



Certain HPV-related cancers, including cervical cancer in women and oropharyngeal and other head & neck cancers in men,^a vary across the United States. ^{1,2}



Understanding state and local rates enables the implementation of tailored intervention strategies.¹⁻⁴

Estimated Rate of New Cervical Cancers in Females and

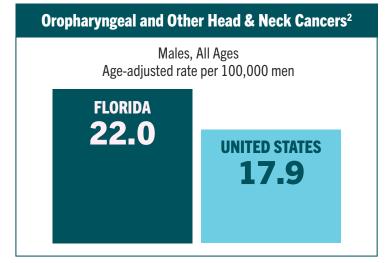
Oropharyngeal and Other Head & Neck Cancers in Males in Florida Compared to the United States, All Ages (2021). 1,2

Cervical Cancer¹

Females, All Ages Age-adjusted rate per 100,000 women

FLORIDA 9.2

UNITED STATES
7.4



Not all cervical or oropharyngeal and other head & neck cancers are caused by HPV.5

Do you know your state's rate?

Data presented are for all ages and all races/ethnicities and represent the rate of cervical cancer per 100,000 women and the rate of oropharyngeal and other head & neck cancers per 100,000 men. Incidence data are compiled from cancer registries meeting United States Cancer Statistics data quality criteria covering 98% of the United States population. Rates are the number of cases per 100,000 people and are age-adjusted to the 2000 United States standard population. Rates and counts are suppressed if fewer than 16 cases (or deaths) were reported in a specific category, such as cancer type, race and/or ethnicity, age, and state. 1.2

^aOropharyngeal and other head & neck cancers does not only occur in men.

These data include new cancer cases diagnosed in 2020 and 2021, the first and second years of the COVID-19 pandemic. The COVID-19 pandemic disrupted health services, leading to delays and reductions in cancer screening, diagnosis, and reporting to some central cancer registries. This may have contributed to the decline in new cancer cases for many sites in 2020. The number of new cases diagnosed in 2021 are still a little lower than expected for some cancer types but have returned to pre-pandemic counts for other cancer types. ^{1,2}

COVID-19, coronavirus-19 disease; HPV, human papillomavirus.

References: 1. United States Cancer Statistics: Data visualizations – Leading cancer cases and deaths, all races and ethnicities, cervical, female, 2021. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2022 submission data (1999-2020). Released in June 2024. Accessed July 18, 2024. https://gis.cdc.gov/Cancer/USCS/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc. gov%2Fcancer%2Fdataviz%2Findex.htm#/AtAGlance/ 2. United States Cancer Statistics: Data visualizations Leading cancer cases and deaths, all races and ethnicities, oral cavity and pharynx male, 2021. Centers for Disease Control and Prevention. U.S. Cancer Statistics Working Group. U.S. Cancer Statistics Data Visualizations Tool, based on 2023 submission data. Released in June 2024. Accessed July 18, 2024. https://gis.cdc.gov/ Cancer/USCS/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcancer%2Fdataviz%2Findex.htm#/ AtAGlance/ 3. National networks come together to help prevent HPV-related cancers. Centers for Disease Control and Prevention. October 8, 2024. Accessed October 23, 2024. https://www.cdc.gov/comprehensive-cancercontrol/success-stories/national-networks.html 4. Brewer SE, Nederveld A, Simpson M. Engaging communities in preventing human papillomavirus-related cancers: two boot camp translations, Colorado, 2017-2018. Prev Chronic Dis. 2020;17:E02. doi:10.5888/pcd17.190250 5. Senkomago V, Henley SJ, Thomas CC, Mix JM, Markowitz LE, Saraiva M, Human papillomavirus—attributable cancers — United States, 2012–2016, MMWR Morb Mortal Wkly Rep. 2019;68:724-728. doi:http://dx.doi.org/10.15585/mmwr.mm6833a3

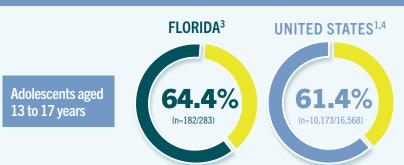
FLORIDA: Know Your Rates

HPV Vaccination Rates Among Adolescents in the United States¹

According to Healthy People 2030, the HPV vaccination target for adolescents aged 13–15 is 80%.²







Study Design: Adolescents (N=16,568) in the NIS-Teen 2023 random-digit-dialed mobile telephone survey were born in January 2005—December 2010. The response rate was 24.4%, and 39.5% of adolescents with completed interviews had adequate provider data. "HPV vaccine" includes nine-valent (9vHPV), quadrivalent (4vHPV), or bivalent (2vHPV) vaccines.

