National Center for Immunization and Respiratory Diseases

Human Papillomavirus Vaccine

Pink Book Web-on-Demand Series

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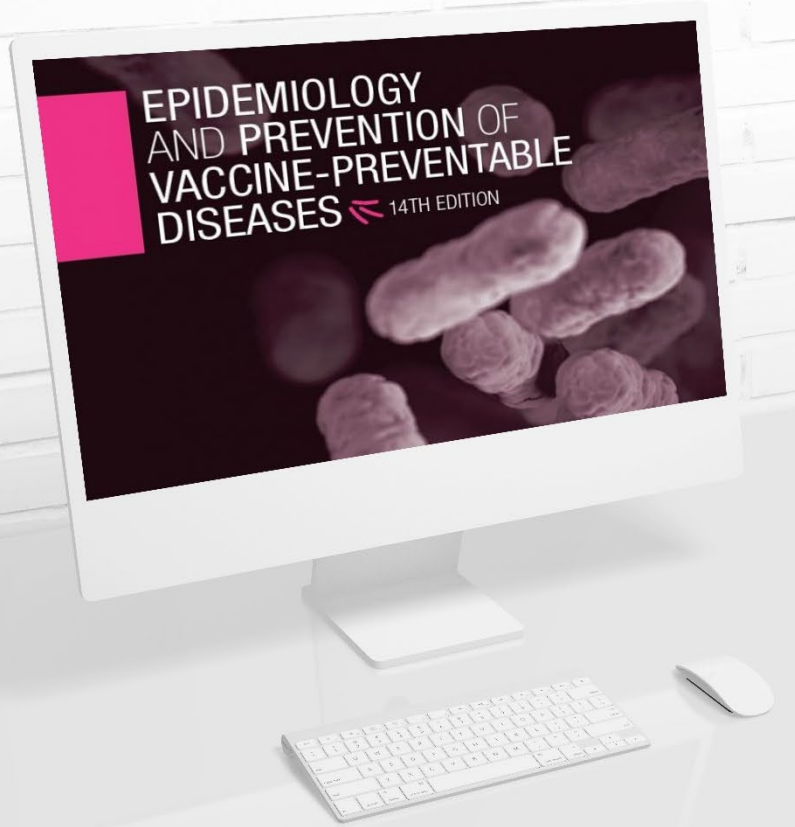

Learning Objectives

- Describe the fundamental principles of the immune response.
- Describe immunization best practices.
- Describe an emerging immunization issue.
- For each vaccine-preventable disease, identify those for whom routine immunization is recommended.
- For each vaccine-preventable disease, describe characteristics of the vaccine used to prevent the disease.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.

