tailored to the Australian context, and additional studies were included that were published since the WHO SAGE literature search was conducted.

The primary GRADE comparisons were:

effectiveness and immunogenicity of 1 dose of 9vHPV vaccine compared with no HPV vaccination

effectiveness and immunogenicity of 1 dose of 9vHPV vaccine compared with 2 or 3 doses of HPV vaccine.

The benefits outcomes considered included:

vaccine effectiveness against HPV infection

vaccine efficacy against cervical intraepithelial neoplasia (a precursor to cervical cancer)

seropositivity (whether the immune system has responded to the vaccine) after 1 vaccine dose compared with 2 or 3 doses

geometric mean titres of antibodies against HPV (an indication of how strongly the immune system has responded to the vaccine).

The harms outcomes considered included:

local adverse events

systemic adverse events

serious adverse events.

The certainty of the evidence for each outcome was determined by assessing the study design, risk of bias, inconsistency, indirectness and imprecision.

## Updated recommendation

**Adolescents and young adults are recommended to receive 9vHPV vaccine from 9 years of age**

Adolescents and young adults are recommended to receive 9vHPV vaccine from 9 years of age and onwards. The optimal age for HPV vaccination is around 12–13 years. At this age, most people have not yet been exposed to HPV. People who have not received HPV vaccine by 14 years of age can still receive the vaccine up to 25 years of age. However, vaccination is most effective if the vaccine is given early in adolescence.

The recommended schedule for adolescents and young adults aged 9–25 years is 1 dose.6-9

People with severely immunocompromising conditions need 3 doses of HPV vaccine, regardless of their age (see [Vaccination for people who are immunocompromised](https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised)).

Women or people with a cervix who have received HPV vaccine are recommended to undergo cervical screening through the National Cervical Screening Program according to the [Guidelines for the management of screen-detected abnormalities, screening in specific populations and investigation of abnormal vaginal bleeding](https://www.cancer.org.au/clinical-guidelines/cervical-cancer-screening/?title=Guidelines:Cervical_cancer/Screening).10 HPV types other than those included in the HPV vaccines can cause cervical cancer. Therefore, both cervical screening and HPV vaccination are recommended.

### Previous recommendation

The previous recommendation was that adolescents aged 9­–18 years are recommended to receive 9vHPV vaccine. The recommendation specified that adolescents aged 9–14 years should receive 2 doses of HPV vaccine, and adolescents aged 15–18 years should receive 3 doses.

### Key differences

The main differences are:

the recommended vaccination schedule has changed from 2 doses to 1 dose for all immunocompetent people aged 9–25 years

the age range for vaccination has changed from 9–18 years to 9–25 years.

The new recommendation also incorporates information about the need for vaccinated women to continue to participate in the National Cervical Screening Program (also see [Deleted recommendation](#_Deleted_recommendation)).

The recommendation to vaccinate people with severely immunocompromising conditions with 3 doses of HPV vaccine is unchanged, as there is not enough evidence to support a reduced-dose schedule.

### Evidence for the updated recommendation

#### Vaccine efficacy of 1 dose of HPV vaccine

Studies of 4vHPV and 2vHPV vaccines show that a single dose given to girls and women aged 9–25 years provides protection against HPV infection that is comparable to 2 or 3 doses of vaccine, and persists over several years.8,9,11,12

A clinical trial showed that 1 dose of 9vHPV vaccine had 97.5% efficacy against persistent HPV infection in young women aged 15–20 years.6

A clinical trial showed that an effective immune response occurs in almost all people who receive a single dose of 9vHPV or 2vHPV vaccine.7 Although the antibody titres induced by a single dose of vaccine are lower than after 2 or 3 doses, they stabilise from 12 months and do not appear to wane after that.7 The same pattern of antibody waning is also seen in people who receive 2 or 3 doses of vaccine.