Normalize HPV vaccination with a high-quality presumptive recommendation to help protect your appropriate patients against certain HPV-related cancers before exposure. 5.6 For most people, HPV clears on its own. But for those who don't clear the virus, it could cause certain cancers and diseases. 7.9

^aHPV UTD includes those who received ≥3 doses and those who received 2 doses when the first HPV vaccine dose was initiated before age 15 years, and there was at least 5 months minus 4 days between the first and second dose. This update to the HPV vaccination recommendation occurred in December 2016.¹

2vHPV, bivalent human papillomavirus; 4vHPV, quadrivalent human papillomavirus; 9vHPV, 9-valent human papillomavirus; CDC, Centers for Disease Control and Prevention; HPV, human papillomavirus; NIS, National Immunization Survey; UTD, up-to-date.

Indication

GARDASIL 9 is a vaccine indicated in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, anal, oropharyngeal and other head and neck cancers caused by human papillomavirus (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; and genital warts caused by HPV Types 6 and 11.

GARDASIL 9 is indicated in males 9 through 45 years of age 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; and 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.

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.

INDICATION AND SELECT SAFETY INFORMATION CONTINUE ON FOLLOWING PAGE.

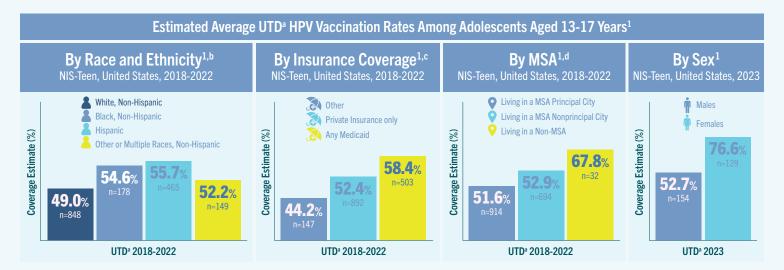
References: 1. Pingali C, Yankey D, Chen M, et al. National vaccination coverage among adolescents aged 13-17 years - National Immunization Survey—Teen, United States, 2023. MMWR Morb Mortal Wkly Rep. 2024;73(33):708-714. doi:10.15585/mmwr.mm7333a1 2. Healthy People 2030: increase the proportion of adolescents who get recommended doses of the HPV vaccine — IID-08. Office of Disease Prevention and Health Promotion (ODPHP). Published 2021. Accessed June 20, 2024. https://health.gov/health.gov/healthypeople/lobjectives-and-data/browse-objectives/vaccination/increase-proportion-adolescents-who-get-recommended-doses-hpv-vaccine-iid-08 3. Vaccination coverage among adolescents in the US by state, sex, urbanicity, insurance coverage, race, and ethnicity. Survey years 2018-2023. TeenVaxView. Centers for Disease Control and Prevention. August 22, 2024. Accessed November 22, 2024. https://www.cdc.gov/teenvaxview/interactive/CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/index.html 4. Vaccination coverage among adolescents (13-17 years) in Alabama, survey year 2023. TeenVaxView. Centers for Disease Control and Prevention. August 22, 2024. Accessed September 24, 2024. https://www.cdc.gov/teenvaxview/interactive/CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/index.html 5. How pediatricians can recommend HPV vaccination to parents and caregivers. American Academy of Pediatrics. Last updated April 5, 2023. Accessed July 11, 2024. https://www.apo.org/en/patient-care/immunizations/human-papillomavirus-vaccines/how-to-recommend-hpv-vaccination/ 6. Recommended child and adolescent immunization schedule for ages 18 years or younger, United States, 2025. Centers for Disease Control and Prevention. Addendum updated November 21, 2024. Accessed November 25, 2024. https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf 7. Meites E, Gee J, Unger E, Markowitz L. Epidemiology and Prevention of Vaccine-Preventabl

18, 2024. https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-11-human-papillomavirus.html 8. Human papillomavirus (HPV) infection. Centers for Disease Control and Prevention. Last reviewed July 22, 2021. Accessed May 13, 2024. https://www.cdc.gov/std/treatment-guidelines/ hpv.htm 9. HPV and oropharyngeal cancer. Centers for Disease Control and Prevention. September 17, 2024. Accessed September 25, 2024. https://www.cdc.gov/cancer/hpv/oropharyngeal-cancer.html



How do HPV vaccination rates vary among different demographic groups in Florida?