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1

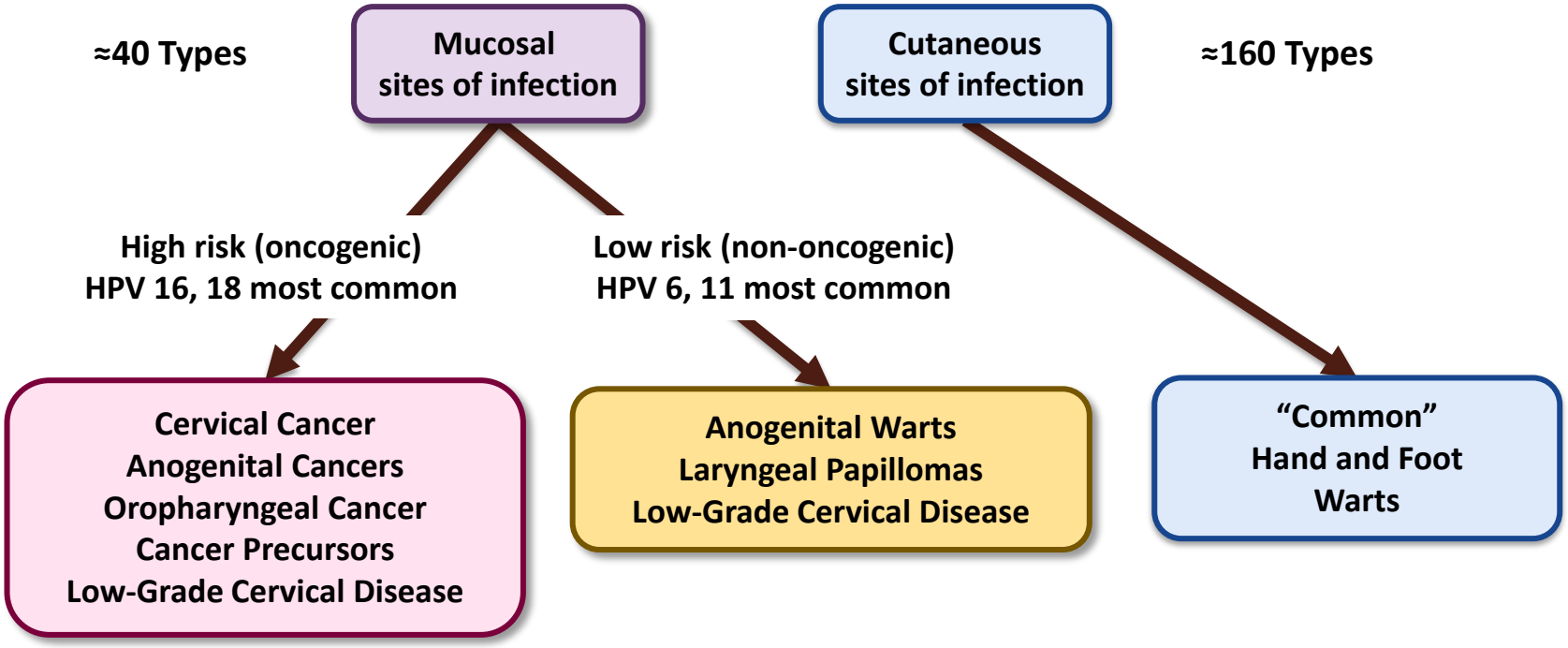
Human Papillomavirus

Human Papillomavirus (HPV)

- **Most common sexually transmitted infection in the U.S.**
- **Small DNA virus**
- **More than 200 types**
- **First vaccine was licensed in 2006**

