

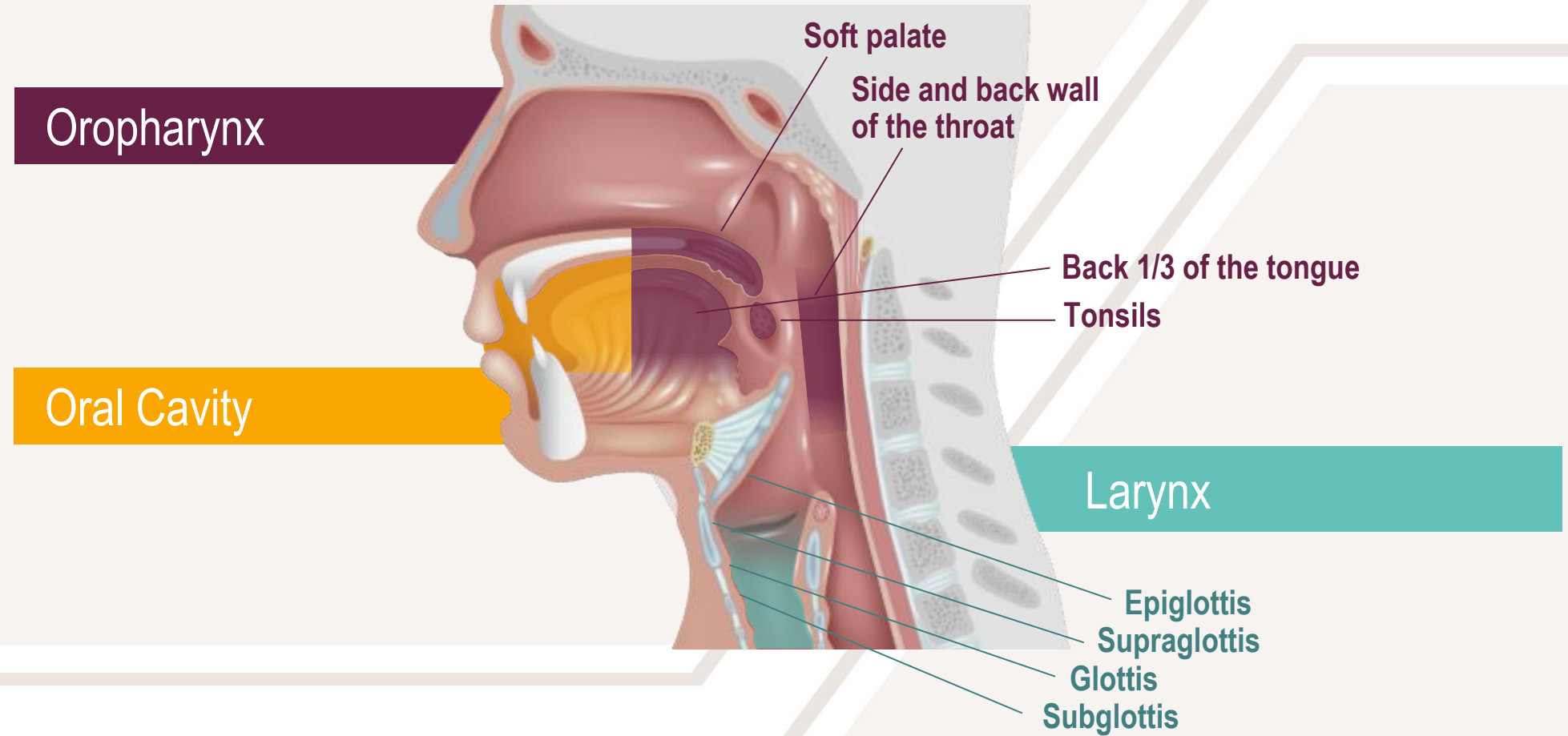
HPV AND HEAD AND NECK CANCERS: DO YOU KNOW THE FACTS?



HPV=human papillomavirus.

