

OREGON HEALTH AUTHORITY
IMMUNIZATION PROTOCOL FOR PHARMACISTS
Human Papilloma Virus Vaccine (Gardasil 9[®])¹

Revisions as of 01-04-2017^{2, 3}: After October 2016, 2vHPV and 4vHPV are no longer distributed in the U.S.

Number of recommended doses is based on age at administration of the first dose.

- The first HPV vaccine dose is routinely recommended at 11–12 years of age. For the 2-dose series, the second dose should be administered 6–12 months after the first dose.
- Persons may initiate the 2-dose series as late as the day before the fifteenth birthday and complete the series with a second dose at least 5 months later.
- Persons who start the series at ages 15–26 years will continue to need three doses.
- Persons aged 9–14 years who have already received two doses of HPV vaccine less than 5 months apart will require a third dose.
- Repeat any dose inadvertently given SQ. There is no minimum spacing between the invalid SQ dose and the IM repeat dose.
- 9vHPV can be used to complete any 2vHPV or 4vHPV series.

I. Order:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients ≥ 7 years for contraindications.
3. Provide a current VIS, answering any questions.
4. Record all required data elements in the client's permanent health record.
5. Give the 0.5-mL dose of HPV vaccine intramuscularly **IM** (deltoid preferred).
6. HPV vaccine may be given simultaneously with all routine adolescent or adult vaccines.
7. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

Immunizing Pharmacist Signature

Date

II. LICENSED HUMAN PAPILLOMAVIRUS (9vHPV) VACCINE^{*◇}

Product Name	Vaccine Components	Acceptable Age Range	Recommended Age	Thimerosal
GARDASIL 9 ^{®1} (9vHPV)	Protein of HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58	Persons 9–26 [◇] years	11–12 years	None
GARDASIL ^{®4*§} (4vHPV)	Protein of HPV types 6, 11, 16, and 18			

* 4vHPV is designed to prevent anogenital warts caused by types 6 and 11, and cancers caused by types 16 and 18. 9vHPV is designed to prevent infection and disease caused by an additional five strains: 31, 33, 45, 52, and 58 which, like 16 and 18, are causes of cervical cancer, cervical dysplasia, vulvar or vaginal dysplasia, and anal cancer.^{1, 4, 5}

◇ ACIP recommends routine HPV vaccination for all persons 9–21 years of age, for all females 22–26 years of age and for some males 22–26 years of age.⁵ See section III recommendations for special populations and medical conditions.²

§ All lots of Gardasil[®] (4vHPV) will expire by May 2017.

III. RECOMMENDATIONS FOR USE

Routine vaccination of persons 11–12 years of age with either the 2-dose or 3- dose series of HPV vaccine. The vaccine series can begin at age 9 years.²

Routinely Recommended for females 13–26 years of age and males 13-21 years of age not previously vaccinated or who have not completed the full HPV series.⁵

Special Populations: For gay, bisexual, and other men who have sex with men (MSM), ACIP recommends routine HPV vaccination as for all adolescents, and initiation of vaccination through age 26 years for those who were not adequately vaccinated previously. For transgender persons, ACIP recommends HPV vaccination through age 26 years for those who were not adequately vaccinated previously.² Other males 22–26 years of age may be vaccinated.⁶

Medical Conditions: ACIP recommends HPV vaccination for immunocompromised females and males aged 9 through 26 years with three doses of HPV vaccine (at 0, 1–2, and 6 months). 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, since immune response to vaccination may be attenuated in these persons.^{2*}

* The recommendation for a 3-dose schedule does not apply to children aged <15 years with asplenia, asthma, chronic granulomatous disease, chronic heart, liver, lung, or renal disease, CNS anatomic barrier defects (e.g., cochlear implant), complement deficiency, diabetes, or sickle cell disease.²

IV. RECOMMENDED BLENDED VACCINE SCHEDULE FOR Gardasil[®] 4 or 9*

Dose and Route: 0.5mL IM [◇]				
2-dose Series: Healthy persons age 9–14 years and healthy persons who began the HPV series before age 15 years				
Dose	Recommended Age [§]	Minimum Age	Recommended Spacing	Minimum Spacing [‡]
1	11–12 years	9 years		
2			6–12 months after 1 st dose	5 months after 1 st dose**
3-dose Series: Healthy persons 15–26 years of age who have not started the 2-dose series				
Immunocompromised persons 9–26 years of age				
Dose	Recommended Age [§]	Minimum Age	Recommended Spacing	Minimum Spacing [‡]
1	15–26 years	9 years		
2			1–2 months after 1 st dose	4 weeks after 1 st dose
3**			6 months after 1 st dose	12 weeks after 2 nd dose and 24 weeks after 1 st dose

* If vaccine history or specific HPV product administered previously is unknown, any available HPV vaccine product may be used to continue or complete the series.²

◇ CDC and the manufacturers recommend that a dose of HPV vaccine given by any route other than intramuscular should be repeated. There is no minimum interval between the invalid (subcutaneous) dose and the repeat dose.⁷

§ Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

‡ For retrospective checking, doses that violate the minimum spacing or age by 4 or fewer days do not need to be repeated. Doses administered 5 days or earlier than the minimum interval or age should be repeated as appropriate for age.⁷

** Persons who receive two doses of HPV vaccine less than 5 months apart require a third dose.²

Note: If the vaccination schedule is interrupted, the vaccine series does not need to be restarted.²

V. CONTRAINDICATIONS:

- Hypersensitivity to any vaccine component¹
- Hypersensitivity to yeast¹
- Pregnancy¹: HPV vaccines are not to be given during pregnancy. If a woman is found to be pregnant after initiation of HPV vaccination series, the remainder of the 3-dose series should be delayed until completion of the pregnancy. Exposure during pregnancy can be reported to the Merck Pregnancy Registry at 1-800-986-8999. All clinics and pharmacies enrolled with the VFC program **must** report to VAERS any instance of HPV vaccination during pregnancy (see section X).