Chapter 11: Human Papillomavirus | Pink Book | CDC

HPV Types Differ in Their Disease Associations



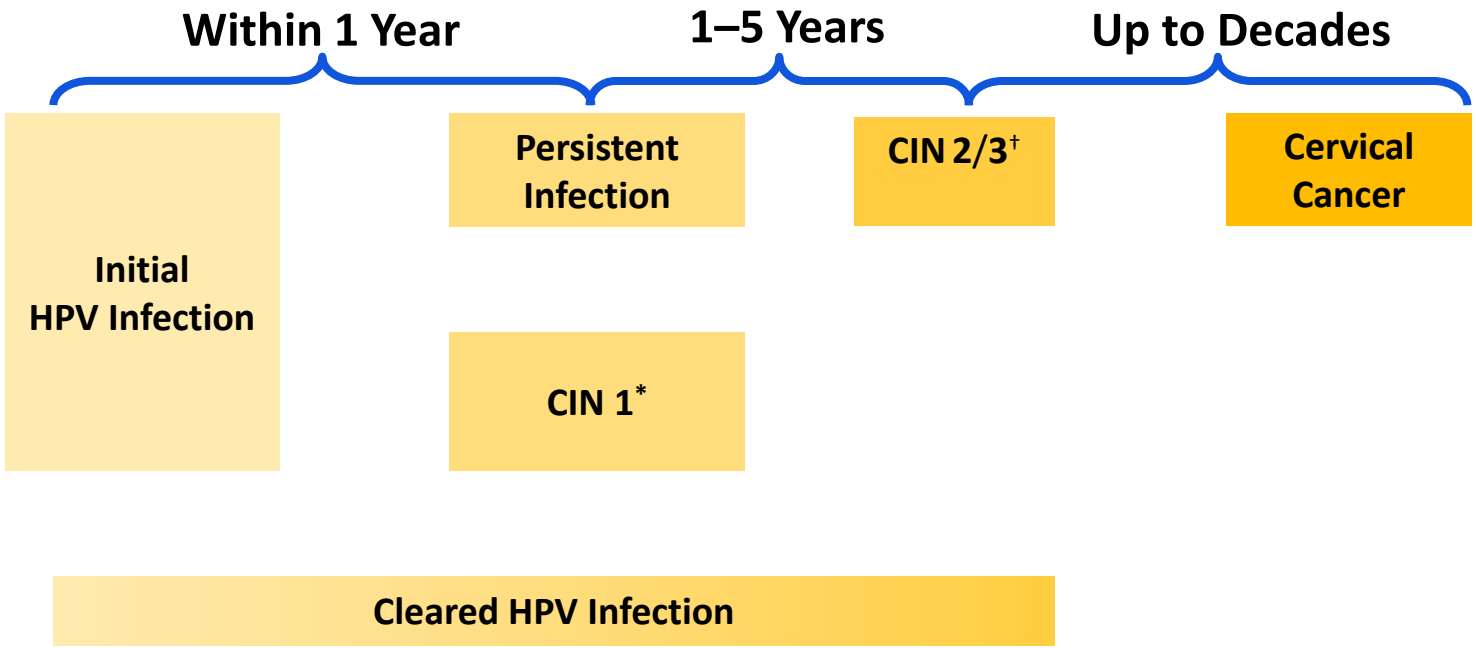
Chapter 11: Human Papillomavirus | Pink Book | CDC

HPV Clinical Features

- **Most HPV infections are *asymptomatic* and result in no clinical manifestations.**
- **Clinical manifestations of HPV infection include:**
  - Anogenital warts
  - Recurrent respiratory papillomatosis
  - Cervical cancer precursors (cervical intraepithelial neoplasia/CIN)
  - Cancer:
    - Cervical
    - Anal
    - Vaginal
    - Vulvar
    - Penile
    - Oropharyngeal

Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR (cdc.gov), Clinical Overview of HPV | HPV | CDC; Chapter 11: Human Papillomavirus | Pink Book | CDC

Natural History of HPV Infection



*CIN 1 = cervical intraepithelial neoplasia (low grade); †CIN 2/3 = cervical intraepithelial neoplasia (medium/high grade)

Chapter 11: Human Papillomavirus | Pink Book | CDC

2

Human Papillomavirus Vaccine

HPV Vaccines Licensed in the United States

	Bivalent 2vHPV (Cervarix)	Quadrivalent 4vHPV (Gardasil)	9-Valent 9vHPV (Gardasil 9)
HPV Types	16, 18	16, 18, 6, 11	16, 18, 6, 11 31, 33, 45, 52, 58
Prevents	Cancers	Cancers and genital warts	Cancers and genital warts
Licensed	2009	2006	2014

Since the end of 2016, 9vHPV has been the only HPV vaccine available in the United States.

