BlueCross BlueShield of Texas

WEBINAR

Closing the Gap: Discussing HPV with Parents of Adolescents

May 26, 12 p.m. and 3 p.m.

Additional Resources

- To support quality care, we are providing information to providers and members to encourage discussions on health topics. On the pages below you'll find quality tip sheets, webinars, resources to view member care gaps, fliers and outreach templates.
  - Resources to support quality care
  - Resources for Medicaid providers to support quality care

CLOSING THE GAP
DISCUSSING HPV WITH PARENTS OF ADOLESCENTS

Actor portrayals

HPV=human papillomavirus.

MERCK

VISE
Vaccine Implementation & Scientific Engagement

HPV Is Common in the United States

An estimated

79 million people

in the United States are infected with HPV[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.[1-3] There is no way to know which patients who have HPV will develop cancer.[4]

HPV=human papillomavirus.

1. CDC. Human PAPILLOMAVIRUS. IN: Hamborsky J, et al, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 13th ed. 2015:175-186. **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. HPV and oropharyngeal cancer. https://www.cdc.gov/cancer/hpv/basic_info/hpv_oropharyngeal.htm. Last reviewed March 14, 2018. Accessed January 21, 2020. **4.** CDC. Types of cancer caused by HPV. CDC website. https://www.cdc.gov/hpv/parents/cancer.html. Updated April 29, 2019. Accessed March 9, 2020.

The CDC Recommends Routine HPV Vaccination at Age 11 or 12 Years

ROUTINE VACCINATION RECOMMENDED

Females and males age 11 or 12 years, but can be given starting at age 9 years[1]

CATCH-UP VACCINATION RECOMMENDED

Females and males through age 26 years who are not adequately vaccinated[1]

SHARED CLINICAL DECISION-MAKING RECOMMENDED

Some females and males ages 27–45 years who are not adequately vaccinated[1]

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 Medical Societies and Organizations Support HPV Vaccination

PROFESSIONAL MEDICAL ASSOCIATIONS[1-3]

American Academy of Family Physicians
American Academy of Pediatrics
The American College of Obstetricians and Gynecologists
American Society of Clinical Oncology

NATIONAL ORGANIZATIONS FOCUSED ON CANCER RESEARCH[4,5]

American Cancer Society
National Cancer Institute

"The AAP recommends starting the series between 9 and 12 years, at an age that the provider deems optimal for acceptance and completion of the vaccination series."
Providers are encouraged to recommend HPV vaccination as they do all other routine childhood and adolescent vaccines.[3]

AAP=American Academy of Pediatrics; HPV=human papillomavirus.

1. Recommended Child and Adolescent Immunization Schedule. CDC website. https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf. Updated January 29, 2020. Accessed February 5, 2020. **2.** ASCO website. https://www.asco.org/practice-policy/policy-issues-statements/asco-in-action/cdc-expands-age-range-human-papillomavirus. Updated July 25, 2019. Accessed March 6, 2020. **3.** AAP. *Red Book®: 2018 Report of the Committee on Infectious Diseases*, 31st Edition. American Academy of Pediatrics; 2018:582-590 **4.** ACS Recommendations for HPV Vaccine Use. ACS Website. https://www.cancer.org/cancer/cancer-causes/infectious-agents/hpv/acs-recommendations-for-hpv-vaccine-use.html. Updated May 31, 2019. Accessed January 10, 2020. **5.** HPV Vaccines. NCI website. https://www.cancer.gov/about-cancer/causes-prevention/risk/infectious-agents/hpv-vaccine-fact-sheet. Updated September 9, 2019. Accessed February 19, 2020.

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.

Indication continues

HPV=human papillomavirus.

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.

Indication continues

HPV=human papillomavirus.

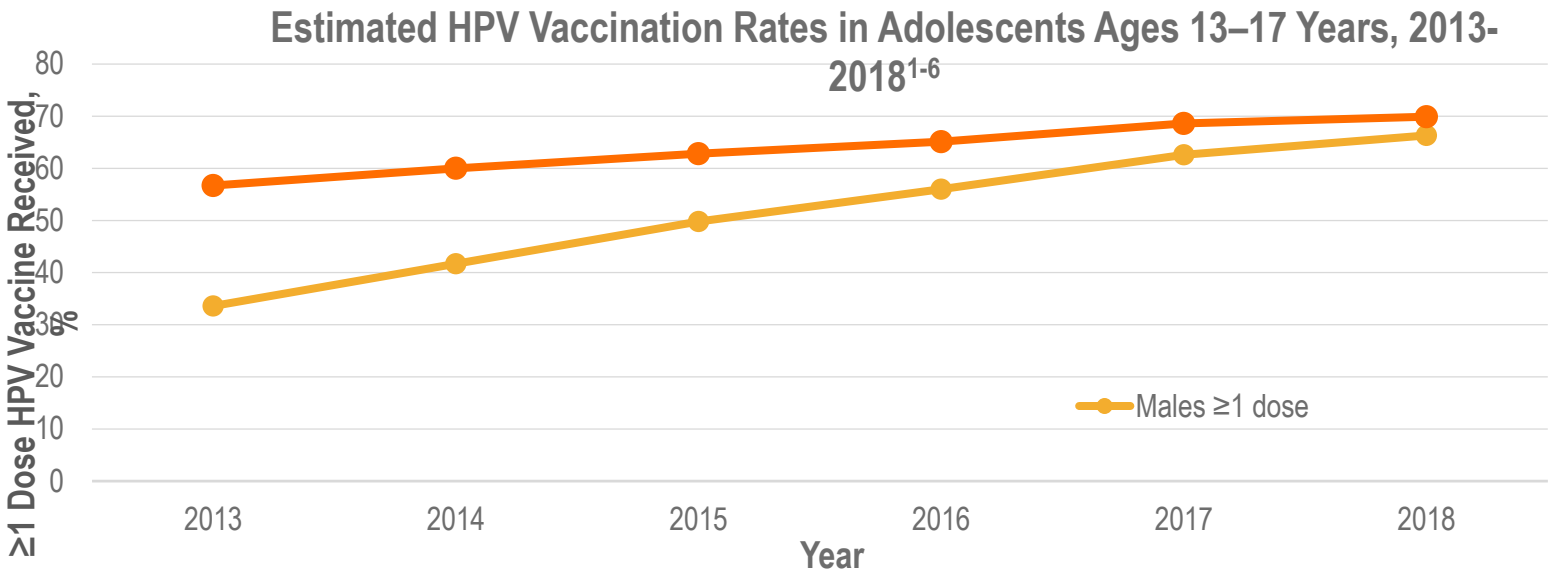
GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Indication *(continued)*—Limitations of Use *(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.