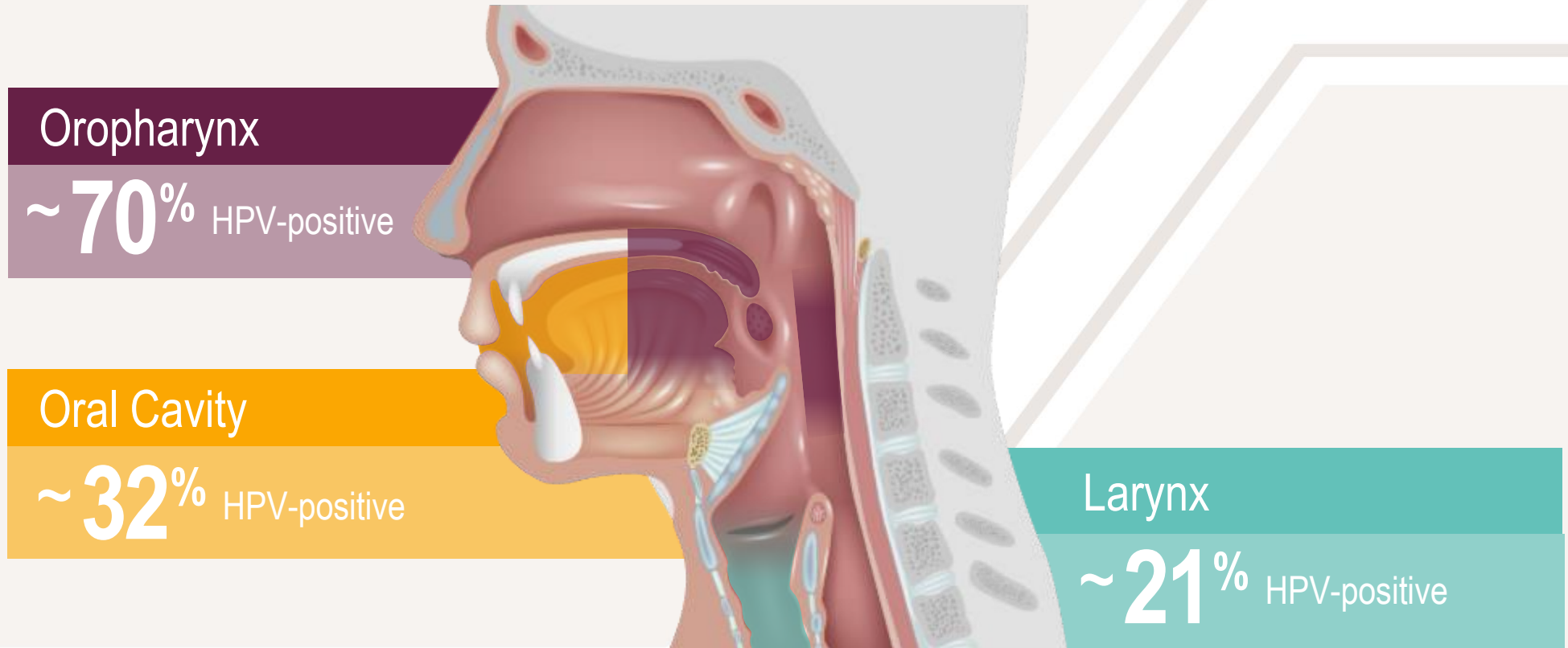


Anatomical Locations of Selected Head and Neck Cancers¹⁻³



1. NCI website. <https://www.cancer.gov/types/head-and-neck/patient/adult>. Last updated November 21, 2019. Accessed February 26, 2020. 2. NCI website. <https://www.cancer.gov/types/head-and-neck/patient/adult/oropharyngeal-treatment-pdq>. Last updated November 21, 2019. Accessed February 25, 2020. 3. NCI website. <https://www.cancer.gov/types/head-and-neck/patient/adult/laryngeal-treatment-pdq>. Last updated November 21, 2019. Accessed February 26, 2020.

