

## Immunization Protocol

### 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE: HPV9 (Gardasil® 9)

Last Reviewed	24 Aug 2023
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### 1. What's new

Added guidance for HPV shared clinical decision-making in patients 27–45 years of age.<sup>7</sup>

## 2. Oregon immunization pharmacy protocol

- A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
- B. Screen clients for contraindications.
- C. Provide a current Vaccine Information Statement (VIS), answering any questions.
- D. Record all required data elements in the client's permanent health record.
- E. Verify needle length for IM injection.
- F. To avoid shoulder injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper intramuscular administration technique.
- G. Give the 0.5-mL dose of HPV vaccine intramuscularly IM, preferably in the deltoid muscle.
- H. HPV may be given simultaneously with all routine adolescent or adult vaccines.
- I. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

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Health Officer Signature

Date

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Health Officer Signature

Date

### 3. Vaccine schedule for HPV9

Dose and Route: 0.5-mL IM <sup>1</sup>				
Dose	Preferred age	Minimum acceptable age	Minimum acceptable spacing	Recommended spacing
2-dose series: <b>Healthy</b> persons who begin the HPV series before their 15 <sup>th</sup> birthday may complete the series with 2 doses. <sup>3</sup>				
1	11 to 12 years	9 years		
2			5 months after dose 1	6–12 months after dose 1
Immunocompromised persons and catch-up for persons beginning the series ≥15 years of age need 3-doses. <sup>3</sup> See § 5, Recommendations for use below.				

### 4. Licensed HPV9 vaccine<sup>1</sup>

Human Papillomavirus 9-Valent		
Trade Name	Presentation	Acceptable age range
Gardasil 9	0.5-mL single dose vials	9–45 years
	0.5-mL prefilled syringes	

### 5. Recommendations for use<sup>3</sup>

Routine HPV9 Vaccine healthy* children, initiated before 15 years of age				
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing	Recommended Spacing
1	11 years	9 years		
2			5 months after dose 1	6–12 months after dose 1

HPV9 Vaccine for immunosuppressed patients* <u>or</u> catch-up initiated at or after 15 years of age			
Dose	Preferred Age	Minimum Acceptable Age	Minimum Acceptable Spacing
1	11–45 years	9 years	
2			4 weeks after dose 1
3			3 months after dose 2 <b>and</b> 5 months after dose 1

\* A 3-dose series should be administered to persons with primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, such as B-lymphocyte or antibody deficiencies, complete or partial T-lymphocyte defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease, or immunosuppressive therapy.

**Shared clinical decision-making (SCDM) for patients 27 through 45 years of age:<sup>7</sup>**

- At any age, having a new sex partner is a risk factor for getting a new HPV infection. However, this is only one possible consideration for SCDM.
- Adults with more HPV risk factors (for example, multiple previous sex partners or certain immunocompromising conditions) are more likely to have been infected with HPV in the past, so might have a lower chance of getting a new HPV infection in the future.
- Adults with fewer HPV risk factors (for example, few or no previous sex partners) are less likely to have been infected with HPV in the past, so might have a higher chance of getting a new HPV infection from a new sex partner in the future.

**6. Contraindications<sup>1</sup>**

- A. Hypersensitivity 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 precautions<sup>6</sup>

- 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. **Adverse Events:** Epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.<sup>6</sup>
- B. **Lactation:** Nursing women can receive HPV vaccine.<sup>5</sup>
- C. Individuals with altered immunocompetence may have reduced immune responses.<sup>6</sup>
- D. Cervical cancer screening should be initiated at 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.<sup>4</sup>
- E. Women with an equivocal or abnormal pap test, positive Hybrid Capture II<sup>®</sup> 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.<sup>5</sup>

## 9. Side effects and adverse reactions<sup>1</sup>

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 handling<sup>1</sup>

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°–8°C (36° to 46°F)	Do not freeze, protect from light	Administer as soon as possible after being removed from refrigeration

## 11. Adverse events reporting<sup>6</sup>

Report suspected adverse events to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>.

VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>

Event and interval from vaccination
A. Anaphylaxis or anaphylactic shock (7 days)
B. Shoulder Injury Related to Vaccine Administration (7 days)
C. Vasovagal syncope (7 days)
D. Any acute complication or sequelae (including death) of above events (interval – not applicable)
E. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval – see package insert).

## 12. References

1. Merck and Company, HPV 9 (Gardasil®9) 2023 package insert. Available at: [www.merck.com/product/usa/pi\\_circulars/g/gardasil\\_9/gardasil\\_9\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf). Accessed 24 Aug 2023.
2. 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 2019; 68:698–702. Available at: [www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf](http://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf) Accessed 24 Aug 2023.
3. 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: [www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf](http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf) Accessed 24 Aug 2023.
4. 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: [www.cdc.gov/mmwr/pdf/wk/mm6411.pdf](http://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf)

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5. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recommendations and Reports 2014; 63. Available at: [www.cdc.gov/mmwr/pdf/rr/rr6305.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf) Accessed 24 Aug 2023.
6. Kroger A, Bahta L, Long S, Sanchez P. General Best Practices Guidelines for Immunization. Available at: [www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf](http://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/downloads/general-recs.pdf) Accessed 24 Aug 2023.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this pharmacy protocol is available at: [protocols](#)