HPV=human papillomavirus.

HPV Vaccination Initiation (≥1 Dose) Rates Among Adolescents Are Increasing



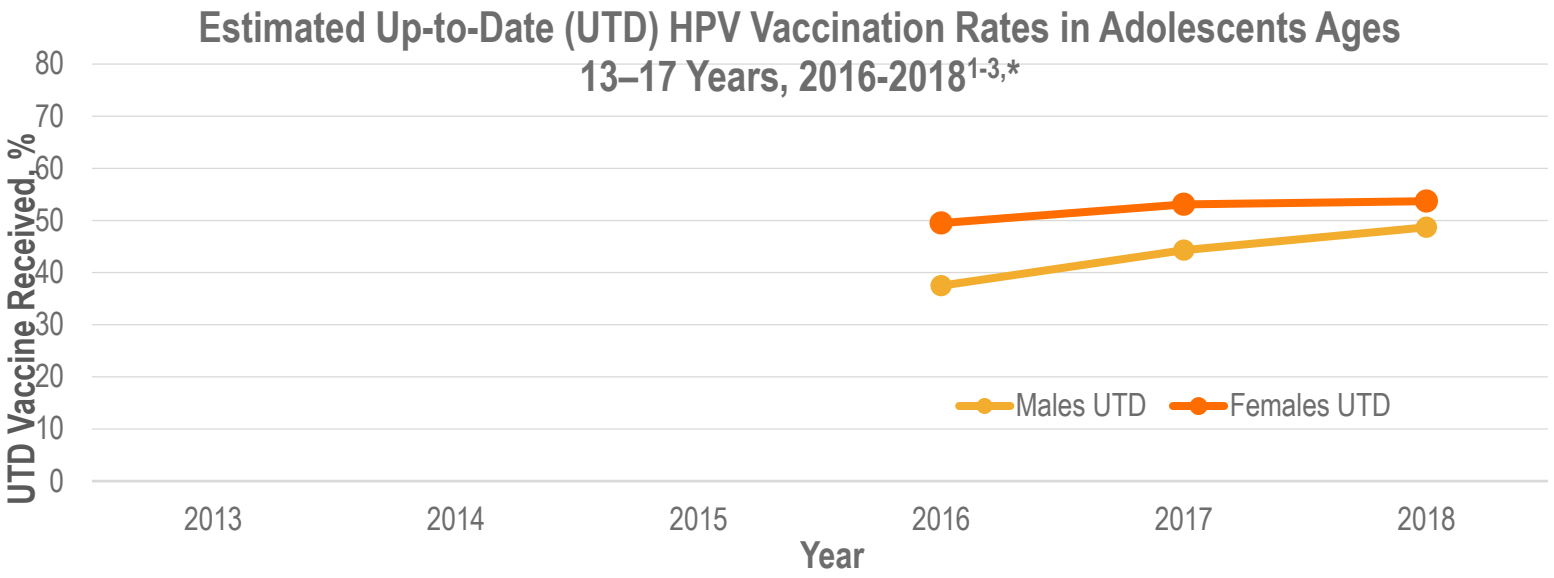
GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) should be administered in a 2- or 3-dose series.

2013 NIS-Teen: N=18,264;[1] 2014 NIS-Teen: N=20,827;[2] 2015 NIS-Teen: N=21,875;[3] 2016 NIS-Teen: N=20,475;[4] 2017 NIS-Teen: N=20,949; [5] 2018 NIS-Teen: N=18,700.[6]

HPV=human papillomavirus; NIS=National Immunization Survey.

1. Elam-Evans LD, et al. *MMWR Morb Mortal Wkly Rep*. 2014;63(29):625-633. **2.** Reagan-Steiner S, et al. *MMWR Morb Mortal Wkly Rep*. 2015;64(29):784-792. **3.** Reagan-Steiner S, et al. *MMWR Morb Mortal Wkly Rep*. 2016;65(33):850-858. **4.** Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2017;66(33):874-882. **5.** Walker, TY, et al. *MMWR Morb Mortal Wkly Rep*. 2018;67(33):909-917. **6.** Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

HPV Vaccination Completion Rates Among Adolescents Are Also Increasing



*HPV 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 the time between the first and second dose was at least 5 months minus 4 days.

2016 NIS-Teen: N=20,475;[1] 2017 NIS-Teen: N=20,949;[2] 2018 NIS-Teen: N=18,700.[3]
HPV=human papillomavirus; NIS=National Immunization Survey.

1. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2017;66(33):874-882. **2.** Walker, TY, et al. *MMWR Morb Mortal Wkly Rep*. 2018;67(33):909-917. **3.** Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

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

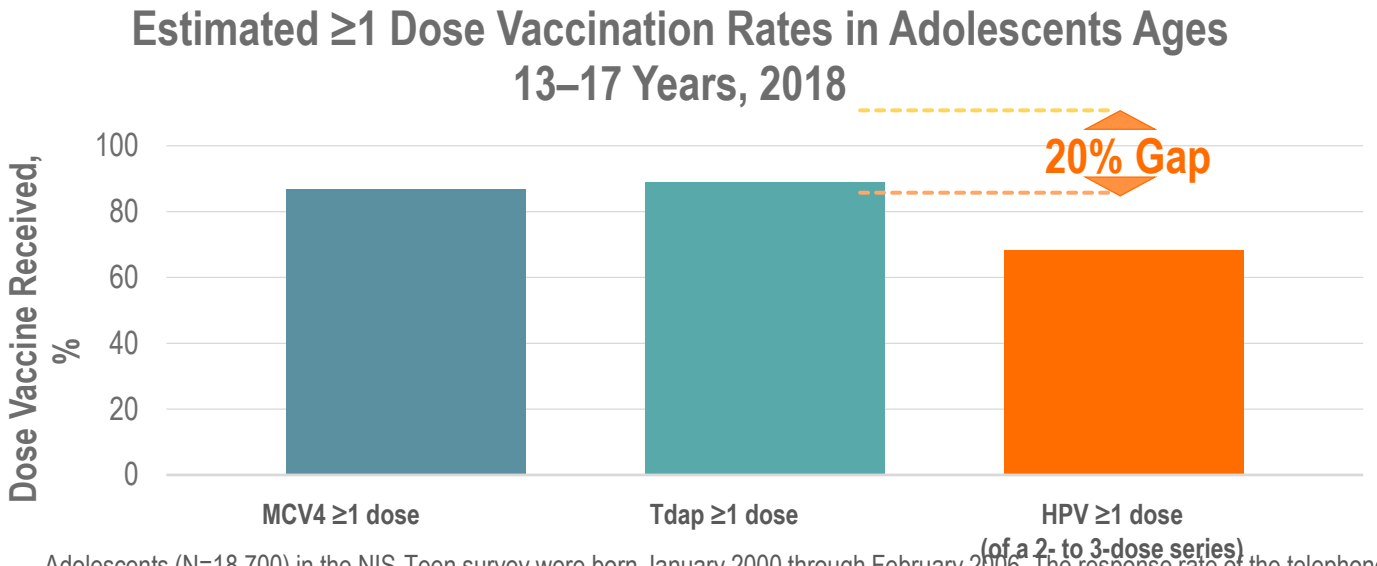
Select Safety Information

- 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.

Select Safety Information continues

HPV=human papillomavirus.

Gaps Exist Between HPV Vaccination Initiation and Other Adolescent Vaccinations[1]



Adolescents (N=18,700) in the NIS-Teen survey were born January 2000 through February 2006. The response rate of the telephone samples was 23.3%, and 48.3% of adolescents with completed interviews had adequate provider data. Includes percentages receiving MCV4 or meningococcal-unknown type vaccine. HPV vaccine includes 9-valent (9vHPV), quadrivalent (4vHPV), or bivalent (2vHPV) vaccines.

HPV=human papillomavirus; MCV4=quadrivalent meningococcal conjugate vaccine; NIS=National Immunization Survey; Tdap=tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis.

1. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) should be administered in a 2- or 3-dose series.

