

**Oregon Immunization School/Facility/College Law
Advisory Committee:**

**Review of Human Papillomavirus (HPV)
Against Twelve Criteria for
School/Facility/College Immunization
Requirements**

Oregon Health Authority
Public Health Division
Immunization Program
800 NE Oregon Street, Suite 370
Portland, Oregon 97232
Phone: 971-673-0300
Fax: 971-673-0278

Web:

<http://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/Pages/index.aspx>

**Oregon School/Facility Immunization Advisory Committee:
Review of HPV Against Twelve Criteria for School/Facility/College
Immunization Requirements**

Process for Reviewing Antigens for Potential Inclusion in OAR 333-050-0050, 333-050-0130 and 333-050-0140.

Request for the inclusion of additional antigens or vaccines can come from the Oregon Immunization Program, IPAT (Immunization Policy Advisory Team), or from the community. Proposed changes to vaccine requirements are discussed with IPAT either in a regularly scheduled meeting or through electronic communication. IPAT will submit their comments and a request for consideration to the Oregon Immunization School Law Advisory Committee.

The Oregon School/Facility Immunization Advisory Committee was established as a part of the school law immunization requirements when the original legislation was passed in 1980. This Committee is composed of immunization stakeholders from the fields of public health, school health, school administration, medicine, day care, child advocacy and consumers (parents). Through consensus, the committee determines what vaccines (antigens) should be included in Oregon school immunization requirements.

Information about new vaccines and the disease they prevent, including transmission within schools, burden of disease, cost-effectiveness, effect on schools/counties and vaccine availability is presented at a scheduled meeting for committee consideration. The following criteria are an integral part of the discussion and the decision-making process. All 12 criteria must be considered. Members of the Committee are expected to rely on their professional and scientific judgment as well as available data when applying the criteria.

The Committee's recommendation is then submitted to the Oregon Immunization Program for consideration and possible action.

The 12 Criteria to Consider in Evaluating HPV

The following information is being presented for Committee consideration. ACIP has recently reduced the number of doses needed to complete the HPV vaccine series from three to two, as long as the series is initiated before the 15th birthday and there is at least five months between the two doses.¹ If the first dose is received on or after the 15th birthday, or fewer than 5 months are between the two doses, then three doses are recommended to complete the series.

1. **The vaccine containing this antigen is recommended by ACIP (Advisory Committee on Immunization Practices) and included on its recommended childhood and adolescent immunization schedule.**

From:

CDC. *Epidemiology and Prevention of Vaccine-Preventable Diseases*, 13th Edition, pages 175-186.²

"Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States... Epidemiologic studies showing a consistent association between HPV and cervical cancer were published in the 1990s. The first vaccine to prevent infection with four types of HPV was licensed in 2006... A 9-valent vaccine (Merck) was approved by the FDA in December 2014... HPV is transmitted by direct contact, usually sexual, with an infected person. Transmission occurs most frequently with sexual intercourse but can occur following non-penetrative sexual activity... Non sexual routes of genital HPV transmission include transmission from a woman to a newborn infant at the time of birth... Most HPV infections are asymptomatic and result in no clinical disease. Clinical manifestations of HPV infection include anogenital warts, recurrent respiratory papillomatosis, cervical cancer precursors (cervical intraepithelial neoplasia), and cancers, including cervical, anal, vaginal, vulvar, penile, and oropharyngeal cancer."

ACIP recommends that the HPV vaccine be administered to all females 11 – 26 years of age and all males 11 – 21 years of age, and males in certain groups 22-26 years of age. The vaccine can be given as young as 9 years of age. The series consists of two doses given over a period of six to twelve months to adolescents that initiate the series before their 15th birthday. Adolescents who initiate the series after age 15 need three doses of HPV vaccine administered over six months.

In October 2016, the Advisory Committee on Immunization Practices (ACIP) recommended a 2-dose vaccine schedule for adolescents initiating the HPV series from 9 through 14 years of age. Adolescents initiating the HPV series on or after their 15th birthday need 3 doses to complete the series.¹

2. The vaccine prevents disease with a significant morbidity and mortality in at least some subset of the Oregon's population.