Long-term studies of 4vHPV and 2vHPV vaccines show that the immune response remains stable from 12 months up to 11 years after vaccination, and protection against HPV infection is maintained during this time.9,13-15 Observational studies show that a single dose of HPV vaccine provides protection up to 11 years after vaccination.8,9

The WHO SAGE assessment found that there was evidence that strongly supports the use of 1 dose of HPV vaccine.4 This was based on 59 studies reviewed in 2022. The findings of this GRADE assessment are consistent with those of the WHO SAGE, and additional studies published since then are also consistent.16-18

There is limited evidence on the effectiveness or efficacy of a single dose of HPV vaccine in males. However, there is no reason to expect that the immune response and clinical protection from the vaccine would be different in males and females.

#### Increasing the upper age limit for vaccination to 25 years

The evidence for a single dose of HPV vaccine includes long-term follow-up of people aged up to and including 25 years who were vaccinated with 1 dose of HPV vaccine.9,11 These studies show that the vaccine has long-term effectiveness in this age group. This evidence underpins the recommendation to provide a dose for all people aged 9–25 years.

## Recommendations with minor changes to align with the updated recommendation

**Adults aged ≥26 years are not recommended to receive HPV vaccine**

Adults aged ≥26 years are not routinely recommended to receive HPV vaccine.

However, some adults may benefit from HPV vaccination. When deciding whether to vaccinate adults, consider:

* the likelihood of previous exposure to HPV
* the future risks of HPV exposure

Many adults are likely to have been exposed to 1 or more HPV types contained in the vaccine through sexual activity (see [Epidemiology](https://immunisationhandbook.health.gov.au/contents/vaccine-preventable-diseases/human-papillomavirus-hpv#epidemiology)). Vaccination will not clear a past infection, but can provide protection against future infections.

The recommended schedule for adults aged ≥26 years is 3 doses, with an interval of 2 months between dose 1 and dose 2, and 4 months between dose 2 and dose 3.

This recommendation has been updated to increases the specified age from ≥19 years to ≥26 years, and clarify that the recommended vaccination schedule for adults aged ≥26 years is 3 doses.

**People with severely immunocompromising conditions are recommended to receive 3 doses of HPV vaccine**

A 3-dose schedule of 9vHPV vaccine is recommended for people with severely immunocompromising conditions, regardless of their age when they started vaccination.

This is because their immune response is likely to be lower than for immunocompetent people. They are also more likely to develop a persistent HPV infection and HPV-related disease.19,20

Severely immunocompromising conditions include:

* primary or secondary immunodeficiencies (complete or partial deficiencies of B-lymphocyte antibody or T-lymphocytes)
* HIV infection
* malignancy
* organ transplantation
* significant immunosuppressive therapy

*People with asplenia or hyposplenia*

People without a spleen are not considered at higher risk of persistent HPV infection and disease and are recommended to receive a 1-dose schedule if they are aged 9–25 years. This is the same as individuals with a functioning spleen.

See also [Vaccination for people who are immunocompromised](https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised).

This recommendation has not changed, but the supporting information for people with asplenia or hyposplenia has been updated to align with the 1-dose schedule for the general population aged 9–25 years.

**Men who have sex with men are recommended to receive HPV vaccine at any age**

HPV vaccine is recommended at any age for men who have sex with men (MSM) who have not previously been vaccinated. The number of doses and the interval between doses should follow the recommendations in [Table. Recommended doses and intervals between doses for human papillomavirus (HPV) vaccines, by age group at the start of the course](https://immunisationhandbook.health.gov.au/resources/tables/table-recommended-doses-and-intervals-between-doses-for-human-papillomavirus-hpv-vaccines-by-age-group-at-the-start-of-the-course).

The decision to vaccinate should consider:

* the likelihood of previous exposure to HPV
* the person’s future risk of HPV exposure

MSM have a higher risk of repeated and persistent HPV infection and associated diseases, such as genital warts and anal cancer, at all ages and regardless of HIV status or other immunocompromising conditions.19,21 Patterns of HPV infection and disease in MSM are markedly different from those of heterosexual men and women. Men have stable incidence and prevalence throughout life. HPV infection incidence among men is highest in young adulthood, shortly after sexual debut, and then declines.22,23 MSM are also less likely to benefit from herd protection attained from HPV vaccination of females.