Chapter 11: Human Papillomavirus | Pink Book | CDC

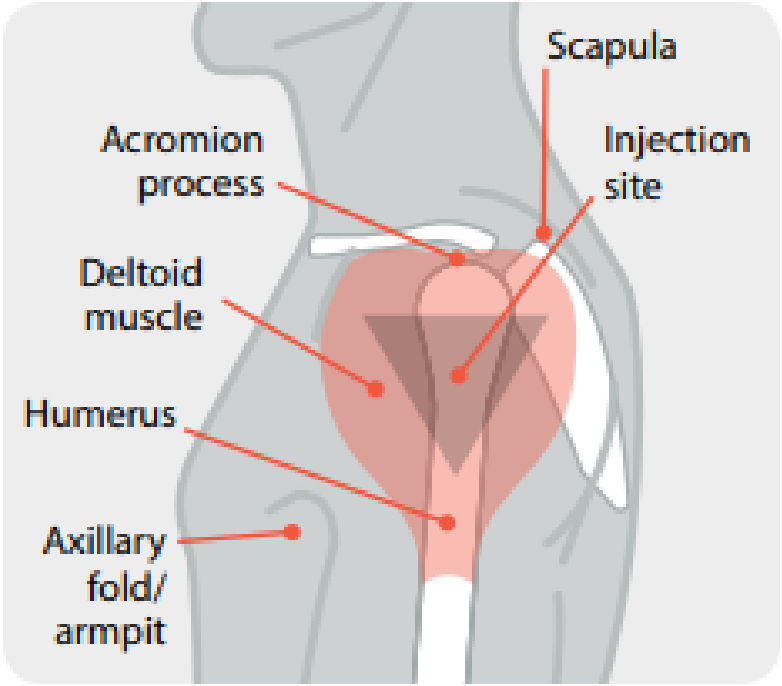
HPV Vaccine

- No antibiotics
- No preservatives
- Aluminum as an adjuvant
- Yeast protein (only 9vHPV and 4vHPV)

Chapter 11: Human Papillomavirus | Pink Book | CDC

HPV Vaccine

- **Administered intramuscularly**



Chapter 11: Human Papillomavirus | Pink Book | CDC

HPV Vaccines Are Highly Efficacious

- **High efficacy among females without evidence of infection with vaccine HPV types**
- **More than 95% reduction in cervical cancer precursors**
- **No evidence of efficacy against existing infection or disease**
- **Prior infection with one HPV type did not diminish the efficacy of the vaccine against other vaccine HPV types.**

Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices

Expanded Age Indication for 9-Valent HPV Vaccine

- **Initial licensure was for ages 9 through 26 years**
- **FDA approved expanded age indication in 2018:**
  - Women and men ages 27 though 45 years
  - Evidence based on bridging data
- **In 2019, ACIP recommended shared clinical decision-making for ages 27 through 45 years.**

Shared Clinical Decision-Making: HPV Vaccination for Adults Aged 27-45 Years (cdc.gov), ACIP Shared Clinical Decision-Making Recommendations | ACIP | CDC, Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

Knowledge Check

A provider is evaluating a 52-year-old woman with a history of multiple sex partners and genital warts. She has not previously received any HPV vaccine. Is HPV vaccine recommended for her?

A. Yes

B. No

Knowledge Check

A provider is evaluating a 52-year-old woman with a history of multiple sex partners and genital warts. She has not previously received any HPV vaccine. Is HPV vaccine recommended for her?

A. Yes

B. No 

3

Vaccination Schedule and Clinical Considerations

HPV Child and Adolescent Vaccination Schedule

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger; 2025 U.S.

HPV Adult Vaccination Schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision–making

No Guidance/ Not Applicable

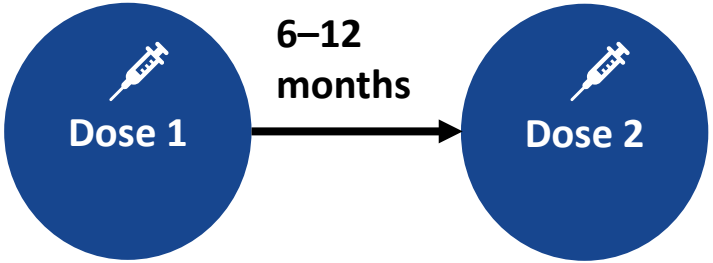
Recommended Adult Immunization Schedule for ages 19 years or older; 2025 U.S.

HPV Vaccine Dosing Schedules, United States

- **Starts vaccination at age 9 through 14 years**

  AND

- **No immunocompromising conditions or autoimmune disease**



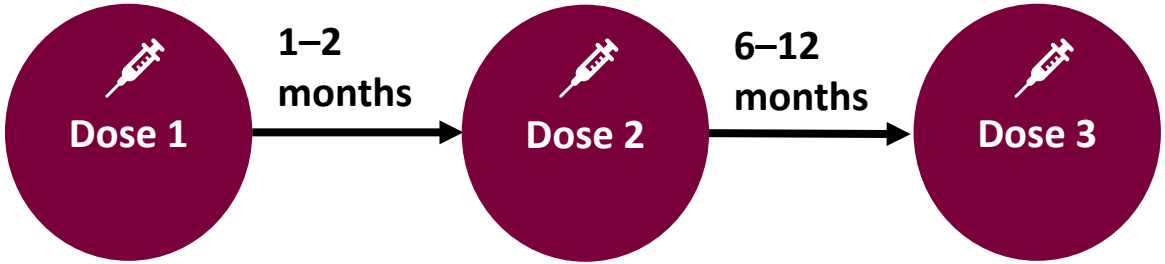
- **Starts vaccination at age 15 through 26 years**

OR

- **Starts vaccination at age 9 through 26 years**

  AND

- **Has an immunocompromising condition or autoimmune disease**



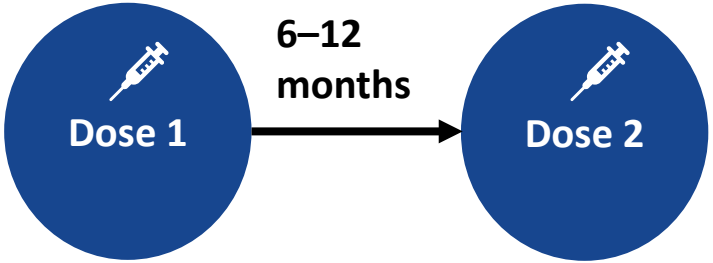
Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

HPV Vaccine 2-Dose Schedule, United States (1)

- **Starts vaccination at age 9 through 14 years**

  AND

- **No immunocompromising conditions or autoimmune disease**



- Starts vaccination at age 15 through 26 years

OR

- Starts vaccination at age 9 through 26 years

  AND

- Has an immunocompromising condition or autoimmune disease

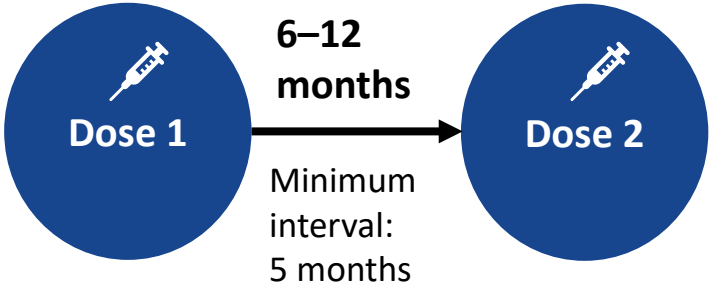
Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

HPV Vaccine 2-Dose Schedule, United States (2)

- **Starts vaccination at age 9 through 14 years**

  AND

- **No immunocompromising conditions or autoimmune disease**



- Starts vaccination at age 15 through 26 years

OR

- Starts vaccination at age 9 through 26 years

  AND

- Has an immunocompromising condition or autoimmune disease

Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

HPV Vaccine 3-dose Schedule, United States (1)

- Starts vaccination at age 9 through 14 years

  AND

- No immunocompromising conditions or autoimmune disease

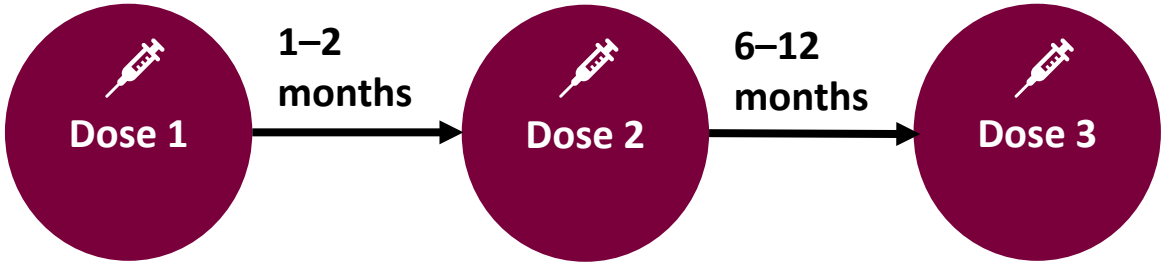
- **Starts vaccination at age 15 through 26 years**

OR

- **Starts vaccination at age 9 through 26 years**

  AND

- **Has an immunocompromising condition or autoimmune disease**



Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

HPV Vaccine 3-dose Schedule, United States (2)

- Starts vaccination at age 9 through 14 years

AND

- No immunocompromising conditions or autoimmune disease

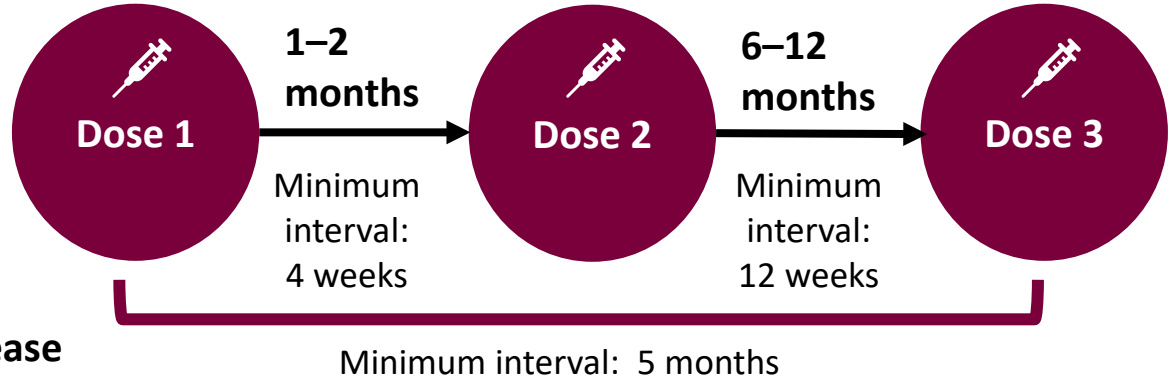
- **Starts vaccination at age 15 through 26 years**

OR

- **Starts vaccination at age 9 through 26 years**

AND

- **Has an immunocompromising condition or autoimmune disease**



Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

Persons With an Incomplete Series or Who Previously Received Incomplete 4vHPV or 2vHPV Series (1)

- **Use 9vHPV to continue or complete a series started with 4vHPV or 2vHPV.**

- **Adequately vaccinated = completed a recommended schedule with 9vHPV, 4vHPV, or 2vHPV vaccine**

Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

Persons With an Incomplete Series or Who Previously Received Incomplete 4vHPV or 2vHPV Series (2)

- **If first dose of 9vHPV, 4vHPV, or 2vHPV administered**
  - Before their 15th birthday, fully vaccinated if received
    - 2 doses at recommended dosing schedule (0, 6–12 months)

      or
    - 3 doses at recommended dosing schedule (0, 1–2, 6 months)
  - On or after their 15th birthday, fully vaccinated if received
    - 3 doses at recommended dosing schedule (0, 1–2, 6 months)
- **All doses do not need to be 9vHPV.**

Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

HPV Vaccination: Adults Ages 27–45 Years

- **Shared clinical decision-making**
  - Including those who may have received doses before 27th birthday

Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

Considerations for Shared Clinical Decision-Making: Adults 27 Through 45 Years of Age (1)

- HPV a common sexually transmitted infection
- Most HPV infections cause no clinical problems
- HPV infections usually acquired in adolescence and young adulthood
- New sex partner a risk factor for new HPV infection at any age
- Persons in a long-term, mutually monogamous sexual partnership not likely to acquire a new HPV infection
- Most sexually active adults have been exposed to HPV.

Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

Considerations for Shared Clinical Decision-Making: Adults 27 Through 45 Years of Age (2)

- **No antibody test for immunity**
- **Vaccine efficacy high among persons not already exposed to vaccine-type HPV**
- **Vaccine effectiveness might be low for people with:**
  - Risk factors for HPV infection or disease
  - Certain immunocompromising conditions
- **HPV vaccines are prophylactic (prevent new HPV infections)**

Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices | MMWR

ACIP HPV Immunization Recommendations: Additional Considerations

- **No therapeutic effect on:**
  - HPV infection
  - Genital warts
  - Cervical lesions
- **Pre-vaccination testing to establish the appropriateness of vaccination not recommended:**
  - Pap or HPV testing
  - Pregnancy testing
- **Does not eliminate need for continued cervical cancer screening**

Chapter 11: Human Papillomavirus | Pink Book | CDC , Screening for Cervical Cancer | Cervical Cancer | CDC

HPV Vaccine and Pregnancy

- **Delay HPV vaccination until after pregnancy**
- **Delay remaining doses if pregnancy occurs after start of HPV series**
- **No cause for alarm if vaccine administered during pregnancy**
- **Anyone vaccinated while pregnant can call the HPV vaccine manufacturer: 1-877-888-4231**
- **Report suspected adverse events following HPV vaccination during pregnancy to VAERS: https://vaers.hhs.gov/reportevent.html**

HPV Vaccination Recommendations | CDC, Vaccine Adverse Event Reporting System (VAERS) (hhs.gov)

Knowledge Check

A 30-year-old woman received a first dose of HPV vaccine at 25 years of age. Is shared clinical decision-making recommended to continue the series?

A. Yes

B. No

Knowledge Check

A 30-year-old woman received a first dose of HPV vaccine at 25 years of age. Is shared clinical decision-making recommended to continue the series?

A. Yes 

B. No

Knowledge Check

A woman becomes pregnant while receiving HPV vaccine. Do you continue with the series?

A. Yes

B. No

Knowledge Check

A woman becomes pregnant while receiving HPV vaccine. Do you continue with the series?

A. Yes

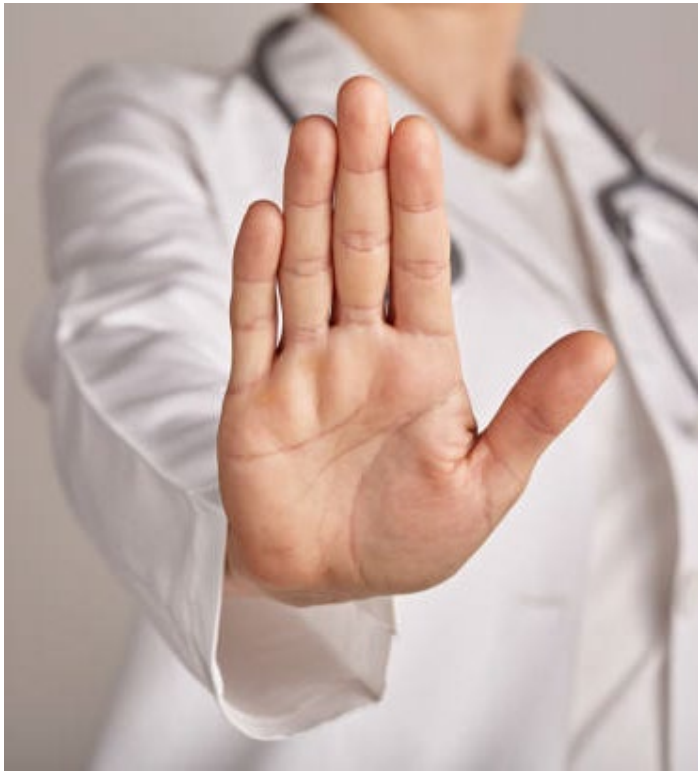
B. No

4

Safety

Contraindications

- **Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component**
- **History of immediate hypersensitivity to yeast, 4vHPV and 9vHPV only**



HPV Vaccination Recommendations | CDC, ACIP Contraindications Guidelines for Immunization | CDC, Package Insert - GARDASIL 9 (fda.gov)

Precautions

- **Moderate or severe acute illness with or without fever**
  - Defer until symptoms improve

HPV Vaccination Recommendations | CDC

HPV Vaccine Adverse Reactions

Nausea

Headache

Injection site pain, swelling, or redness

Muscle or joint pain

Fever

HPV Vaccine Safety and Effectiveness Data | HPV | CDC
Gee J, et al. *Hum Vaccin Immunother.* 2016 Jun 2;12(6):1406-17. . doi: 10.1080/21645515.2016.1168952 - Search

HPV Vaccine Adverse Reactions

- **Life-threatening allergic reaction can occur after any vaccination, including HPV vaccination.**
- **Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine.**
- **Patients should be seated (or lying down) during vaccination and remain in that position for 15 minutes.**

Human Papillomavirus (HPV) Vaccine Safety | Vaccine Safety | CDC; HPV Vaccine Safety and Effectiveness Data | HPV | CDC; and Gee J, et al. Hum Vaccin Immunother. 2016 Jun 2;12(6):1406-17. doi: 10.1080/21645515.2016.1168952 - Search .

Knowledge Check

All of the following strategies can be used to help to prevent syncope when vaccinating adolescents *except*:

A. Vaccinating while in a sitting position

B. Vaccinating while in a standing position

C. Vaccinating while in a lying down position

D. Observing patients for 15 minutes following vaccination

Knowledge Check

All of the following strategies can be used to help to prevent syncope when vaccinating adolescents *except*:

A. Vaccinating while in a sitting position

B. Vaccinating while in a standing position

C. Vaccinating while in a lying down position

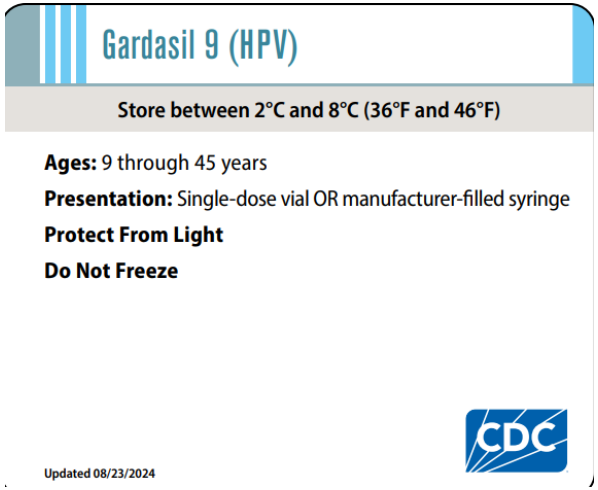
D. Observing patients for 15 minutes following vaccination

5

Storage & Handling

Vaccine Storage and Handling

- **Store HPV vaccine in a refrigerator between 2°C and 8°C (36°F and 46°F).**
- **Store HPV vaccines:**
  - In the original packaging with the lids closed
  - In a clearly labeled bin of the storage unit
- **Do not freeze the vaccine.**
- **Protect the vaccine from light.**



Vaccine storage label example is available at: [Vaccine Labels: Storage and Beyond-Use Date Tracking]

6 Resources

CDC Clinical Resources

www.cdc.gov/vaccines/

- Advisory Committee on Immunization Practices (ACIP) Vaccine Recommendations and Guidelines
- Recommended Immunization Schedules
- Vaccine Storage and Handling Toolkit
- Vaccine Information Statements

Pink Book Training Materials

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https://www.train.org/cdctrain/welcome

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