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

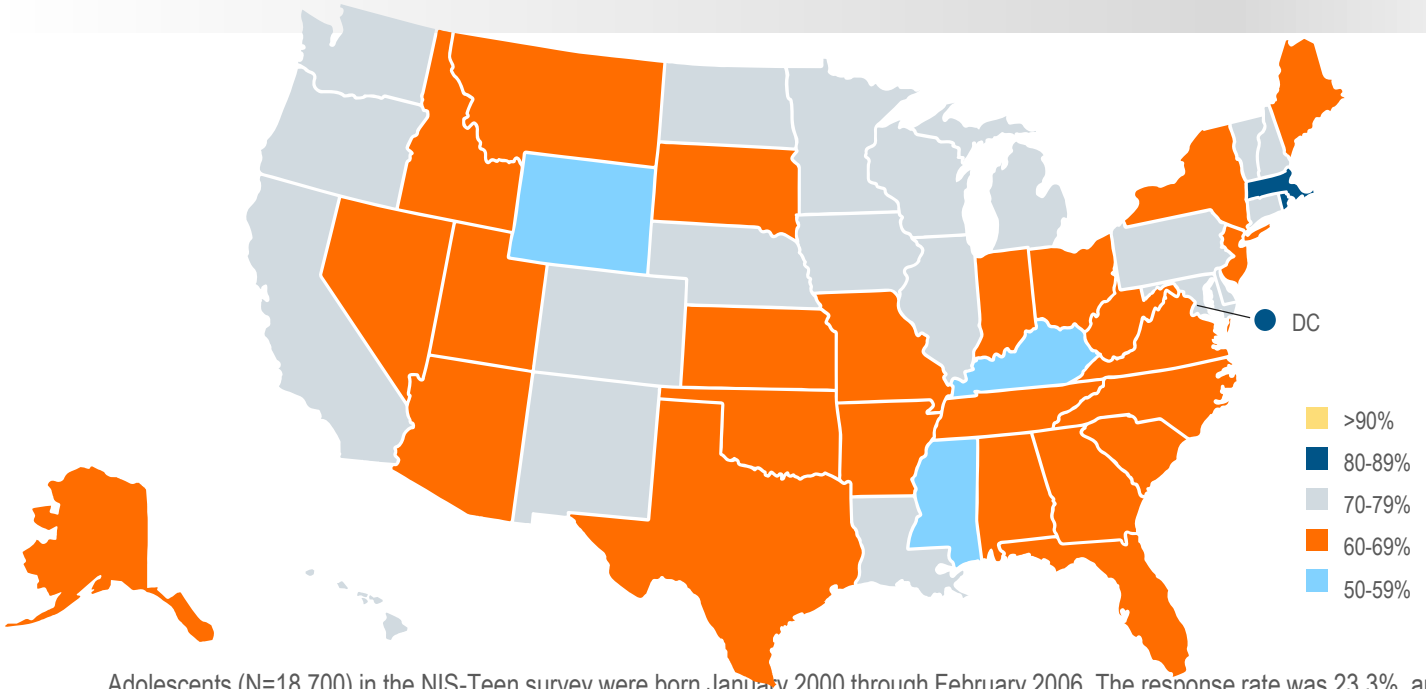
Select Safety Information

- The rates of injection-site adverse reactions were similar between the concomitant group and nonconcomitant group (vaccination with GARDASIL 9 separated from vaccination with *Menactra* and *Adacel* by 1 month) with the exception of an increased rate of swelling reported at the injection site for GARDASIL 9 in the concomitant group (14.4%) compared to the nonconcomitant group (9.4%). The majority of injection-site swelling adverse reactions were reported as being mild to moderate in intensity.

Select Safety Information continues later in the presentation

Regional Gaps in Adolescent HPV Vaccination Rates[1]

Percentage of adolescents ages 13–17 years who received ≥1 dose HPV vaccine in the United States, NIS-Teen 2018



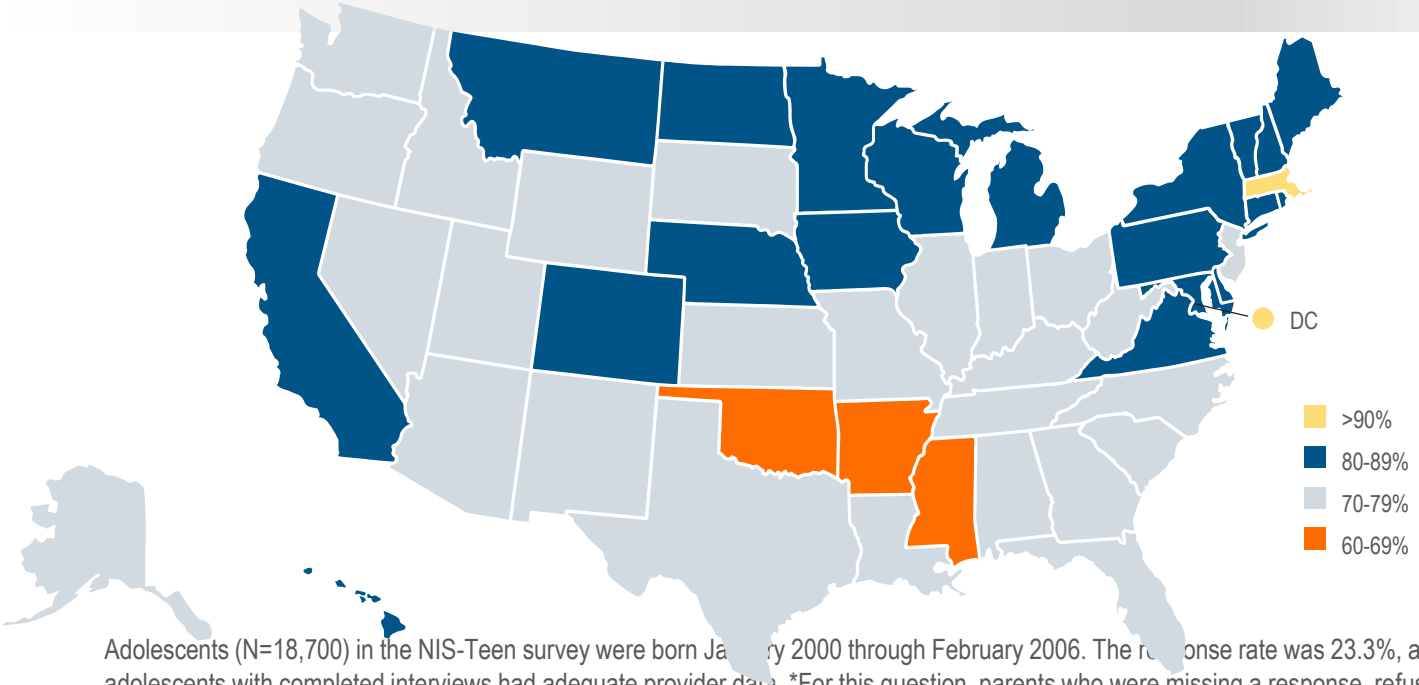
Adolescents (N=18,700) in the NIS-Teen survey were born January 2000 through February 2006. The response rate was 23.3%, and 48.3% of adolescents with completed interviews had adequate provider data. HPV vaccine includes 9-valent (9vHPV), quadrivalent (4vHPV), or bivalent (2vHPV) vaccines.

HPV=human papillomavirus; NIS=National Immunization Survey.

1. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

Regional Gaps in HCP Recommendations for Adolescent HPV Vaccination[1]

Percentage* of parents who reported receiving a provider recommendation for HPV vaccine, NIS-Teen 2018

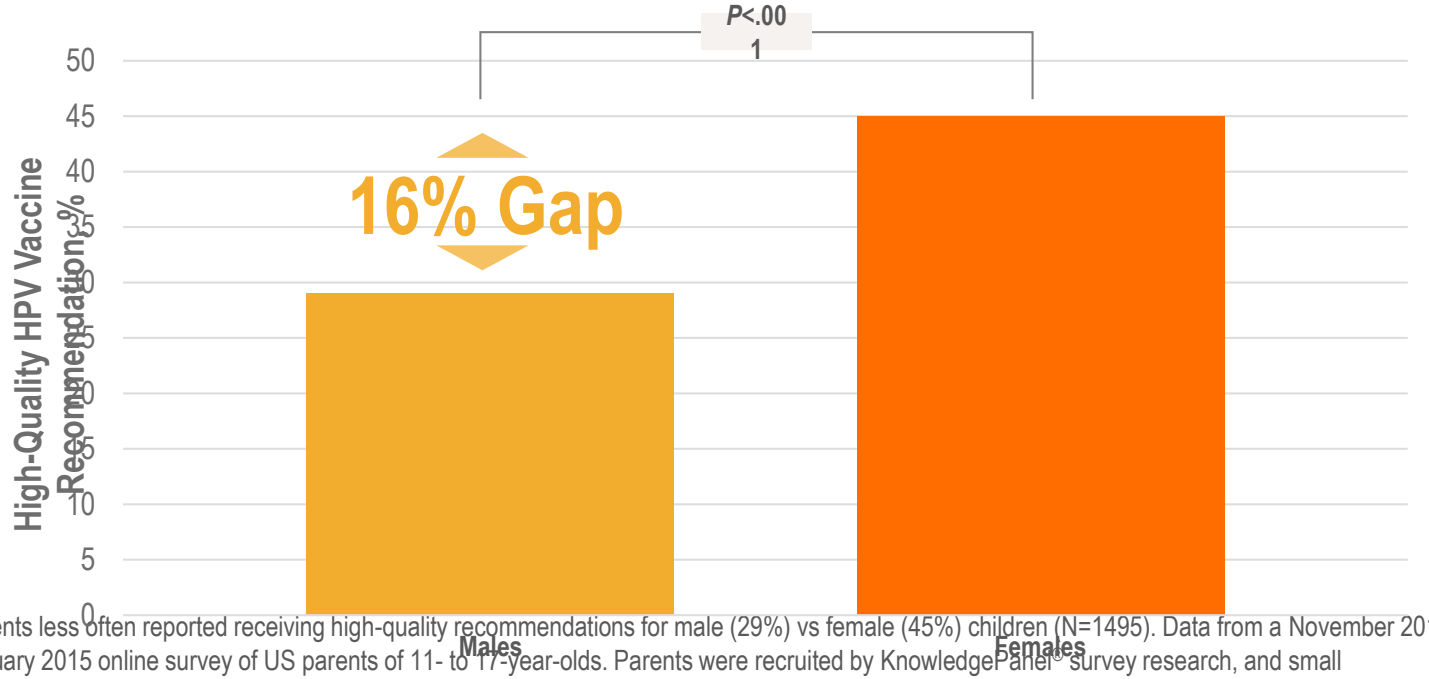


Adolescents (N=18,700) in the NIS-Teen survey were born January 2000 through February 2006. The response rate was 23.3%, and 48.3% of adolescents with completed interviews had adequate provider data. *For this question, parents who were missing a response, refused to respond, or responded "don't know" (n=1448) were not included in the estimates.

HCP=health care professional; HPV=human papillomavirus; NIS=National Immunization Survey.

1. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

Disparities in HPV Vaccine Provider Recommendation Quality Between Males and Females, 2014[1]

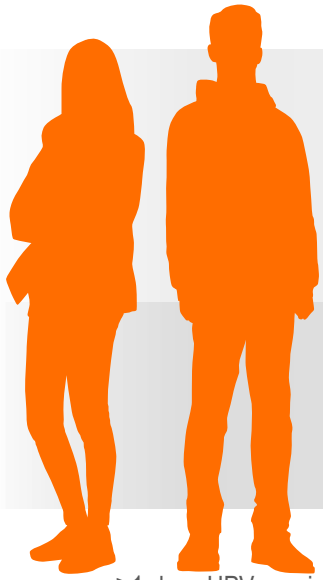


Parents less often reported receiving high-quality recommendations for male (29%) vs female (45%) children (N=1495). Data from a November 2014-January 2015 online survey of US parents of 11- to 17-year-olds. Parents were recruited by Knowledge Panel® survey research, and small participation incentives were provided; response rate was 61%. The cross-sectional survey design prevented the assessment of directionality between recommendation quality and HPV vaccination behavior.

HCP=health care professional; HPV=human papillomavirus.

1. Gilkey MB, et al. *Vaccine*. 2016;34:1187-1192.

Help Increase Vaccination Rates by Making a High-Quality Recommendation[1]



A high-quality recommendation includes

- ✓ A cancer prevention message
- ✓ A strong endorsement for the HPV vaccination
- ✓ Same-day vaccination recommendation

A high-quality recommendation can significantly increase the odds of HPV vaccine initiation by

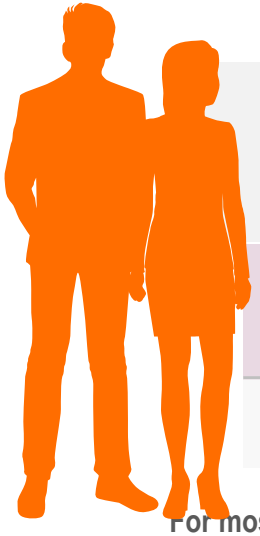
more than 9X vs saying nothing

≥1-dose HPV vaccination rates in adolescents ages 11–17 years when parents received a high-quality recommendation (n=544) vs parents who received no recommendation (n=714). Data from a November 2014-January 2015 online survey of US parents of adolescents. Parents were recruited by KnowledgePanel® survey research, and small participation incentives were provided; response rate was 61%. The cross-sectional survey design prevented the assessment of directionality between recommendation quality and HPV vaccination behavior.