HPV DNA Detection by Anatomic Location of Certain Head and Neck Cancers^{1,2}



The CDC partnered with 7 United States population-based cancer registries to obtain archival tissue for cancers diagnosed from 1993-2005, before the introduction of HPV vaccination. HPV testing was performed on 2670 case patients who were fairly representative of all participating cancer registry cases by age and sex. HPV type-specific detection percentages were determined by anatomic site and demographic characteristics.¹

Not all oropharyngeal, laryngeal, and oral cavity cancers are caused by HPV.¹

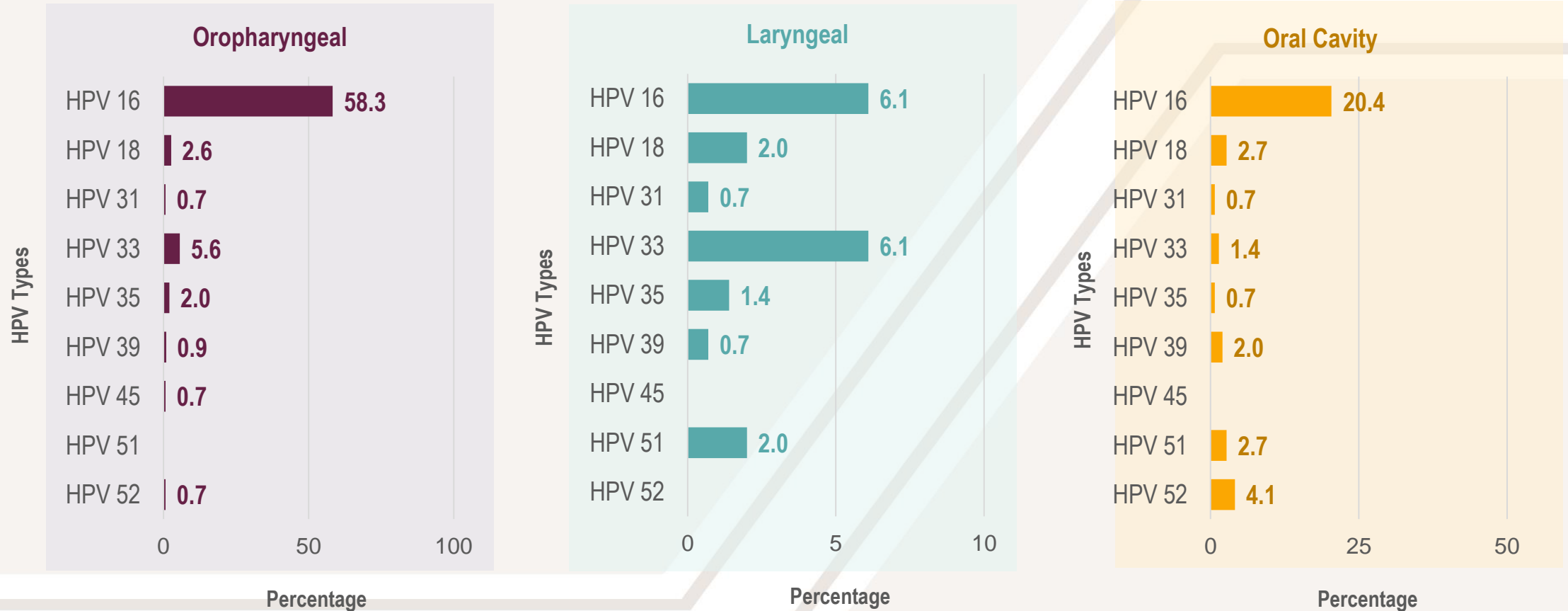
Detection of HPV DNA in an HPV study is insufficient to indicate a causal relation with the tumor.¹

CDC=Centers for Disease Control and Prevention; DNA=deoxyribonucleic acid; HPV=human papillomavirus.

