OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM

9-Valent Human Papilloma Virus Vaccine (Gardasil 9®) ¹

Reviewed July 16, 2017

- No changes from the previous version.

**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 who initiate the 2-dose series as late as the day before the fifteenth birthday may complete the series at any time with a second dose at least 6 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 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.
II. LICENSED HUMAN PAPILLOMAVIRUS (9vHPV) VACCINE

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Vaccine Components</th>
<th>Acceptable Age Range</th>
<th>Recommended Age</th>
<th>Thimerosal</th>
</tr>
</thead>
</table>
| GARDASIL 9®¹  
(9vHPV)       | Protein of HPV types 6, 11, 16, 18, 31, 33, 45, 52, 58 | Persons 9–26⁰ 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

⁰ACIP 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.

The 3-dose series can be started at age 26 even if it will not be completed at age 26. The series should be completed regardless of the age of the patient (i.e., even if the patient is older than 26).⁶
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*

<table>
<thead>
<tr>
<th>Dose</th>
<th>Recommended Age§</th>
<th>Minimum Age</th>
<th>Recommended Spacing</th>
<th>Minimum Spacing‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11–12 years</td>
<td>9 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>6–12 months after 1st dose</td>
<td>5 months after 1st dose **</td>
</tr>
</tbody>
</table>

**2–dose Series: Healthy** persons age 9–14 years and healthy persons who began the HPV series before age 15 years

**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

<table>
<thead>
<tr>
<th>Dose</th>
<th>Recommended Age§</th>
<th>Minimum Age</th>
<th>Recommended Spacing</th>
<th>Minimum Spacing‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>15–26 years</td>
<td>9 years</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td>1–2 months after 1st dose</td>
<td>4 weeks after 1st dose</td>
</tr>
<tr>
<td>3**</td>
<td></td>
<td></td>
<td>6 months after 1st dose</td>
<td>12 weeks after 2nd dose and 24 weeks after 1st dose</td>
</tr>
</tbody>
</table>

* 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

Revised 07-2017
**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 REACTIONS

Table 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®.

<table>
<thead>
<tr>
<th>Number followed for Safety</th>
<th>Girls and Women N=7071</th>
<th>Boys and Men N=1394</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Injection Site Adverse Reactions</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain (any)</td>
<td>89.9</td>
<td>63.4</td>
</tr>
<tr>
<td>Redness (any)</td>
<td>34.0</td>
<td>20.7</td>
</tr>
<tr>
<td>Swelling (any)</td>
<td>40.0</td>
<td>20.2</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td>N=7022</td>
<td>N=1394</td>
</tr>
<tr>
<td>Temperature ≥100</td>
<td>6.0</td>
<td>4.4</td>
</tr>
<tr>
<td>Temperature ≥102</td>
<td>1.0</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Age in Years 9–15

<table>
<thead>
<tr>
<th>N=299</th>
<th>N=639</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Injection Site Adverse Reactions</strong></td>
<td></td>
</tr>
<tr>
<td>Pain (any)</td>
<td>89.3</td>
</tr>
<tr>
<td>Redness (any)</td>
<td>34.1</td>
</tr>
<tr>
<td>Swelling (any)</td>
<td>47.8</td>
</tr>
<tr>
<td><strong>Systemic Adverse Reactions</strong></td>
<td>N=299</td>
</tr>
<tr>
<td>Temperature ≥100</td>
<td>6.7</td>
</tr>
<tr>
<td>Temperature ≥102</td>
<td>1.3</td>
</tr>
</tbody>
</table>

GARDASIL 9® package insert table 1 page 5 and table 3 page 7

* 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.
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.\textsuperscript{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\textsuperscript{®} 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.\textsuperscript{6}

C. Lactating women can receive HPV vaccine. \textsuperscript{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.\textsuperscript{5,6}

E. It is unclear whether there will be any difference in response to vaccination between immunocompromised and immunocompetent persons.\textsuperscript{6}
IX. STORAGE AND HANDLING

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).

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GARDASIL® (4vHPV) and</td>
<td>Store at 2°–8°C (36 to</td>
<td>Do not freeze</td>
<td>Administer as soon as possible after being</td>
</tr>
<tr>
<td>GARDASIL 9® (9vHPV)</td>
<td>46°F)</td>
<td>Protect from light</td>
<td>removed from refrigeration</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

X. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html

1. Save a copy of the report number for your records
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table*:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

Event and interval from vaccination

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Anaphylaxis or anaphylactic shock (7 days)</td>
<td></td>
</tr>
<tr>
<td>B. Shoulder Injury Related to Vaccine Administration (7 days)</td>
<td></td>
</tr>
<tr>
<td>C. Vasovagal syncope (7 days)</td>
<td></td>
</tr>
<tr>
<td>D. Any acute complication or sequelae (including death) of above events</td>
<td></td>
</tr>
</tbody>
</table>
E. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval - see package insert)

Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

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 standing order is available at:
http://1.usa.gov/OregonStandingOrders
REFERENCES

1. Gardasil 9® package insert (p5). 2016. Available at:

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:


4. Gardasil 4vHPV package insert. 2015. Available at:

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:
