ACTIONS TO INCREASE HPV VACCINATION WITHIN YOUR POPULATION

Unmet need Barriers Strategies Resources Achieving Goals Prescribing Information

Actor portrayal.
HPV=human papillomavirus.
Indication for GARDASIL 9

• 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.

• 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.

Indication continues.
WHY YOU SHOULD TAKE ACTION
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✅ You identified HPV vaccination as an organizational goal.

✅ You determined cohorts to focus on.

✅ You assessed the current vaccination rates within these cohorts.

✅ You set a benchmark and a timeline to achieve your goal.
The American Cancer Society has recognized that HPV vaccination is underutilized.8

The time to do something is now

According to the CDC in 2019, adolescents remain the most important focus of HPV vaccination.1

HPV vaccination is a type of cancer prevention2,3:

- The HPV vaccine is recommended before exposure through sexual activity.3
- For most people, HPV clears on its own, but for others who don’t clear the virus, it can lead to certain cancers and diseases.3,4,5
- A 2018 survey of 13- to 17-year-olds found that 53.7% of females and 48.7% of males had completed the HPV vaccine series, which is lower than other recommended adolescent vaccines.6
- In a 2017 survey, CDC estimated that ~48% of women and ~78% of men ages 19 to 26 had not received any dose of the HPV vaccine.7,a

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

*a Subset of data from National Health Interview Survey (NHIS) surveys of 19- to 26-year-olds (females n=1322, males n=1200). Response rate was 53% (total adult sample=26,430).

Indication for GARDASIL 9 (continued)

- 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.
2019 CDC UPDATE
HPV VACCINATION RECOMMENDATIONS

Routine vaccination recommended
For males and females at age 11 or 12 years, but can be given starting at age 9 years

Catch-up vaccination recommended
For males and females through age 26 years who are not adequately vaccinated

Shared clinical decision-making recommended
For some males and females ages 27 through 45 years who are not adequately vaccinated

Safety and effectiveness of GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) have not been established in pregnant women.

Select Safety Information for GARDASIL 9

- 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.
BARRIERS IMPACTING HPV VACCINATION RATES

HPV=human papillomavirus.
A VARIETY OF BARRIERS MAY PREVENT HIGHER VACCINATION RATES

Potential issues vary based on local ecosystem dynamics.

Clinical
Inconsistent or unclear provider recommendation for HPV vaccination.¹
Parental need for information about the HPV vaccine.¹

Financial
Regardless of their type of coverage, men and women in the US reported putting off or postponing preventive services in the past year due to cost.²
The Affordable Care Act generally requires coverage for all vaccines administered in accordance with final CDC recommendations.³
This requirement applies to all non-grandfathered commercial plans and Medicaid expansion beneficiaries.³

Operational
Most states do not require HPV vaccination for children in secondary school.⁴

POTENTIAL STRATEGIES TO OVERCOME BARRIERS AND INCREASE HPV VACCINATION RATES

HPV=human papillomavirus.
Permitting HPV vaccinations to be administered in alternative locations, such as pharmacies, could help increase series completion rates.9

A POTENTIAL OPPORTUNITY TO SET PRIORITIES AND SUPPORT ACTION AT A LOCAL LEVEL

Deliver a simple and consistent vaccine message.

1. **Set the goal**
   - The Healthy People 2020 goal is an 80% vaccination rate (series completion) by the end of 2020 for males and females aged 13 through 15 years.1,a

2. **Set the priority**
   - Motivate your team and encourage their immunization conversations with parents.2
   - Implement systems to ensure you never miss an opportunity to vaccinate.2

3. **Identify local stakeholders to partner with**
   - State health departments.3
   - Medical associations (eg, American Academy of Pediatrics, American Academy of Family Physicians) and societies (eg, Society for Adolescent Health and Medicine).3

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**National Vaccine Advisory Committee recommends that all stakeholders collaborate to coordinate communications to encourage consistent messages.**3

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**HCP**=health care provider; **HPV**=human papillomavirus.

*aThe Healthy People 2020 goal is to increase the vaccination rate level of: 2 or 3 doses of HPV vaccine for males and females aged 13 to 15 years to 80%.1

CONSIDER COORDINATION ACROSS ALL STAKEHOLDERS

Click on a stakeholder to see their role and actions in the HPV vaccination process

- Encourage HPV regimen initiation and completion\(^1,2\)
- Increase the recommended routine vaccination for males and females at age 11 or 12 years, or starting at age 9 years in certain circumstances, and the recommended catch-up vaccination for males and females through age 26 years who are not adequately vaccinated\(^1,2\)

ACO=accountable care organization; CIN=clinically integrated network; EHR=electronic health record; HPV=human papillomavirus; IDN=integrated delivery network; IIS=immunization information systems.

CONSIDER COORDINATION ACROSS ALL STAKEHOLDERS

Health plan

THINGS TO CONSIDER:

• Identify members, provide member lists to providers, encourage utilization of EHR systems and IIS (registries) to identify appropriate patients.1
• Encourage appropriate unvaccinated individuals to initiate and complete the series.2,3

References:
Consider Coordination Across All Stakeholders

Provider (IDNs, CINs/ACOs, Solo Practitioners)

**THINGS TO CONSIDER:**

- Use EHR systems to identify appropriate patients.¹
- Develop targeted communication strategies with recommendations to appropriate patients and parents.²
- Be advocates for prevention of certain HPV-related cancers and diseases for patients.²

CONSIDER COORDINATION ACROSS ALL STAKEHOLDERS

Pharmacist

THINGS TO CONSIDER:

- Take a proactive role in making a clear vaccination recommendation and vaccinating appropriate patients.¹
- Identify and determine patient coverage.²

CONSIDER COORDINATION ACROSS ALL STAKEHOLDERS

Employer

THINGS TO CONSIDER:

- Raise awareness of the employees’ health plan benefit design.¹
- Encourage HPV vaccination as part of a health policy initiative.²

CONSIDER COORDINATION ACROSS ALL STAKEHOLDERS

Member/Patient

THINGS TO CONSIDER:

- Understand their insurance coverage.¹
- Talk to their provider about the potential risks and benefits of vaccination.