1. Saraiya M, et al. *J Natl Cancer Inst.* 2015;107(6):djv086. 2. NCI website. <https://www.cancer.gov/types/head-and-neck/patient/adult/oropharyngeal-treatment-pdq>. Last updated November 21, 2019. Accessed February 25, 2020.

HPV Type Detection Differed Depending on Anatomical Location

Selected HPV types per Saraiya (2015)



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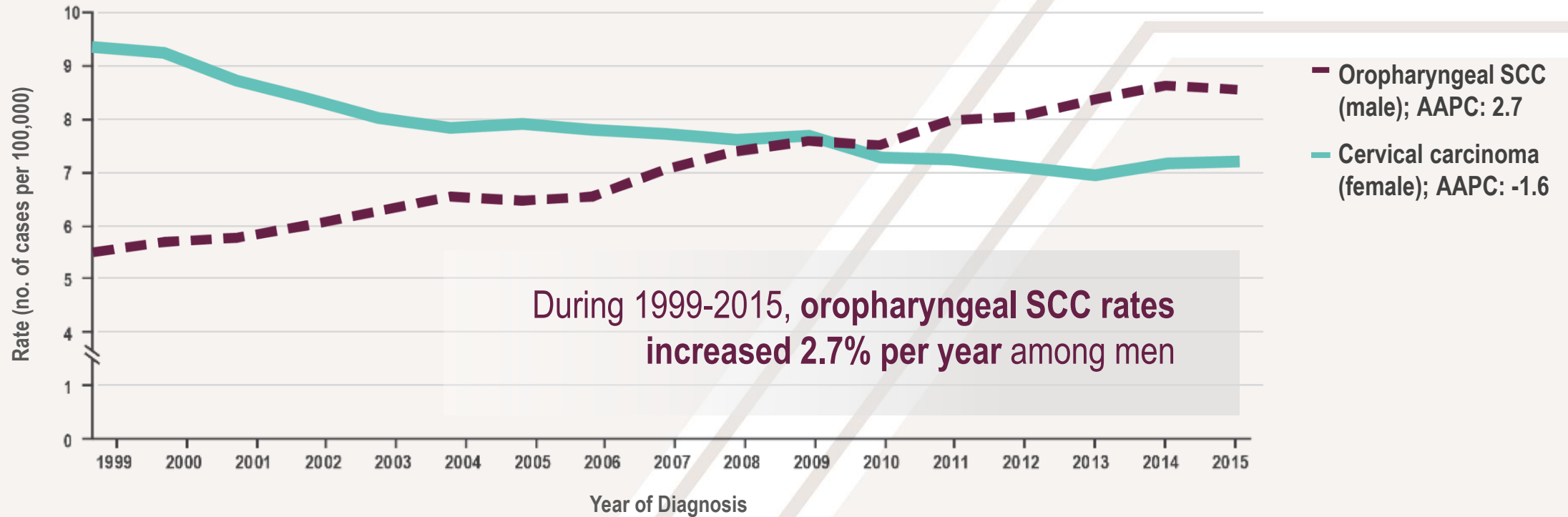
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1. Saraiya M, et al. *J Natl Cancer Inst.* 2015;107(6):djv086.

HPV-Associated Oropharyngeal Cancer Rates in Males Surpassed Cervical Cancer Rates in Females¹



Trends in age-adjusted incidence of cervical carcinoma among females and oropharyngeal SCC among men in the United States, 1999-2015. The CDC analyzed data from population-based cancer registries that participate in the CDC's National Program of Cancer Registries and the NCI's SEER program that met the criteria for high data quality for all years from 1999 to 2015. These data cover approximately 97.8% of the US population. Cancer registries' incidence data met the following 5 United States Cancer Statistics criteria: 1) $\leq 5\%$ of cases ascertained solely on the basis of death certificate; 2) $\leq 3\%$ of cases missing information on sex; 3) $\leq 3\%$ of cases missing information on age; 4) $\leq 5\%$ of cases missing information on race; and 5) $\geq 97\%$ of registry's records passed a set of single-field and interfiled computerized edits that test the validity and logic of data components. HPV-associated cancers were defined as cancers at specific anatomic sites with specific cell types in which HPV DNA is frequently found. All cancers were microscopically confirmed.