In Oregon, there are approximately 23,000 abnormal pap smears, 120 new cases of cervical cancer and 40 deaths from cervical cancer annually.³ Additionally, men in Oregon have a rate of HPV-associated oropharyngeal cancer of 8.54 men per 100,000, a rate surpassed by only 13 other states.⁴

3. The vaccine (antigen) is cost-effective from a societal perspective in Oregon.

From:

Kim and Goldie. Health and Economic Implications of HPV Vaccination in the United States. *N Engl J Med.* 2008 Aug 21;359(8):821-32.⁵

"On the assumption that the vaccine provided lifelong immunity, the cost-effectiveness ratio of vaccination of 12-year-old girls was \$43,600 per quality-adjusted life-year (QALY) gained, as compared with the current screening practice. Under baseline assumptions, the cost-effectiveness ratio for extending a temporary catch-up program for girls to 18 years of age was \$97,300 per QALY... The results were sensitive to the duration of vaccine-induced immunity; if immunity waned after 10 years, the cost of vaccination of preadolescent girls exceeded \$140,000 per QALY, and catch-up strategies were less cost-effective than screening alone. The cost-effectiveness ratios for vaccination strategies were more favorable if the benefits of averting other health conditions were included or if screening was delayed and performed at less frequent intervals and with more sensitive tests; they were less favorable if vaccinated girls were preferentially screened more frequently in adulthood."

"The cost-effectiveness of HPV vaccination will depend on the duration of vaccine immunity and will be optimized by achieving high coverage in preadolescent girls, targeting initial catch-up efforts to women up to 18 or 21 years of age, and revising screening policies."

"When the potential benefits associated with preventing noncervical HPV-16-related and HPV-18-related cancers and HPV-6-related and HPV-11-related juvenile-onset recurrent respiratory papillomatosis were included, cost-effectiveness ratios were reduced. The magnitude of these reductions depended on the specific outcomes that were included and on assumptions about the efficacy of the vaccine. In all scenarios, the cost of vaccination of preadolescent girls remained below \$50,000 per QALY, and catch-up vaccination of girls to 18 years of age remained between \$50,000 and \$100,000 per QALY."

"Population-level effectiveness and cost-effectiveness of 2-dose and 3-dose schedules of 9vHPV in the United States have been modeled. Assuming both efficacy and duration of protection are similar with either schedule, a 2-dose series would be cost-saving and have similar population impact to a 3-dose series. Even if duration of protection is 20 years for a 2-dose series and lifelong for a 3-dose series, additional benefits of a 3-dose series would be relatively small, and a 2-dose series would be more cost-effective."¹

How do the morbidity/mortality statistics and cost-effectiveness estimates support or oppose the addition of this vaccine to school/facility/college requirements?

4. **The vaccine (antigen) has been used in the general population to demonstrate reduction in disease activity with similar level of effectiveness to that demonstrated prior to FDA approval.**

From the Vaccine Information Statement for HPV⁶

"Mild or moderate problems following HPV vaccine:

- Reactions in the arm where the shot was given:
 - Soreness (about 9 people in 10)
 - Redness or swelling (about 1 person in 3)
- Fever:
 - Mild (100°F) (about 1 person in 10)
 - Moderate (102°F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)"

Syncope or fainting has also been reported. It is suggested that patients wait 15 minutes after receiving the vaccine before leaving.²

It is difficult to demonstrate a reduction in disease outcomes as potential cases of cervical and other cancers may not appear until many years later.⁷ Reductions in precancerous lesions after HPV vaccination have been reported.

5. **The vaccine is necessary to prevent diseases known to be spread in schools or facilities, respectively and will increase safety in the school/facility environment.**

HPV vaccine does not prevent a disease that is readily spread in school settings. However, HPV infection is common in adolescents, with 7 million new HPV infections annually in the US in persons 15-24 years.²

6. **Requiring the vaccine for school law will make a significant difference in vaccine coverage in the preschool/school/college populations and vaccinating the infant, child, adolescent or young adult against this disease reduces the risk of person-to-person transmission.**

Vaccination provides protection because the virus has less opportunity to spread within the community, but risk factors related to sexual behavior including number of sex

partners, lifetime history of sex partners, and the partners' sexual histories affect the outcomes and potential for infection. Consideration should be given as to how the disease is transmitted and whether disease will spread in the school or college environment.

