

## Recommendations for 2-Dose HPV Vaccination Schedule

### Background

Cervical cancer is the most prevalent human papillomavirus (HPV)-related cancer, and the fourth most common cancer in women worldwide; HPV types 16 and 18 are responsible for approximately 70 percent of cervical cancer cases.[1] In 2012, there were 528,000 new cases of and more than 266,000 deaths as a result of cervical cancer globally; the majority of these deaths occurred in less developed regions. Additionally, the leading cause of oropharyngeal cancers is prior HPV infection. HPV 16 is most strongly associated with this type of cancer with approximately 72% of current oropharyngeal cancers in the US being caused by HPV16.[2] HPV is also the cause of 91% of anal cancers, 75% of vaginal cancers, 69% of vulvar cancers, and 63% of penile cancers; HPV 16 is the cause of the majority of HPV-related cancers at these sites.[2]

Two HPV vaccines available, Gardasil (Merck) and Cervarix (GSK), are currently approved in about 100 countries, offering complete protection for females against HPV genotypes 16 and 18. On December 10, 2014, the Food and Drug Administration (FDA) announced approval of Gardasil-9 for the prevention of diseases caused by nine types of HPV. Gardasil-9 (9vHPV) adds protection against five additional types of HPV compared with Gardasil and Cervarix. 9vHPV has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58. Merck has since announced that the company will discontinue sales of Gardasil within the US by October 31, 2016.

The Centers for Disease Control and Prevention (CDC) recommends all boys and girls ages 11 or 12 years old get vaccinated. Catch-up vaccines are recommended for males through age 21 and females through age 26. Further, CDC recommends the vaccine for men who have sex with men through age 26; and for men and women with compromised immune systems through age 26 if they did not get fully vaccinated at a younger age.

### Issue

In December 2014, acknowledging the availability of at least two of the vaccines being available in most countries, the World Health Organization released *“Comprehensive cervical cancer control: a guide to essential practice”* calling for the vaccination of all girls ages 9 to 13 with a two-dose vaccine schedule when the first dose is received prior to age 15, and an interval of six months between first and second dose, noting the change will make it easier to administer and reduce cost.[3]

On October 7, 2016, the FDA approved a 2-dose schedule for 9vHPV for use in girls and boys ages 9-14, with the second dose given between 6-12 months after initiation. Further, in response to emerging data demonstrating the response generated with the 2-dose regimen is not inferior to that observed with three doses, the CDC’s Advisory Committee on Immunization Practices voted unanimously (with one recusal) to recommend the 9vHPV 2-dose schedule for persons initiating vaccination before their 15<sup>th</sup> birthday.

### Recommendation

ASCO is committed to supporting policies that will lessen the burden of cancer, and to promoting interventions that have the potential to save millions of lives through cancer prevention. Therefore, ASCO supports the recommendation for a 2-dose series of 9vHPV and encourages the CDC and primary care specialty organizations to work quickly to engage the primary care community about the benefits of the new schedule and strongly recommend efficient dissemination and implementation strategies.

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1. de Sanjose, S., et al., *Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study*. *The lancet oncology*, 2010. **11**(11): p. 1048-1056.
  2. Gillison, M.L., A.K. Chaturvedi, and D.R. Lowy, *HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women*. *Cancer*, 2008. **113**(S10): p. 3036-3046.
  3. *Comprehensive cervical cancer control: a guide to essential practice*; 2<sup>nd</sup> Ed: Available from: [http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/144785/1/9789241548953_eng.pdf).