AAPC=average annual percent change; CDC=Centers for Disease Control and Prevention; DNA=deoxyribonucleic acid; HPV=human papillomavirus; NCI=National Cancer Institute; SCC=squamous cell carcinoma; SEER=Surveillance, Epidemiology, and End Results.

1. Van Dyne EA, et al. *MMWR Morb Mortal Wkly Rep.* 2018;67(33):918-924.

Indication for GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant)



9–45 years old
FEMALES

INDICATED FOR THE PREVENTION OF:

- Cervical, vulvar, vaginal, anal, **oropharyngeal and other head and neck cancers** caused by HPV Types 16, 18, 31, 33, 45, 52, and 58
- Cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV Types 6 and 11



9–45 years old
MALES

INDICATED FOR THE PREVENTION OF:

- Anal, **oropharyngeal and other head and neck cancers** caused by HPV Types 16, 18, 31, 33, 45, 52, and 58
- Anal precancerous or dysplastic lesions caused by HPV Types 6, 11, 16, 18, 31, 33, 45, 52, and 58
- Genital warts caused by HPV Types 6 and 11

The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Indication (*continued*)—Limitations of Use

- GARDASIL 9 does not eliminate the necessity for vaccine recipients to undergo screening for cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers as recommended by a health care provider.
- GARDASIL 9 has not been demonstrated to provide protection against diseases caused by:
 - HPV types not covered by the vaccine
 - HPV types to which a person has previously been exposed through sexual activity.
- Not all vulvar, vaginal, anal, oropharyngeal and other head and neck cancers are caused by HPV, and GARDASIL 9 protects only against those vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.
- GARDASIL 9 is not a treatment for external genital lesions; cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers; or cervical intraepithelial neoplasia (CIN), vulvar intraepithelial neoplasia (VIN), vaginal intraepithelial neoplasia (VaIN), or anal intraepithelial neoplasia (AIN).
- Vaccination with GARDASIL 9 may not result in protection in all vaccine recipients.

GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Select Safety Information

- GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL[®] [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].
- Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following HPV vaccination. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.
- Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.
- The most common ($\geq 10\%$) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common ($\geq 10\%$) local and systemic reactions in males were injection-site pain, swelling, and erythema.
- The duration of immunity of GARDASIL 9 has not been established.

Oropharyngeal Cancer Is the Most Prevalent Type of HPV-Attributed Cancer in the United States (2012-2016)

According to a model of the CDC's estimated 2012-2016 US incidence of cancer cases attributed to 7 HPV types (16, 18, 31, 33, 45, 52, and 58)¹:



For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.²⁻⁴ There is no way to know which patients who have HPV will develop cancer.⁵

The CDC analyzed data from the United States Cancer Statistics (USCS) to assess the incidence of HPV-associated cancers and to estimate the annual number of cancers caused by HPV, overall and by state, during 2012-2016.

The estimated number of cancers attributable to HPV was calculated by multiplying the average number of HPV-associated cancers by the percentage of cancers diagnosed from 1993-2005 that were attributable to HPV.^{1,6}

Not all cervical and oropharyngeal cancers are caused by HPV.¹

Detection of HPV DNA in an HPV study is insufficient to indicate a causal relation with the tumor.⁶

CDC=Centers for Disease Control and Prevention; DNA=deoxyribonucleic acid; HPV=human papillomavirus.

