

Protocol for Human Papillomavirus Vaccine (Gardasil® 9)

1. What's New

A. N/A

2. Immunization Protocol

- A. Administer a 0.5-mL dose, IM, of HPV vaccine to persons ≥9 years of age.
- B. HPV vaccine may be given simultaneously with all routine adolescent or adult vaccines.

3. Vaccine Schedule¹

HPV Vaccine ¹ (Gardasil® 9) Dose and Route – 0.5-mL, IM		
2 Dose Series		
Dose	Acceptable Age Range	Dose spacing
1	9-14 years	
2		5-12 months after dose 1
3 Dose Series*		
1	15-45 years [◊]	
2		4 weeks after dose 1
3		3 months after dose 2 and 5 months after dose 1

*Healthy persons who begin the HPV series before their 15th birthday may complete the series with 2 doses.² Immunocompromised persons and catch-up for persons beginning the series ≥15 years of age need 3 doses to complete series.²

◊ Shared clinical decision-making regarding HPV vaccination is recommended for some adults aged 27 through 45 years who are not adequately vaccinated.³ See section 5 for guidance.

4. Licensed Vaccines¹

Product Name	Vaccine Components	Presentation	FDA Approved Age Range	Thimerosal
Gardasil® 9 ¹	Human Papillomavirus 9-valent Vaccine, Recombinant Suspension	0.5-mL single-dose vials 0.5-mL pre-filled syringes	9 – 45 years	None

5. Recommendations for Use²

- A. Children and adults aged 9 through 26 years: HPV vaccination is routinely recommended at age 11 or 12 years; vaccination can be given starting at age 9 years. Catch-up HPV vaccination is recommended for all persons through age 26 years who are not adequately vaccinated.
- B. Adults aged >26 years: Ideally, HPV vaccination should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. Catch-up HPV vaccination is not recommended for all adults aged >26 years. Instead, ACIP recommends HPV vaccination for persons aged 27–45 years on the basis of shared clinical decision-making. Shared clinical decision-making refers to an individually based vaccine

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recommendation informed by a decision-making process between the health care provider and the patient or parent/guardian.

- Pharmacists can engage in shared clinical decision making to discuss HPV vaccination with persons aged 27-45 years who are not adequately vaccinated and are most likely to benefit. HPV vaccination does not need to be discussed with most adults aged >26 years. HPV vaccines are not licensed for use in adults aged >45 years.
- Pharmacists are authorized to administer HPV vaccine if one of the following risk factors is present:
 - At any age, having a new sex partner is a risk factor for acquiring a new HPV infection
 - Adults with few or no previous sex partners might not have been infected with HPV in the past, therefore they may have a higher chance of getting HPV infection from a new sex partner in the future

C. Special populations and medical conditions: These recommendations for children and adults aged 9 through 26 years and for adults aged >26 years apply to all persons, regardless of behavioral or medical risk factors for HPV infection or disease. For persons who are pregnant, HPV vaccination should be delayed until after pregnancy; however, pregnancy testing is not needed before vaccination. Persons who are breastfeeding or lactating can receive HPV vaccine.

6. Contraindications¹

- A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
- B. Hypersensitivity to yeast
- C. Pregnancy: HPV vaccines should not be administered during pregnancy. Exposure during pregnancy can be reported to the Merck Pregnancy Registry at 1-800-986-8999.

7. Warnings and Precautions⁴

- A. Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.
- B. Syncope after immunization is common among adolescents. Have the client sit for 15 minutes after vaccination

8. Other Considerations

- A. Individuals with altered immunocompetence may have reduced immune responses.⁴
- B. Cervical cancer screening should be initiated at 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.⁶
- C. Women with an equivocal or abnormal pap test, positive Hybrid Capture II® high-risk test or genital warts can receive HPV vaccine. Recipients should be advised that the vaccine has no therapeutic value and will only provide protection against infection with HPV types not already acquired.⁵

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9. Side Effects and Adverse Reactions¹

Adverse Event	Frequency
Injection Site Reactions	
Pain, redness, or swelling at vaccination site	Up to 90%
Systemic Adverse Reactions	
Low-grade fever of up to 101°F	Up to 10%
Fever of 102°F or more	Up to 1.5%

10. Storage and Handling¹

- A. Store medications according to OAR 855-041-1036.
- B. All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

Vaccine	Temp	Storage Issues	Notes
Gardasil® 9	Store at 2° to 8°C (36° to 46°F)	Do not freeze, protect from light	Administer as soon as possible after being removed from refrigeration

11. References

1. Merck and Company, HPV 9 (Gardasil® 9) 2014 package insert. Available at: <https://www.fda.gov/files/vaccines,%20blood%20&%20biologics/published/Package-Insert--Gardasil.pdf>. Accessed 5 June 2023.
2. Meites E, Kempe A, Markowitz LE. Use of a 2-dose schedule for human papillomavirus vaccination: updated recommendations of the Advisory Committee on Immunization Practices. MMWR 2016; 65:1405–8. Available at: <http://dx.doi.org/10.15585/mmwr.mm6549a5> Accessed 5 June 2023.
3. Meites E, Szilagyi PG, Chesson HW, Unger ER, Romero JR, Markowitz LE. Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices. MMWR Morb Mortal Wkly Rep 2019;68:698–702. Available at: <http://dx.doi.org/10.15585/mmwr.mm6832a3> Accessed 23 July 2023.
4. Ezeanolue E, Harriman K, Hunter P, Kroger A, Pellegrini C. General Best Practices Guidelines for Immunization. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html> Accessed 5 June 2023.
5. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2014; 63(RR05). Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6305a1.htm> Accessed 5 June 2023.
6. Petrosky E, Bocchini JA, Hariri S, Chesson H, Curtis CR, Saraiya M, et al. Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the Advisory Committee on Immunization Practices. MMWR 2015; 64;300–4. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm> Accessed 5 June 2023.

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12. Appendix

- A. Centers for Disease Control and Prevention (CDC). Shared Clinical Decision-Making HPV Vaccination for Adults Aged 27-45 Years: Job Aid for Healthcare Professionals. Atlanta, GA: US Department of Health and Human Services, CDC; 2019.

<https://www.cdc.gov/vaccines/hcp/admin/downloads/ISD-job-aid-SCDM-HPV-shared-clinical-decision-making-HPV.pdf>

PROPOSED