VI. PRECAUTIONS:

- HPV vaccine can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever)¹
- Vaccination of people with moderate or severe acute illnesses should be deferred until after the illness improves.¹
- Have the client sit or lie down, with feet elevated if possible, for 15 minutes of observation in case of syncope.¹

VII. SIDE EFFECTS AND ADVERSE REACTIONSTable 1: Injection site and systemic adverse reactions occurring within five days of vaccination of persons 16–26 years of age with any dose of Gardasil 9[®].¹

Number followed for Safety	Girls and Women N=7071 %	Boys and Men N=1394 %
Injection Site Adverse Reactions		
Pain (any)	89.9	63.4
Redness (any)	34.0	20.7
Swelling (any)	40.0	20.2
Systemic Adverse Reactions	N=7022	N=1394
Temperature ≥100	6.0	4.4
Temperature ≥102	1.0	0.6
Age in Years		
	9–15	
	N =299	N=639
Injection Site Adverse Reactions		
Pain (any)	89.3	71.5
Redness (any)	34.1	24.9
Swelling (any)	47.8	26.9
Systemic Adverse Reactions	N=299	N=639
Temperature ≥100	6.7	10.4
Temperature ≥102	1.3	1.4
GARDASIL 9 [®] package insert table 1 page 5 and table 3 page 7 ¹		

* Rates of adverse reactions for all ages and genders were higher for Gardasil 9[®] than for Gardasil 4[®]. See Gardasil 4[®] package insert for specifics.⁴

VIII. OTHER CONSIDERATIONS

- A. Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.⁵
- B. Abnormal Pap test: This vaccine can be given to females who have an equivocal or abnormal Pap test, a positive Hybrid Capture II® high-risk test, or genital warts. However, vaccine recipients should be advised that the vaccine will not have any therapeutic effect on existing Pap test abnormalities, HPV infection or genital warts. Vaccination of these females would provide protection against infection with vaccine HPV types not already acquired.⁶
- C. Lactating women can receive HPV vaccine.⁶
- D. HPV vaccine is recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those who have had transplants or HIV infection), who have not been vaccinated previously or have not completed series. These individuals are more likely to develop HPV-associated disease and cancer.^{5,6}
- E. It is unclear whether there will be any difference in response to vaccination between immunocompromised and immunocompetent persons.⁶

IX. STORAGE AND HANDLING ^{1, 4}

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 [®] (4vHPV) and GARDASIL 9 [®] (9vHPV)	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

X.ADVERSE EVENTS REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS). The VAERS online report form is available at <https://vaers.hhs.gov/esub/step1>.

A pharmacist who administers any vaccine must report to the OHA ALERT Immunization Information System in a manner prescribed by OHA within 15 days of administration. This replaces the former requirement to notify the primary health care provider. A pharmacist is not required to notify the primary health care provider. Oregon Administrative Rule 855-019-0290-(2)(3).^{8, 9}

Electronic copy of this standing order is available at:
1.usa.gov/PharmacyImmunizationProtocols

REFERENCES

1. Gardasil 9[®] package insert (p5). Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf. Accessed 30 December 2016.
2. CDC. Use of a 2-dose schedule for human papilloma virus vaccination. Updated recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2016; 65:1405–8. Available at: www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6549a5.pdf Accessed 30 December 2016.
3. CDC. Advisory Committee on Immunization Practices (ACIP). Vaccines for Children (VFC). Vaccines to prevent human papilloma virus infections. Resolution No. 18/16-2. Available at: www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2016-10-2-hpv.pdf Accessed 30 December 2016.
4. Gardasil 4vHPV package insert. 2015. Available at: www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf Accessed 30 December 2016.
5. CDC. Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the Advisory Committee on Immunization Practices (ACIP), 2015. MMWR 2015; 64:300–4. Available at: www.cdc.gov/mmwr/pdf/wk/mm6411.pdf. Accessed 30 Dec 2016.
6. CDC. Human papillomavirus vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2014. MMWR 2014; 63 (RR-5):1–30. Available at: www.cdc.gov/mmwr/preview/mmwrhtml/rr6305a1.htm?s_cid=rr6305a1_e Accessed 30 Dec 2016.
7. CDC. General Recommendations on Immunizations. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2011; 60 (RR-2):1–61. Available at: www.cdc.gov/mmwr/pdf/rr/rr6002.pdf. Accessed 30 December 2016.
8. State of Oregon, Administration of Vaccines by Pharmacists: 855–019–270. Available at: www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf Accessed 11 August 2015.

9. Oregon Administrative Rule. Board of Pharmacy. Division 19. Licensing of pharmacists: 855-019-0290 (2). Available at:
http://www.oregon.gov/pharmacy/Imports/Rules/December10/855-019_Perm.pdf
Accessed 11 September 2015.

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.