In Florida, adolescent HPV vaccination rates vary by race and ethnicity, insurance coverage, urbanicity, and sex.¹



 8 HPV UTD includes those who received $_{2}$ 3 doses and those who received 2 doses when the first HPV vaccine dose was initiated before age 15 years, and there was at least 5 months minus 4 days between the first and second dose. This update to the HPV vaccination recommendation occurred in December 2016.

bAdolescents' race and ethnicity was reported by their parent or guardian. Adolescents identified in this report as White, Black or African American, Asian, American Alaska Native or Indian, Native Hawaiian or other Pacific Islander, or multiple races were reported by the parent or guardian as non-Hispanic. Adolescents identified as having multiple races had more than one race category selected. Adolescents identified as Hispanic or Latino might be of any race. Estimates for Native Hawaiian or other Pacific Islander and multiracial adolescents were suppressed because of small sample size.²

Adolescents' health insurance status was reported by their parent or guardian. "Other insurance" includes the Children's Health Insurance Program, military insurance, Indian Health Service, and any other type of health insurance not mentioned elsewhere.²

⁴MSA status was determined from household-reported city and county of residence and was grouped into three categories: MSA principal city, MSA nonprincipal city, and non-MSA. MSA nonprincipal city and MSA principal city were defined by the United States Census Bureau (https://www.census.gov/programs-surveys/metro-micro.html).²

HPV, human papillomavirus; MSA, metropolitan statistical area; NIS, National Immunization Survey; UTD, up-to-date.

Indication (continued)

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

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.

Select Safety Information (continued)

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 a 2-dose schedule of GARDASIL 9 has not been established.

INDICATION AND SELECT SAFETY INFORMATION CONTINUE ON FOLLOWING PAGE.

References: 1. Vaccination coverage among adolescents (13-17 years) in the US by state, sex, urbanicity, insurance coverage, race, and ethnicity. Survey years 2018-2023. TeenVaxView. Centers for Disease Control and Prevention. August 22, 2024. Accessed November 22, 2024. https://www.cdc.gov/teenvaxview/interactive//CDC_AAref_Val=https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/index.html 2. Pingali C, Yankey D, Elam-Evans LD, et al. Vaccination coverage among adolescents aged 13-17 years—National Immunization Survey—Teen, United States, 2022. MMWR Morb Mortal Wkly Rep. 2023;72(34):912-919. doi:10.15585/mmwr.mm7234a3



To strive for the future elimination of certain vaccine-preventable HPV-related cancers and diseases in the United States, starting with cervical cancer, there needs to be increased 1-4:







Routine Screening

Treatment

Screening guidelines only exist for cervical and anal cancers.^{5,6}

Vaccination with GARDASIL 9 is an important factor to help achieve the elimination of certain HPV-related cancers and diseases, including cervical cancer.^{1,2}

The goal to eliminate certain HPV-related cancers and diseases requires collective effort.

Prioritizing vaccination is an important step towards this goal.^{1,2}

HPV, human papillomavirus.

Indication (continued)

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.

Select Safety Information (continued)

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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Before administering GARDASIL 9, please read the accompanying <u>Prescribing Information</u>. The <u>Patient Information</u> also is available.

References: 1. ACS elimination statement on HPV cancers. American Cancer Society. Revised July 2020. Accessed April 22, 2024. https://www.cancer.org/content/dam/cancer-org/online-documents/en/pdf/flyers/acs-elimination-statement-on-hpv-cancers.pdf 2. Cervical cancer elimination initiative. World Health Organization. Accessed June 19, 2024. https://www.who.int/initiatives/cervical-cancer-elimination of human papillomavirus (HPV). American College of Obstetricians and Gynecologists. Accessed June 19, 2024. https://www.acog.org/-/media/project/acog/acogorg/files/pdfs/news/joint-statement. hpv-012121-v1.pdf 4. NCI-designated cancer centers endorse goal of eliminating HPV-related cancers. National Cancer Institute. June 2018. Accessed April 23, 2024. https://hpvroundtable.org/wp-content/uploads/2018/06/Cancer-Center-HPVConsensusStatement_FINAL_06.01.2018.pdf 5. Fontham ETH, Wolf AMD, Church TR, et al. Cervical cancer screening for individuals at average risk: 2020 guideline update from the American Cancer Society. *CA Cancer J Clin*. 2020;70(5):321-346. doi:10.3322/caac.21628 6. Stier EA, Clarke MA, Deshmukh AA, et al. International Anal Neoplasia Society's consensus guidelines for anal cancer screening. *Int J Cancer*. 2024;154(10):1694-1702. doi:10.1002/ijc.34850



GARDASIL.9
Human Papillomavirus
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