HPV=human papillomavirus.

1. Gilkey MB, et al. *Vaccine*. 2016;34:1187-1192.

Focus on Cancer Prevention: HPV-Related Cancer Affects Males and Females in the United States



According to a 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]

~18,800 cases* **of certain HPV-related anogenital cancers occur each year**

Cervical ~9700	Vaginal ~600	Vulvar ~2500	Anal ~6000

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 predict which patients who have HPV will develop cancer.[5]

CDC analyzed data from the U.S. 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, vulvar, vaginal, and anal 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]

*Cervical, vulvar, vaginal, and anal cancer cases combined.[1]

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

1. Senkomago V, et al. *MMWR Morb Mort Wkly Rep*. 2019;68(33):724-728. **2.** CDC. HUMAN PAPILLOMAVIRUS. IN: HAMBORSKY J, ET AL, EDS. *EPIDEMIOLOGY AND PREVENTION OF VACCINE-PREVENTABLE DISEASES*. 13TH ED. 2015:175-186. **3.** 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. **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. UPDATED APRIL 29, 2019. ACCESSED MARCH 9, 2020. **6.** Saraiya M, et al. *J Natl Cancer Inst*. 2015;107(6):1-12.

Make a Strong Recommendation: Use an Announcement-Based Approach

Using an **announcement-based approach** when recommending the HPV vaccine has been shown to increase HPV vaccine initiation over a participatory conversation[1]

At routine well visits, simply state

"Your child needs three vaccines today—one to prevent meningitis, one to prevent certain HPV-related cancers, and a Tdap booster."[2,*,†]

*There was an increase in injection-site swelling reported at the injection site for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) when administered concomitantly with *Menactra* and *Adacel*. The majority of injection-site swelling adverse experiences were reported as being mild to moderate in intensity.

†*Menactra* [Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] and *Adacel* [Tetanus Toxoid, Reduced Diphtheria Toxoid, and Acellular Pertussis Vaccine Adsorbed (Tdap)] are trademarks of their respective owners and are not trademarks of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.

HPV=human papillomavirus.

1. Brewer NT, et al. *Pediatrics*. 2017;139(1):1-9. **2**. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

Prevent Missed Opportunities for Vaccination: Make a Same-Day Recommendation

Among commercially insured patients **ages 11–12 years** (N=4,239,637)[1]*

62% had a well visit in 2016 (n=2,616,271)

36% had a well visit in the subsequent 2 years (2016-2018) (n=1,526,170)

Administer all in one visit—recommend GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) along with other CDC-recommended vaccines[2]

employer-sponsored insured population from January 1, 2016, to December 31, 2018, and provide a complete view of care for these patients. Patients with other insurance types, uninsured patients, and patients treated at public health clinics are excluded. Data are presented for well visits only. Patients who were 11- to 12-years-old in 2016 and had continuous enrollment in their health plan from 2016 to 2018 were included. The continuous eligibility requirement ensures a complete view of each patient's claims activity and provides a stable underlying sample for projections.

CDC=Centers for Disease Control and Prevention; COBRA=CONSOLIDATED OMNIBUS BUDGET RECONCILIATION ACT.

1. Data available on request from Merck Professional Services-DAP, WP1-27, PO Box 4, West Point, PA 19486-0004. Please specify information package US-GSL-01415.
2. Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723.

Countering Vaccine Hesitancy: A Report From the AAP[1]

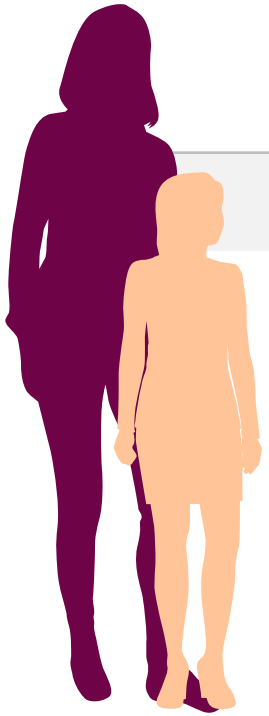
- ✓ Strongly support the benefits of vaccination
- ✓ Use a presumptive (announcement-based*) approach when recommending vaccines
- ✓ Address parental questions and concerns about vaccines

*Researchers have used various names for announcements, including “paternalistic,” “presumptive,” and “efficient communication.”[2]

AAP=American Academy of Pediatrics.

1. Edwards, KM, et al. *Pediatrics*. 2016;138(3):e20162146. **2.** Brewer NT, et al. *Pediatrics*. 2017;139(1):1-9.

Answering Common Parent Questions About HPV Vaccination



Why does my child need the HPV vaccine?

