OREGON STATE PUBLIC HEALTH DIVISION, DHS
IMMUNIZATION PROGRAM

QUADRIVALENT HUMAN PAPILLOMAVIRUS (HPV) VACCINE

Revisions as of 01/08

- Lowered the recommended age for starting to administer HPV vaccine to Oregon females to 9 years. Section IV, p. 3.(Footnote 3 is new).
- Syncope after HPV vaccine added as a precaution. Section VI-C, p. 3.

I. ORDER:

1. Screen for contraindications.
2. Provide the current HPV Vaccine Information Statement (VIS), answering any questions.
3. Obtain a signed Vaccine Administration Record (VAR).
   a. Give HPV vaccine (0.5 ml) intramuscularly into the deltoid muscle or the higher anterolateral area of the thigh of female vaccinees 9–26 years of age.
   b. Simultaneous vaccination may be given with all routine childhood or adult vaccines.

Signature Health Officer or Medical Provider Date

January 2008

II. LICENSED QUADRIVALENT HUMAN PAPILLOMAVIRUS (HPV) VACCINE[1]

Product Name	Vaccine components	Acceptable Age Range	Thimerosal
Gardasil®	Recombinant protein of HPV types 6, 11, 16, and 18	9–26 years[2]	None

[1] Designed to prevent cervical cancer, cervical dysplasia, vulvar or vaginal dysplasia, and genital warts caused by HPV types in the vaccine. This vaccine is not licensed for males.
[2] i.e., ≥9 years, but <27 years of age.

III. RECOMMENDATION FOR USE [1,2]

1. Routine vaccination with three doses of quadrivalent HPV vaccine is recommended for females 11–12 years of age.
2. The vaccination series can be started in females as young as 9 years of age.
3. Catch-up vaccination is recommended for females 13–26 years of age who have not been vaccinated previously or who have not completed the full vaccine series.

[1] This vaccine is not recommended for use in pregnancy.
[2] Females who are immunocompromised either from disease or medication can receive quadrivalent HPV vaccine. However, the immune response and vaccine effectiveness might be less than in females who are immunocompetent.

IV. VACCINE SCHEDULE

Dose and Route: 0.5 ml IM

DOSE	RECOMMENDED AGE [1,2]	MINIMUM AGE	RECOMMENDED SPACING	MINIMUM SPACING[4]
1	9–12 years[3]	9 years		
2			2 months after 1st dose	4 weeks after 1st dose
3			6 months after 1st dose	12 weeks after 2nd dose

[1] Catch-up vaccination is recommended for females 13–26 years of age who have not been vaccinated previously or who have not completed the full vaccine series.

[2] Ideally, vaccine should be administered before potential exposure to HPV through sexual contact.

[3] The ACIP-recommended age for vaccination is 11–12 years, but HPV vaccine may be administered to girls as young as 9 years of age. To maximize the likelihood that females will complete the 3-dose HPV series, the Oregon State Immunization Program's Medical Director and Immunization Policy Advisory Team, have recommended that providers take advantage of any opportunity to vaccinate girls as young as 9 years of age.

[4] Minimum spacing may be used when a person is behind schedule and needs to be brought up-to-date as quickly as possible or when travel is imminent. Although the effectiveness of accelerated schedules has not been evaluated in clinical trials, the Advisory Committee on Immunization Practices (ACIP) believes that the immune response induced with accelerated schedules will be adequate.

V. CONTRAINDICATIONS

A. History of immediate hypersensitivity to yeast or to any vaccine component.

VI. PRECAUTIONS

A. This vaccine can be administered to females with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections, with or without fever).
B. Vaccination of people with moderate or severe acute illness should be deferred until after the illness improves.
C. Syncope after vaccination. (Consider observing patients for 15 minutes after receipt of HPV vaccine).

VII. SIDE EFFECTS AND ADVERSE REACTIONS

Vaccine-related Injection-site and Systemic Adverse Experiences*			
Adverse Experience 1–5 days after vaccination	**Gardasil®** **(N = 5088)** **%**	**Aluminum-Containing Placebo** **(N = 3470)** **%**	**Saline Placebo** **(N = 320)** **%**
Injection Site			
Pain	83.9%	75.4%	48.6%
Swelling	25.4%	15.8%	7.3%
Erythema	24.6%	18.4%	12.1%
Pruritus	3.1%	2.8%	0.6%
Adverse Experience 1–15 Days after vaccination	**Gardasil®** **(N=5088)** %	**Placebo** **(N=3790)** **%**	
Systemic Fever	10.3%	8.6%	

***** This table copied from page 10 of the June 2006 Gardasil® package insert.

VIII. SPECIAL SITUATIONS

A. Pregnancy: Quadrivalent HPV vaccine is not recommended for use in pregnancy. The vaccine is in Pregnancy Category B; it has not been associated causally with adverse outcomes of pregnancy or adverse effects on the developing fetus. Data on vaccination during pregnancy are limited. If a vaccine dose has been administered during pregnancy no intervention is needed; but any exposure to vaccine during pregnancy should be reported to Merck's vaccine pregnancy registry at (800) 986-8999.

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 data from clinical trials do not indicate that the vaccine will 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.

C. Lactating women may receive quadrivalent HPV vaccine.

D. Immunocompromised females, either from disease or medication, may receive this vaccine. However, the immune response to vaccination and vaccine effectiveness might be less than in females who are immunocompetent.

E. Preventing syncope after vaccination: Through January 2007, the second most common report to VAERS following receipt of HPV vaccine was syncope (CDC, unpublished data). Vaccine administrators should consider observing patients for 15 minutes after they receive HPV.

IX. ADVERSE EVENT REPORTING

Adverse events following immunization should be reported by public providers to the Oregon State Public Health Immunization Program, using a Vaccine Adverse Events Reporting System (VAERS) form, according to state guidelines. Private providers report all adverse events directly to VAERS. VAERS phone number: 800- 822-7967, and the website address is: **www.vaers.org**

X. REFERENCES

1. CDC. Quadrivalent human papillomavirus vaccine. MMWR 2007; 56. Early Release. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr56e312.pdf.
2. Human Papillomavirus. In: *Epidemiology and Prevention of Vaccine-Preventable Diseases* ("Pink Book"). Atkinson W, Hamborsky J, Wolfe S, eds. 10th ed. Washington, DC: Public Health Foundation, 2007 283–93. Available at: http://www.cdc.gov/vaccines/pubs/pinkbook/default.htm.
3. CDC Advisory Committee on Immunization Practices Vaccines For Children Program. Vaccine to prevent human papillomavirus (HPV) infection. Resolution No. 6/06-2. Available at: http://www.cdc.gov/nip/vfc/acip_resolutions/0606hpv.pdf
4. Merck & Co., Inc. Gardasil® package insert. Available at http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf.

For more information or to clarify any part of the above order, consult with your health officer or call the Oregon Public Health Division's Immunization Program at 971-673-0300.

For a copy of this order visit our website at http://oregon.gov/DHS/ph/imm/provider/stdgordr.shtml. To request this material in an alternate format (e.g., braille), please call 971- 673-0300