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## 9-Valent HPV Vaccine Now Available through the Alaska Immunization Program

### Background

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States; about 1 in 100 sexually active U.S. adults have genital warts at any given time.<sup>1</sup> Most HPV infections are asymptomatic and are eventually cleared by the immune system; however, some of these common infections persist and can lead to HPV-associated cancers and genital warts in both men and women. Additional information on the burden of HPV in the United States is provided below (Box).

#### Box. Burden of HPV Infection in the United States<sup>1</sup>

- ~79 million people currently infected
- ~14 million new infections occur annually
- Most new infections occur in persons aged 15–24 years
- Almost all cervical cancers are caused by HPV
- ~18,000 females and ~9,000 males are diagnosed with a cancer caused by HPV each year
- ~\$7 billion are spent annually on the prevention and treatment of HPV-related conditions

Roughly 40 HPV types are known to infect human mucosal and genital epithelium, and it is possible for someone to become infected with more than one HPV type. Certain HPV types can cause genital warts, oral and laryngeal papillomas, and low-grade cervical disease. Other HPV types act as carcinogens in the development of cervical, other anogenital, and oropharyngeal cancers; types 16 and 18 are associated with the majority of HPV-associated cancers.

A person can still be infected with HPV even if years have passed since having had sexual contact with an infected person. Most people do not realize they are infected. As such, they also don't know that they may be passing HPV to their sex partner(s).

### HPV Vaccine

In December 2014, a 9-valent HPV vaccine (9vHPV *Gardasil 9*<sup>®</sup>, Merck) was licensed for use in females and males in the United States.<sup>2</sup> The 9vHPV vaccine is a noninfectious virus-like particle (VLP) vaccine. The vaccine contains HPV 6, 11, 16, and 18 VLPs--the types targeted by the current quadrivalent HPV (4vHPV)--as well as five additional types, HPV 31, 33, 45, 52, and 58 VLPs.<sup>1</sup> The vaccine is manufactured using recombinant DNA technology; it does not contain live virus, thimerosal, or antibiotics.

### Efficacy

Vaccine efficacy is 99% for prevention of external genital lesions caused by all HPV vaccine types.<sup>2</sup> In a review of efficacy trials comparing 9vHPV with 4vHPV, 9vHPV was more cost-effective and had 97% efficacy in the prevention of cervical intraepithelial neoplasia grade 2 ( $\geq$ CIN2).<sup>3</sup> The vaccine should be administered before potential exposure to HPV; however, because there are a variety of HPV types covered by the vaccine, persons who have already been exposed to HPV should also be vaccinated so they are protected against the other HPV types. HPV vaccination does not preclude the need for Pap test screening.

### Adverse Reactions

The safety profiles were similar in 4vHPV and 9vHPV vaccines. Among females aged 9–26 years and males aged 9–15 years, mild to moderate local reactions were the most common adverse events reported and include injection site swelling (females 40%, males 29%), and erythema (females 34%, males 26%).<sup>3</sup>

### Recommendations for Immunization<sup>3</sup>

The 9vHPV vaccine is recommended by the Advisory Committee on Immunization Practice (ACIP) for females aged 9 through 26 years and males aged 9 through 21 years. The routine recommended age for administration is 11 through 12 years, but

catch-up immunization is recommended for unvaccinated females aged 13 through 26 years and males aged 13 through 21 years. Vaccination is recommended for previously unvaccinated males who are aged 22 through 26 years and who are either men who have sex with men (MSM) or who have an immunocompromising condition. ACIP does not recommend an additional 9vHPV booster dose for persons who previously completed a 2vHPV or 4vHPV series.

### Vaccine Availability

The 9vHPV vaccine is now available on the Alaska Vaccine Distribution Program's formulary. All females and males aged 9 through 18 years are eligible to receive state-supplied vaccine. In addition, females aged 19 through 26 years and males aged 19 through 21 years who meet eligibility criteria may receive state-supplied HPV vaccine.<sup>3</sup> Moreover males aged 22 through 26 years who are MSM or have an immunocompromising condition are also eligible. Providers are required to screen patients at each immunization visit to determine eligibility, and accurately document administration data into VacTrAK (Alaska's immunization information system).

Providers must administer the majority of their state-supplied 4vHPV vaccine before ordering and receiving 9vHPV supply. The 4vHPV vaccine should be used if it is the only HPV vaccine available in stock when patients are due for vaccination, and 9vHPV should be used to complete their series at subsequent visits.

### Recommended Schedule

HPV vaccine is administered intramuscularly in a 3-dose schedule.<sup>4</sup> The second dose is administered at least 1–2 months after the first dose and the third dose at least 6 months after the first dose. If the vaccine schedule is interrupted, the vaccination series does not need to be restarted. The vaccine may be administered at the same visit as other age-appropriate vaccines, including Tdap and meningococcal conjugate vaccines.

### Contraindications and Precautions

The only contraindication to administration of HPV vaccine is hypersensitivity, including severe allergic reaction to yeast or a vaccine component. Precautions to vaccination include moderate or severe acute illness, although a minor acute illness is not a reason to defer vaccination.

HPV vaccine is not recommended during pregnancy; however, if vaccine is administered during pregnancy, no intervention is needed. Patients and health care providers should report exposure to HPV vaccine during pregnancy by calling the manufacturer's pregnancy registry at (877) 888-4231.<sup>2</sup>

### Vaccine Storage

The 9vHPV vaccine should be stored at 35°–46° F (2°–8° C), protected from light, and removed from refrigeration immediately before administration. Vaccine must not be exposed to freezing temperatures; frozen vaccine should not be used and should be returned to the Alaska Immunization Program.

### References

1. CDC. HPV Vaccine Questions and Answers. Available at: <http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm>
2. CDC. Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of Advisory Committee on Immunization Practices. *MMWR* 2015;64(11):300-04. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm>
3. Alaska Vaccine Distribution Program homepage. Available at: <http://dhss.alaska.gov/dph/Epi/iz/Pages/vaxpacket/default.aspx>
4. Food and Drug Administration. Product approval information-licensing action, package insert. 2015. Available at: [http://www.merck.com/product/usa/pi\\_circulars/g/gardasil/gardasil\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/g/gardasil/gardasil_pi.pdf)