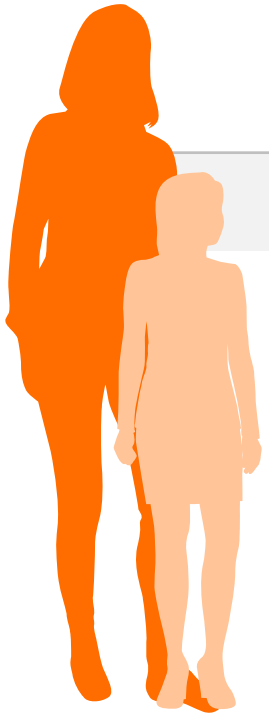
HPV can cause certain related cancers and diseases. While your child may not be at risk for HPV exposure now, you can start to help protect them from diseases and from cancers that can potentially occur later in life by vaccinating now.[1,2]

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.[1,3,4] There is no way to predict which patients who have HPV will develop cancer.[5]

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

1. CDC. Human papillomavirus. In: Hamborsky J, et al, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 13th ed. 2015:175-186. **2.** Senkomago V, et al. *MMWR Morb Mort Wkly Rep*. 2019;68(33):724-728. **3.** 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. **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.** HPV cancers. CDC website. https://www.cdc.gov/hpv/parents/cancer.html. Updated April 29, 2019. Accessed March 9, 2020. **6.** Meites E, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(32):698-702. **7.** About HPV. CDC website. https://www.cdc.gov/hpv/parents/about-hpv.html. Updated April 29, 2019. Accessed February 20, 2020.

Answering Common Parent Questions About HPV Vaccination



Why is the HPV vaccine given at age 11 or 12 years?

The CDC recommends giving HPV vaccination at 11 or 12 years of age. Vaccines are used for prevention. GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) is a type of cancer prevention and should be given prior to exposure to cancer-causing HPV types.[6,7]

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.[1,3,4] There is no way to predict which patients who have HPV will develop cancer.[5]

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

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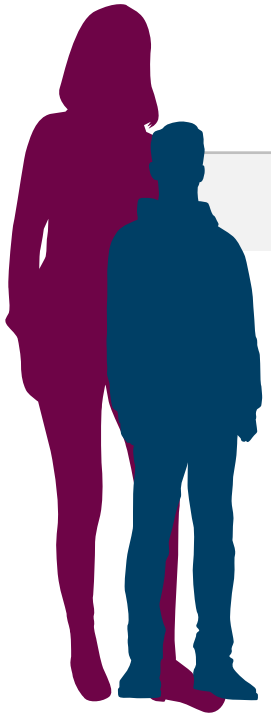
Answering Common Parent Questions About HPV Vaccination



Why do boys need the vaccine?

It's important that both girls and boys receive the HPV vaccine; in addition to cervical, vulvar, and vaginal cancer in women, HPV has also been linked to anal cancer in both men and women.[2]

For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.[1,3,4] There is no way to predict which patients who have HPV will develop cancer.[5]

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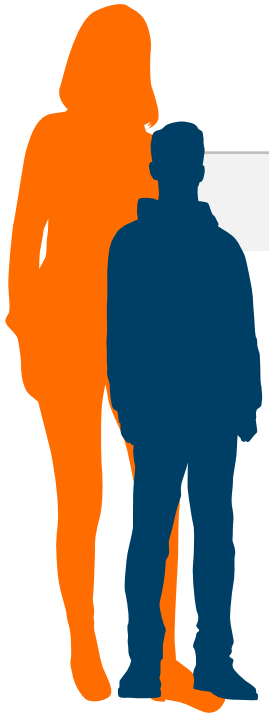
1. CDC. Human papillomavirus. In: Hamborsky J, et al, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 13th ed. 2015:175-186. **2.** Senkomago V, et al. *MMWR Morb Mort Wkly Rep*. 2019;68(33):724-728. **3.** CDC. 2015 sexually transmitted diseases treatment guidelines: human papillomavirus (HPV) infection. https://www.cdc.gov/std/tg2015/hpv.htm. Last reviewed June 4, 2015. Accessed February 3, 2020. **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.** HPV cancers. CDC website. https://www.cdc.gov/hpv/parents/cancer.html. Updated April 29, 2019. Accessed March 9, 2020. **6.** Meites E, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(32):698-702. **7.** About HPV. CDC website. https://www.cdc.gov/hpv/parents/about-hpv.html. Updated April 29, 2019. Accessed February 20, 2020.

Answering Common Parent Questions About HPV Vaccination



How common is HPV?

HPV is common, with an estimated 14 million new infections every year in the United States. About 7 million of them occur in 15- to 24-year-olds.[1]

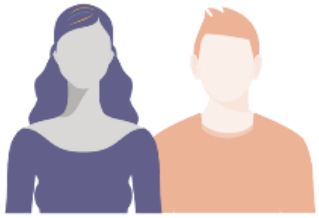
For most people, HPV clears on its own. But, for those who don't clear the virus, it could cause certain cancers and diseases.[1,3,4] There is no way to predict which patients who have HPV will develop cancer.[5]

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

1. CDC. Human papillomavirus. In: Hamborsky J, et al, eds. *Epidemiology and Prevention of Vaccine-Preventable Diseases.* 13th ed. 2015:175-186. **2.** Senkomago V, et al. *MMWR Morb Mort Wkly Rep*. 2019;68(33):724-728. **3.** 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. **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.** HPV cancers. CDC website. https://www.cdc.gov/hpv/parents/cancer.html. Updated April 29, 2019. Accessed March 9, 2020. **6.** Meites E, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(32):698-702. **7.** About HPV. CDC website. https://www.cdc.gov/hpv/parents/about-hpv.html. Updated April 29, 2019. Accessed February 20, 2020.