1. Senkomago V, et al. *MMWR Morb Mortal Wkly Rep.* 2019;68(33):724-728. 2. CDC. 2015 sexually transmitted diseases treatment guidelines: human papillomavirus (HPV) infection. <https://www.cdc.gov/std/tg2015/hpv.htm>. Last reviewed June 4, 2015. Accessed February 3, 2020. 3. CDC. Human papillomavirus. In: Hamborsky J, et al, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 13th ed. 2015:175-186. 4. CDC. HPV and oropharyngeal cancer. https://www.cdc.gov/cancer/hpv/basic_info/hpv_oropharyngeal.htm. Last reviewed March 14, 2018. Accessed January 21, 2020. 5. CDC. Types of cancer caused by HPV. CDC website. <https://www.cdc.gov/hpv/parents/cancer.html>. Last reviewed April 29, 2019. Accessed March 9, 2020. 6. Saraiya M, et al. *J Natl Cancer Inst.* 2015;107(6):1-12.

The Majority of HPV-Attributed Oropharyngeal Cancer Occurs in Males (2012-2016)

Model of the CDC's estimated 2012-2016 United States incidence of cancer cases attributed to 7 HPV types (16, 18, 31, 33, 45, 52, and 58)¹:



The CDC analyzed data from the United States Cancer Statistics (USCS) to assess the incidence of HPV-associated cancers and to estimate the annual number of cancers caused by HPV, overall and by state, during 2012-2016.

The estimated number of cancers attributable to HPV was calculated by multiplying the average number of HPV-associated cancers by the percentage of cancers diagnosed from 1993-2005 that were attributable to HPV.^{1,2}

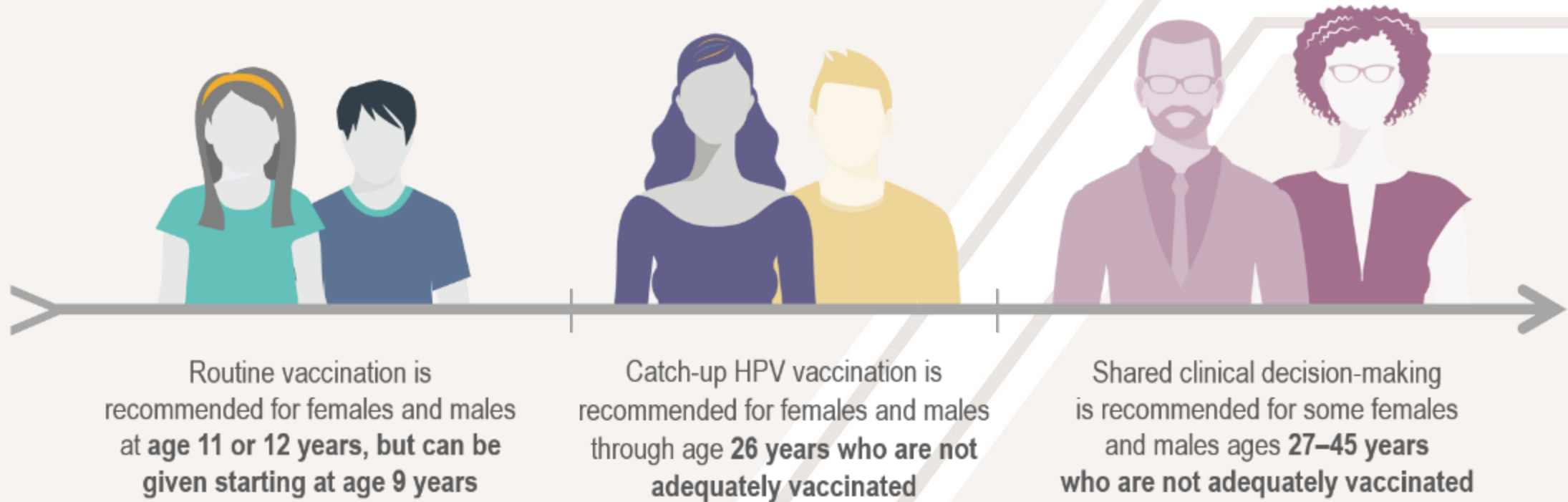
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CDC Recommendation for HPV Vaccination¹



CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus.