References:


EHRs CAN BE AN EFFECTIVE TOOL FOR PROVIDERS TO IDENTIFY APPROPRIATE PATIENTS

Potential benefits of EHR systems include:

- Real-time alerts identifying appropriate patients for initial vaccination or series completion.²
- Improved public health reporting and surveillance.¹
- Provides a more meaningful look at patient health needs.¹

Health plans can encourage providers to use EHRs to identify completion statistics of vaccine protocols.

- Add protocols in EHRs that identify appropriate patients due for HPV vaccination initiation or series completion.³
- Increase gender-neutral vaccination rates in individuals aged 19 to 26 years.⁴
- Encourage a clear provider prompt through EHRs about vaccination.²
- Improve public health reporting and surveillance with EHRs through¹:
  — Immunization registries
  — Communication with public health officials
  — Sending patient reminders

EHR=electronic health record; HPV=human papillomavirus.

DON’T MISS THE OPPORTUNITY TO ENGAGE

Coverage¹
Ensure patients are aware of their insurance coverage for vaccinations.

Uninsured and underinsured families may be eligible to receive assistance from programs that will cover certain vaccine costs.

Education²
For adolescent patients, provide parents with educational information on the importance of HPV vaccination.


HPV=human papillomavirus.
Select Safety Information for GARDASIL 9 (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.
RESOURCES TO INCREASE HPV VACCINATION RATES

HPV=human papillomavirus.
Consider how you can help relevant stakeholders prioritize HPV vaccinations.

RESOURCES EXIST THAT MAY HELP EDUCATE PROVIDERS, PHARMACISTS, EMPLOYERS, AND MEMBERS/PATIENTS

Share the following tips:

- Per the CDC, encourage providers to recommend HPV vaccination the same day and the same way they recommend other vaccines for adolescent patients¹
- Recommend vaccination consistently for appropriate patients²
- Use the available resources to increase awareness and education²
- Use your electronic health systems to identify and track eligible patients due for vaccination initiation and completion³

References:

Additional Resource

CDC: The CDC provides educational resources on the importance of vaccines, disease education, and vaccination recommendations.

CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus.
RESOURCES EXIST THAT MAY HELP EDUCATE PROVIDERS, PHARMACISTS, EMPLOYERS, AND MEMBERS/PATIENTS

Consider how you can help relevant stakeholders prioritize HPV vaccinations.

Remind pharmacists that they can acquire support and resources through the Merck Adult Vaccination Program.

Additional Resource

The CDC provides educational resources on the importance of vaccines, disease education, and vaccination recommendations.

CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus.
Consider how you can help relevant stakeholders prioritize HPV vaccinations.

### Resources Exist That May Help Educate Providers, Pharmacists, Employers, and Members/Patients

#### Providers

- **Remind employers that there are resources available to assist them in raising awareness:**
  - Raise awareness of the employees’ health plan benefit design\(^1\)
  - Encourage HPV vaccination as part of a health policy initiative\(^2\)

#### Pharmacists

- • Raise awareness of the employees’ health plan benefit design\(^1\)
- • Encourage HPV vaccination as part of a health policy initiative\(^2\)

#### Employers

**References:**

#### Members/Patients

### Additional Resource

**CDC**

The CDC provides educational resources on the importance of vaccines, disease education, and vaccination recommendations.

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\(^1\) CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus.
RESOURCES EXIST THAT MAY HELP EDUCATE PROVIDERS, PHARMACISTS, EMPLOYERS, AND MEMBERS/PATIENTS

Merck offers various resources that can be provided to members/patients to educate them on the importance of vaccinations

www.gardasil9.com

Consider how you can help relevant stakeholders prioritize HPV vaccinations.

Additional Resource

CDC

The CDC provides educational resources on the importance of vaccines, disease education, and vaccination recommendations.

CDC=Centers for Disease Control and Prevention; HPV=human papillomavirus.
Dosage and Administration for GARDASIL 9

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.
ACHIEVING YOUR GOAL
1. Choose the problems to focus on.

2. Identify goals, population, and desired outcomes.

3. Find existing programs or best practices worth adopting.

4. Modify the program or best practice to fit your needs.

5. Assess capacity (staff, financing, etc) to implement the program.

6. Make a plan to implement: who, what, when, where, and how.

7. Establish a way to measure program results.

8. Establish a plan for continuous quality improvement.

9. Consider how to keep the program going to ensure success.

LEAD A UNIFIED APPROACH TO INITIATE CHANGE

Set clear priorities and support activity of national and local partners.

**Aim for consistency and collaboration among stakeholders.**

**Encourage all stakeholders to make vaccination a standard of care and support initiation and series completion.**

**Join forces with local partners and embrace their ability to enhance your cause.**

**Utilize the Immunizations for Adolescents measure from the Healthcare Effectiveness Data and Information Set (HEDIS®) to track HPV vaccination rates.**

**References:**

HPV=human papillomavirus.
Before administering GARDASIL®9 (Human Papillomavirus 9-valent Vaccine, Recombinant), please read the accompanying Prescribing Information. The Patient Information also is available.