HPV Vaccine Efficacy Against Cancer and Diseases Caused by HPV Types 6, 11, 16, and 18 in Females and Males Ages 16–26 Years

5 AAHS-CONTROLLED CLINICAL STUDIES



16–26 years old

20,541 FEMALES | 4055 MALES

Vulvar cancer HPV 16- or 18-related VIN 2/3	100% n=7772
Vaginal cancer HPV 16- or 18-related VaIN 2/3	100% n=7772
Cervical cancer HPV 16- or 18-related CIN 2/3 or AIS	98% n=8493
Genital warts HPV 6-, 11-, 16-, or 18-related genital warts	99% IN FEMALES n=7900 89% IN MALES n=1394
Anal cancer in males HPV 6-, 11-, 16-, or 18-related AIN 2/3	75% n=194

Efficacy of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] was assessed in 5 AAHS-controlled, double-blind, randomized clinical studies evaluating 24,596 individuals (20,541 girls and women 16–26 years of age and 4055 boys and men 16–26 years of age). The per protocol efficacy population received all 3 vaccinations within 1 year of enrollment, had no major deviations from the study protocol, were naïve to the relevant HPV type(s) (Types 6, 11, 16, and 18) prior to dose 1, and remained PCR-negative to the relevant HPV type(s) through 1 month post-dose 3 (month 7).

AAHS=amorphous aluminum hydroxyphosphate sulfate; AIN=anal intraepithelial neoplasia; AIS=adenocarcinoma in situ; CIN=cervical intraepithelial neoplasia; HPV=human papillomavirus; PCR=polymerase chain reaction; VaIN=vaginal intraepithelial neoplasia; VIN=vulvar intraepithelial neoplasia.

HPV Vaccine Efficacy Against Cancers Caused by HPV Types 31, 33, 45, 52, and 58 in Females Ages 16–26 Years

ACTIVE COMPARATOR-CONTROLLED STUDY

16–26 years old

14,204 FEMALES

Vulvar, vaginal, and cervical cancer HPV 31-, 33-, 45-, 52-, 58-related CIN 2/3, AIS, cervical cancer, VIN 2/3, VaIN 2/3, vulvar cancer, and vaginal cancer

97%

n=6016
95% CI: 80.9%, 99.8%

1 case in the group receiving GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) (n=6016) vs 30 cases in the group receiving GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] (n=6017)

Efficacy of GARDASIL 9 in 16- through 26-ye
clinical study that included 14,204 females (G
the presence of HPV infection. Subjects were
efficacy for all endpoints was measured starting after the month 7 visit. The per protocol efficacy population received all 3 vaccinations within 1 year of enrollment, had no major deviations from the study protocol, were naïve to the relevant HPV type(s) (Types 31, 33, 45, 52, and 58) prior to dose 1, and remained PCR-negative to the relevant HPV type(s) through 1 month post-dose 3 (month 7).

AIS=adenocarcinoma in situ; CI=confidence interval; CIN=cervical intraepithelial neoplasia; HPV=human papillomavirus; PCR=polymerase chain reaction; VaIN=vaginal intraepithelial neoplasia; VIN=vulvar intraepithelial neoplasia.

Safety Profile for GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)

Selected Common Solicited and Unsolicited Injection Site and Systemic Adverse Reactions Post Any Dose in Persons Ages 9 Through 26 Years[a]

Population (n)	Injection Site, % (1 to 5 days postvaccination)			Systemic, %	
	Pain	Swelling	Erythema	Headache (1 to 15 days postvaccination)	Oral Temperature ≥100.0°F[b] (1 to 5 days postvaccination)
Females ages 9–15 y (n=299)	89.3	47.8	34.1	11.4	6.7
Females ages 16–26 y (n=7071)	89.9	40.0	34.0	14.6	6.0
Males ages 9–15 y (n=639)	71.5	26.9	24.9	9.4	10.4
Males ages 16–26 y (n=1394)	63.4	20.2	20.7	7.3	4.4

Safety of GARDASIL 9 in individuals ages 27–45 years is inferred from the safety data of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] in individuals ages 9 through 45 years and GARDASIL 9 in individuals ages 9 through 26 years.

7576 individuals who received at least 1 dose of GARDASIL as a control, both groups had safety follow-up. The vaccines were administered on the day of enrollment, and the subsequent doses administered approximately 2 and 6 months thereafter. Safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL 9 or GARDASIL. Injection-site reactions (pain, swelling, and erythema) and oral temperature were solicited using VRC-aided surveillance for 5 days after each injection of GARDASIL 9 during the clinical studies. [b]For subjects reporting temperature data: females 16 through 26 years of age, N=7022; boys 9 through 15 years of age, N=637; boys and men 16 through 26 years of age, N=1386.

y=years.

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

Select Safety Information *(continued)*

- Safety and effectiveness of GARDASIL 9 have not been established in pregnant women.
- The most common (≥10%) local and systemic adverse reactions in females were injection-site pain, swelling, erythema, and headache. The most common (≥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.
- There was an increase in injection-site swelling reported at the injection site for GARDASIL 9 when administered concomitantly with *Menactra* and *Adacel*. The majority of injection-site swelling adverse experiences were reported as being mild to moderate in intensity.

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.

Help Close the Gap by Discussing HPV Vaccination With Parents of Adolescents

The CDC recommends routine HPV vaccination for adolescents at age 11 or 12 years[1]

In the United States, gaps exist in HPV vaccination rates[2]

To help close the gaps, HCPs can[3]

- Focus on cancer prevention when discussing HPV vaccination
- Make a strong HPV vaccination recommendation
- Recommend HPV vaccination on the same day

CDC=Centers for Disease Control and Prevention; HCP=health care professionals; HPV=human papillomavirus.

1. Meites E, et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(32):698-702. **2.** Walker TY et al. *MMWR Morb Mortal Wkly Rep*. 2019;68(33):718-723. **3.** Gilkey MB, et al. *Vaccine*. 2016;34:1187-1192.

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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