

Model Immunization Protocol

| 9-VALENT HUMAN PAPILLOMAVIRUS VACCINE: HPV9 (Gardasil® 9) | |
|--|------------------|
| Last Reviewed | 9 September 2020 |
| Last Revised | 9 September 2020 |
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1. What’s new

Expands the recommended age range for men through 26 years of age.²

2. Oregon model immunization 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 and precautions.
- 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.
- J. This order does **not** cover Advisory Committee on Immunization Practices (ACIP) recommendations that involve shared clinical decision making. Shared clinical decision making means the decision to vaccinate should be based on a discussion of benefits and risks between the patient and the clinician, and the clinician would then prescribe the vaccine.

Health Officer Signature

Date

Health Officer Signature

Date

3. Vaccine schedule for HPV9

| Dose and Route: 0.5-mL IM ¹ | | | | |
|---|----------------|------------------------|----------------------------|--------------------------|
| Dose | Preferred age | Minimum acceptable age | Minimum acceptable spacing | Recommended spacing |
| 2-dose series: Healthy persons who begin the HPV series before their 15 th birthday may complete the series with 2 doses. ³ | | | | |
| 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. ³ See § 5, Recommendations for use below. | | | | |

4. Licensed HPV9 vaccine¹

| Human Papillomavirus 9-Valent | | |
|-------------------------------|---------------------------|----------------------|
| Trade Name | Presentation | Acceptable age range |
| Gardasil® 9 | 0.5-mL single dose vials | 9–26 years* |
| | 0.5-mL prefilled syringes | |

*27–45 years by prescription only.

5. Recommendations for use³

| 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* or
catch-up initiated at or after 15 years of age**

| Dose | Preferred Age | Minimum Acceptable Age | Minimum Acceptable Spacing |
|------|---------------|------------------------|--|
| 1 | 11-15 years | 9 years | |
| 2 | | | 4 weeks after dose 1 |
| 3 | | | 3 months after dose 2 and 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.

6. Contraindications¹

- 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 precautions⁶

- 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.⁶
- B. **Lactation:** Nursing women can receive HPV vaccine.⁵
- C. Individuals with altered immunocompetence may have reduced immune

responses.⁶

- D. Cervical cancer screening should be initiated at 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.⁴
- E. 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

9. Side effects and adverse reactions¹

| Injection Site Reactions | |
|---|---------------------|
| Pain, redness or swelling at vaccination site | Frequent, up to 75% |
| Systemic Adverse Reactions | |
| Low-grade fever of up to 101°F | Uncommon, up to 10% |
| Fever of 102°F or more | Rare, up to 1.5% |

10. Storage and handling¹

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 reporting⁶

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) |

Event and interval from vaccination

- 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) 2014 package insert. Available at: www.merck.com/product/usa/pi_circulars/g/gardasil_9/gardasil_9_pi.pdf. Accessed 24 March 2020.
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: <https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf> Accessed 24 March 2020.
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: <https://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf> Accessed 24 March 2020.
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: <https://www.cdc.gov/mmwr/pdf/wk/mm6411.pdf> Accessed 24 March 2020.
5. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR 2014; 63(RR05). Available at: <https://www.cdc.gov/mmwr/pdf/rr/rr6305.pdf> Accessed 24 March 2020.
6. 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/downloads/general-recs.pdf> Accessed 24 March 2020.

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 immunization protocol is available at: [immunization protocols](#)

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

13. Appendix