This recommendation has not changed, but clarifies that MSM are recommended to receive HPV vaccine at any age.

## Deleted recommendation

The following recommendation has been deleted:

Women who have received HPV vaccine are recommended to undergo cervical screening according to current guidelines.

The supporting information in this recommendation has been incorporated into the updated recommendation ‘Adolescents and young adults are recommended to receive 9vHPV vaccine from 9 years of age’. The information has been consolidated to refer to the current cervical screening guidelines, and includes a link to the guidelines.

## Benefits

There are several key benefits from the new recommendations:

The recommendation for people who previously missed their HPV vaccination to be vaccinated up to the age of 25 years aligns with changes to the NIP, which provides funded vaccine for this age group. This will increase opportunities for young people who miss their scheduled dose 1 to be protected against HPV-associated disease, including cancer.

Potential adverse events that may occur after dose 2 or 3 will be avoided by changing to a 1-dose schedule.

A single dose is likely to be more acceptable to people receiving the vaccine.

The current school-based program can continue to be used to deliver 1 dose instead of 2 doses. Reducing the number of doses may also simplify program delivery.

The resources saved by reducing the number of doses can be used to monitor and increase vaccination coverage, address and reduce inequities in coverage, and monitor HPV disease and related cancers.

## Potential risks

The potential risks that may arise from the new recommendations include the following:

HPV vaccination coverage may be affected. Reducing the number of school visits by changing to a 1-dose schedule means that people who are absent from school on the day of vaccination may not receive the vaccine through the school program that year, and may have to be vaccinated through another healthcare provider. However, first-dose vaccination coverage is high for both males and females in all states and territories,2 and 10–30% of first doses are already given through GPs or in other health settings outside the school program.24 While 1-dose coverage of HPV vaccination is currently high, we may potentially see declines in 1-dose coverage without specific efforts to maintain high and equitable coverage, especially in high-risk and vulnerable populations.

Any decreases in vaccination coverage, especially in girls, and reductions in long-term coverage (if protection is not lifelong) could affect Australia’s timeline for cervical cancer elimination, which is currently expected to be achieved as early as 2028. High rates of cervical screening will be essential to detect any decreases in vaccine effectiveness over time.

## Preference and values

The proposed changes to the use of HPV vaccines are in line with best clinical advice. It is expected that the changes will help to ensure that vaccination continues to provide a high level of protection, while avoiding unnecessary adverse events and allowing more efficient use of health resources. This is consistent with societal expectations of the best use of vaccines in Australia, including under the NIP.

Anyone can receive HPV vaccine for free under the NIP up to the age of 25. People aged 26 and over who are recommended to receive the vaccine will need to pay out-of-pocket costs to receive the vaccine.

## Additional information to be included in the Australian Immunisation Handbook

The Handbook section [Vaccination for people who are immunocompromised](https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised) has also been updated in line with updates to HPV vaccine recommendations. Changes have been made in the following sections:

[People who have completed cancer therapy](https://immunisationhandbook.health.gov.au/contents/vaccination-for-special-risk-groups/vaccination-for-people-who-are-immunocompromised#people-who-have-completed-cancer-therapy)

[Table. Recommended vaccines for people before and after a solid organ transplant](https://immunisationhandbook.health.gov.au/resources/tables/table-recommended-vaccines-for-people-before-and-after-a-solid-organ-transplant)

[Table. Recommendations for revaccination after haematopoietic stem cell transplant in children and adults](https://immunisationhandbook.health.gov.au/resources/tables/table-recommendations-for-revaccination-after-haematopoietic-stem-cell-transplant-in-children-and-adults)

## Glossary

A [glossary of technical terms](https://immunisationhandbook.health.gov.au/technical-terms) is available on the Australian Immunisation Handbook website.

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