Vaccine uptake historically has increased when vaccines are added to the school requirements, as evidenced by current coverage for hepatitis A and B vaccines in Oregon. Only Rhode Island, Virginia and the District of Columbia currently include HPV vaccination as a school requirement.⁸ NIS-Teen data indicate that Rhode Island and the District of Columbia have higher HPV vaccination rates than Oregon, while Virginia has a lower vaccination rate than Oregon.⁹ Rhode Island does not enforce exclusion for lack of HPV vaccine.¹⁰ It is unclear if a requirement for HPV vaccine would increase vaccine uptake to the extent of other required vaccines in Oregon.

Would this vaccine requirement have the potential to reduce the spread of disease in the school/facility/college setting, or is the goal to reduce disease in the community at large? Would this vaccine requirement have the potential to reduce the number of cases of disease, or would it have the potential to prevent outbreaks?

7. The vaccine is acceptable to the Oregon medical community and the general public.

As of May 2016, the HPV up-to-date rate for teens aged 13 to 17 in Oregon was 32.8%, based on data from ALERT IIS. Recalculating the rate based on the two and three dose recommendations, the up-to-date rate increased to 41.1%.

HPV vaccine uptake may be hindered by the perception that the vaccine isn't necessary for adolescents before they initiate sexual activity. Additionally, vaccine providers may be uncomfortable discussing the benefits of the vaccine with young adolescents and their parents.

What level of provider/public acceptance and vaccine uptake are necessary so that addition of this vaccine to school/facility/college law would be most effective? If uptake and acceptance are very high, the requirement would have little impact, and if very low, the requirement would face a lot of resistance.

8. Ensure that sufficient funding is available on a state level to purchase vaccines for children who would need to meet the new law requirements.

Costs for the vaccine would be incurred by the local health department and both local health department and school staff would incur additional work load and programming costs as with other new vaccine requirements. Schools with approved computer system would face costs for programming and report changes to these computer systems.

9. There is a stable and adequate supply of vaccine.

GARDASIL®9 is the only product available for purchase in the U.S. at present time. Vaccine supply appears to be sufficient.

10. The administrative burdens of delivery and tracking of vaccine and Oregon school/facility rule implementation is reasonable in light of any other vaccines currently being phased in to law.

There would be significant financial costs in adding a new vaccine to the school law requirements. Projected costs are from \$100,000 – 150,000 for programming to track the vaccine and revise exclusion orders in the systems. Approximately 90% of children attending public schools are tracked through school-based computer assessment systems. These computer assessment systems must submit test cases and have their programs approved by the state.

The Hepatitis A requirements will be fully implemented in school year 2020-2021. Implementing overlapping phase-in schedules at the same time is difficult. The Advisory Committee previously affirmed their position to not add immunization requirements during the phase-in of other requirements, although consideration could be made in special circumstances such as increased disease incidence.¹¹

11. The burden of compliance for the vaccine is reasonable for the parent/caregiver.

Parents are already taking students in for the Tdap vaccine, a visit where adolescents are also recommended to receive MCV4 and HPV. A second dose of HPV could be administered at age 16 when the booster dose of MCV4 is recommended.

12. The vaccine is included in Oregon ALERT IIS for tracking and reporting purposes.

The vaccine is included in ALERT for tracking and reporting purposes.

What is a reasonable administrative burden for the school/facility/college, and would a new requirement for this vaccine create an acceptable or unacceptable burden on schools/facilities/colleges? What is a reasonable burden for the parent/caregiver?

References:

1. Available at: <https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm>
2. Available at: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hpv.pdf>
3. Available at: <http://www.oregon.gov/DHS/ph/imm/docs/HPVGuideintro.pdf>
4. Available at: <https://www.cdc.gov/cancer/hpv/statistics/state/oropharyngeal.htm>
5. Available at: <http://www.nejm.org/doi/pdf/10.1056/NEJMsa0707052>
6. Available at: <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/hpv.pdf>
7. Available at: http://ceip.us/wordpress/wp-content/uploads/2015/03/2015_Hariri_Redux_in_HPV_16-18_associated_high_Grade_cervical_lesions_following_HPV_Vaccine_intro_in_the_US.pdf
8. Available at: <http://www.immunize.org/laws/hpv.asp>
9. Available at: <https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/hpv/dashboard/2015.html>
10. Available at: <http://health.ri.gov/immunization/for/schools/index.php>
11. Minutes from the Immunization School/Facility Law Advisory Committee Meeting, November 13, 2008

Notes:

This document is expected to be updated in the future, as recommendations for immunization change and new data become available.