1. Meites E, et al. *MMWR Morb Mortal Wkly Rep.* 2019;68(32):698-702.

Leading Organizations Also Support HPV Vaccination

The following organizations align with recommendations for HPV vaccination from the CDC, which recognizes certain **oropharyngeal cancers as HPV-related:**

American Academy of Pediatrics^{1,2}

American Academy of Family Physicians^{1,3,4}

American College of Obstetricians and Gynecologists^{3,5}

American Dental Association⁶

The American Head and Neck Society also strongly encourages HPV vaccination for prevention of certain oropharyngeal and anogenital cancers⁷

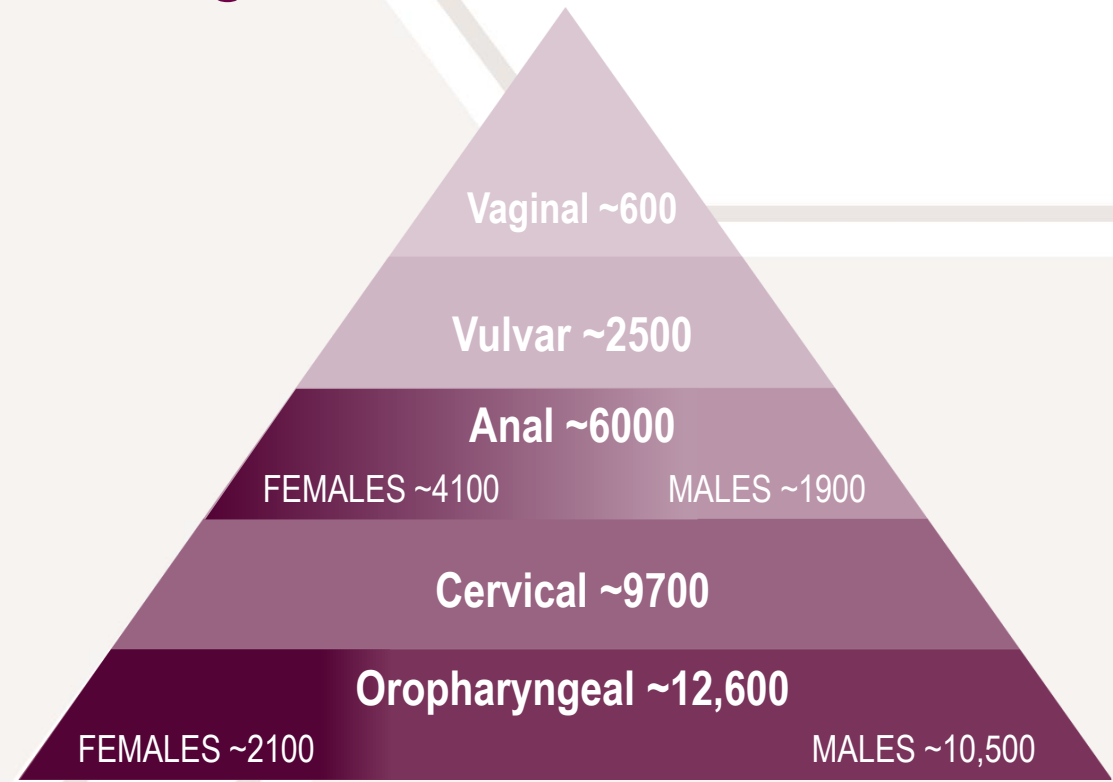
HPV=human papillomavirus.

