IMMUNIZATION PROTOCOL FOR PHARMACISTS

QUADRIVALENT HUMAN PAPILLOMAVIRUS (HPV) VACCINE

I. ORDER:

1. Screen for contraindications.
2. Provide the current 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 of female vaccinees 18–26 years of age.
   b. Simultaneous vaccination may be given with all routine adolescent or adult vaccines.

Pharmacist signature Date

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

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

[1] Designed to prevent HPV 6, 11, 16, and /or 18 related cervical cancer, cervical dysplasias, vulvar or vaginal dysplasias, or genital warts.

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III. RECOMMENDATIONS FOR USE:

1. Routine vaccination with three doses of quadrivalent HPV vaccine is recommended for females 11-12 years of age.[1, 2]
2. The vaccination series can be started in females as young as 9 years of age.[1,2]
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, 2]

[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]	RECOMMENDED SPACING	MINIMUM SPACING[3]
1	18–26 years of age		
2		2 months after 1st dose	4 weeks after 1st dose
3		6 months after 1st dose	8weeks after 2nd dose

[1] Catch-up vaccination is recommended for 18-26 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] This can occur when a person is behind schedule and needs to be brought-up-to-date as quickly as possible or when travel is impending. Although the effectiveness of all accelerated schedules has not been evaluated in clinical trials, the Advisory Committee on Immunization Practices (ACIP) believes that the immune response when accelerated intervals are used is acceptable and will lead to adequate protection.

V. CONTRAINDICATIONS	VI. PRECAUTIONS
A. History of immediate hypersensitivity to yeast or to any vaccine component.	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 illnesses should be deferred until after the illness improves.

VII. SPECIAL SITUATIONS

A. Pregnancy: Quadrivalent HPV vaccine is not recommended for use in pregnancy. The vaccine has not been associated causally with adverse outcomes of pregnancy or adverse events to the developing fetus.
   - Data on vaccination during pregnancy are limited. Any exposure to vaccine during pregnancy should be reported to the vaccine pregnancy registry at 1-800-986-8999.

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.
   - Vaccine recipients should be advised that data from clinical trials do not indicate 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 can receive quadrivalent HPV vaccine.

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

VIII. SIDE EFFECTS AND ADVERSE REACTIONS

Vaccine-related Injection-site and Systemic Adverse Experiences*			
Adverse Experience 1 to 5 days postvaccination)	**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 to 15 Days postvaccination	**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.

IX. ADVERSE EVENT REPORTING

Adverse events following immunization must be reported to the Vaccine Adverse Events Reporting System (VAERS) at 1-800-822-7967. Forms and procedures can be found at the VAERS website: www.vaers.orgT. In addition, a copy of the completed VAERS form should be sent to the patient's primary provider, per ORS 855-041-0510

X. REFERENCES

1. CDC. ACIP Provisional Recommendations for the Use of Quadrivalent HPV Vaccine. August 14, 2006. Available at: http://www.cdc.gov/nip/recs/provisional_recs/hpv.pdf.
2. CDC. Resolution No. 6/06-2; Advisory Committee on Immunization Practices Vaccines For Children Program Vaccine to Prevent Human Papillomavirus (HPV) Infection. Available at: http://www.cdc.gov/nip/vfc/acip_resolutions/0606hpv.pdf
3. Merck & CO. Inc. Gardasil® package insert. Available at http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasilpi.pdf

For more information or to clarify any part of the above order, consult with the vaccine recipient's primary health care provider, a consulting physician, or contact the Oregon State Public Health Immunization Program at (971) 673-0300.

Electronic copy of this protocol available at:
http://www.oregon.gov/dhs/ph/imm/provider/pharmpro.shtml
To request this material in an alternate format (e.g., braille), please call (971) 673-0300