1. CDC website. <https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>. Updated January 29, 2020. Accessed January 29, 2020. 2. AAP. *Red Book®: 2018 Report of the Committee on Infectious Diseases*, 31st Edition. American Academy of Pediatrics; 2018:582-590. 3. CDC website. <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>. Updated January 29, 2020. Accessed March 2, 2020. 4. AAFP website. <https://www.aafp.org/patient-care/public-health/immunizations/disease-population/hpv.html>. Accessed January 24, 2020. 5. ACOG website. <https://www.acog.org/About-ACOG/News-Room/Statements/2019/ACOG-Statement-on-HPV-Vaccination?IsMobileSet=false>. Updated June 26, 2019. Accessed March 12, 2020. 6. ADA website. <https://www.ada.org/en/member-center/oral-health-topics/cancer-head-and-neck>. Updated January 17, 2019. Accessed November 1, 2019. 7. AHNS website. <https://www.ahns.info/wp-content/uploads/2019/03/Signed-Joint-position-statement-HPV.pdf>. Updated December 18, 2018. Accessed February 6, 2020.

Focus on Cancer Prevention When Discussing the HPV Vaccine With Patients

Model of the CDC's estimated 2012-2016 **United States incidence of cancer cases** attributed to 7 HPV types (16, 18, 31, 33, 45, 52, and 58)¹

~31,400 total cases each year



For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.²⁻⁴ There is no way to know which patients who have HPV will develop cancer.⁵

The CDC analyzed data from the United States Cancer Statistics (USCS) to assess the incidence of HPV-associated cancers and to estimate the annual number of cancers caused by HPV, overall and by state, during 2012-2016.

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Not all cervical, vulvar, vaginal, anal, and oropharyngeal cancers are caused by HPV.¹

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A photograph of three young people (two women and one man) smiling and looking towards the camera. They are wearing denim jackets. The image is overlaid with a semi-transparent purple filter. The text is centered over the image.

**Important Information About
GARDASIL[®]9 (Human Papillomavirus
9-valent Vaccine, Recombinant)**

GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Select Safety Information

- GARDASIL 9 is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL 9 or GARDASIL[®] [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].
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GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Dosage and Administration

- GARDASIL 9 should be administered intramuscularly in the deltoid or anterolateral area of the thigh.
 - For individuals 9 through 14 years of age, GARDASIL 9 can be administered using a 2-dose or 3-dose schedule. For the 2-dose schedule, the second dose should be administered 6–12 months after the first dose. If the second dose is administered less than 5 months after the first dose, a third dose should be given at least 4 months after the second dose. For the 3-dose schedule, GARDASIL 9 should be administered at 0, 2 months, and 6 months.
 - For individuals 15 through 45 years of age, GARDASIL 9 is administered using a 3-dose schedule at 0, 2 months, and 6 months.

Discuss Certain HPV-Related Oropharyngeal and Other Head and Neck Cancers With Your Appropriate Patients

~ 1 2 6 0 0

According to a model of the CDC's estimated 2012-2016 United States annual number of cancer cases attributed to 7 HPV types (16, 18, 31, 33, 45, 52, and 58), **oropharyngeal cancer is the most prevalent type of HPV-attributed cancer** in the United States¹

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.²⁻⁴ There is no way to know which patients who have HPV will develop cancer.⁵

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Discuss Certain HPV-Related Oropharyngeal and Other Head and Neck Cancers With Your Appropriate Patients

~5x



According to a model of the CDC's estimated 2012-2016 United States annual number of cancer cases attributed to 7 HPV types (16, 18, 31, 33, 45, 52, and 58), **oropharyngeal cancer affects men ~5x more than women¹**

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Discuss Certain HPV-Related Oropharyngeal and Other Head and Neck Cancers With Your Appropriate Patients



APPROVED

GARDASIL 9 is a vaccine indicated for the **prevention of oropharyngeal and other head and neck cancers**

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.¹⁻³
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Discuss Certain HPV-Related Oropharyngeal and Other Head and Neck Cancers With Your Appropriate Patients



Be sure to discuss certain HPV-related oropharyngeal and other head and neck cancers with your patients when recommending HPV vaccination

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.¹⁻³
There is no way to know which patients who have HPV will develop cancer.⁴

HPV=human papillomavirus.

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Before administering GARDASIL[®]9 (Human Papillomavirus 9-valent Vaccine, Recombinant), please read the Prescribing Information available at this presentation. The Patient Information also is available.



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