Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Updates from the Advisory Committee on Immunization Practices and shared clinical decision-making for vaccines

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1

Disclosure and Disclaimer

- Dr. Meyer has no relevant relationships with commercial entities whose products are mentioned in this presentation.
- Use of trade names of vaccine products is for identification purposes and does not imply endorsement by the Centers for Disease control and Prevention (CDC)
- Use of vaccines in a manner not approved by the U.S. Food and Drug Administration may be discussed.
  - But in accordance with recommendations by the Advisory Committee on Immunization Practices (ACIP)
- The findings and conclusions in this presentation are those of the presenters and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

2

2

Overview

- Overview of the 2022 Immunization Schedules
- Updates for Children and Adolescents
- Updates for Adults
- Recent COVID-19 Vaccine updates
- Shared Clinical Decision Making for Vaccines

3

3

2022 Immunization Schedules

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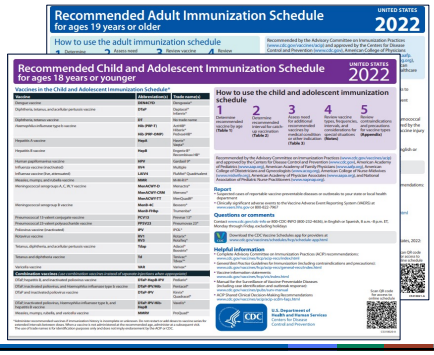

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Major Updates: 2022 Child/Adolescent Immunization Schedule

– Dengue[1]

1. Grohskopf LA et al. Recommendations for preventing and controlling 2021-22 influenza with vaccination in the United States. *MMWR* Aug 2021; 70(No. RR-5); 1-28
2. Paz-Bailey G et al. Recommendations for use of dengue vaccine in the United States. *MMWR* Dec 2010; 70(No. RR-6): 1-16

6

6

Major Updates: 2022 Adult Immunization Schedule

- Pneumococcal[1]
- Hepatitis B[2]
- Herpes zoster[3]

1. Grohskopf LA et al. Recommendations for preventing and controlling 2021-22 influenza with vaccination in the United States. *MMWR* Aug 2021; 70(No. RR-5); 1-28
2. Kobayashi M et al. Recommendations for use of PCV15 and PCV20 vaccines in the United States. *MMWR* Jan 2022; 71: 109–117
3. Weng M et al. Recommendations for universal hepatitis B vaccination for persons aged ≥19 years. ACIP Meeting November 3, 2021 (Vote)
4. Anderson TC et al. Recommendations for use of recombinant zoster vaccine in immunocompromised adults aged ≥19 years, United States. *MMWR* Jan 2021;71:80-84

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Updates for Children and Adolescents

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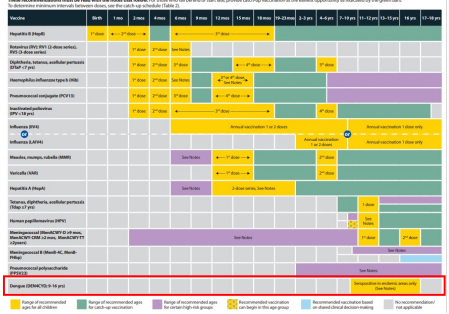
Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2022



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Dengue

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Dengue vaccine recommendations

- Dengvaxia is a tetravalent, live-attenuated vaccine approved for use in:
  - People 9 through 16 years of age living in dengue-endemic areas
  - AND **who have laboratory confirmation of previous dengue infection**
- 3-dose series (0, 6, and 12 months)
- Subcutaneous (SQ) injection
- May be administered the **same day** as other vaccines, but live-attenuated vaccines not administered simultaneously should be **separated by at least 4 weeks**.

11

11

Dengue-endemic areas

- American Samoa
- Puerto Rico
- U.S. Virgin Islands
- Federated States of Micronesia
- Republic of the Marshall Islands
- Republic of Palau

https://www.cdc.gov/dengue/vaccine/hcp/index.html

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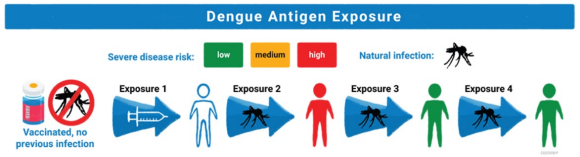
Dengvaxia administration to dengue-naïve people associated with increased risk of severe disease when vaccinated person subsequently infected



https://www.cdc.gov/dengue/vaccine/hcp/index.html

13

13

Dengvaxia should only be administered to people with serologic evidence of prior infection

https://www.cdc.gov/dengue/vaccine/hcp/index.html

14

14

Dengue Contraindications

- **Contraindicated** in:
  - Persons with immunocompromising conditions, including those with severe immunosuppression due to HIV infection
  - Persons without a laboratory-confirmed previous dengue virus infection
  - Persons who have had a severe (life-threatening) allergic reaction to a previous dose of the vaccine or ingredient
- Vaccine may be indicated if the **benefit of protection outweighs the risk** of adverse reaction
  - Persons who are pregnant
  - Persons with HIV infection who do not have severe immunosuppression

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Updates for Adults

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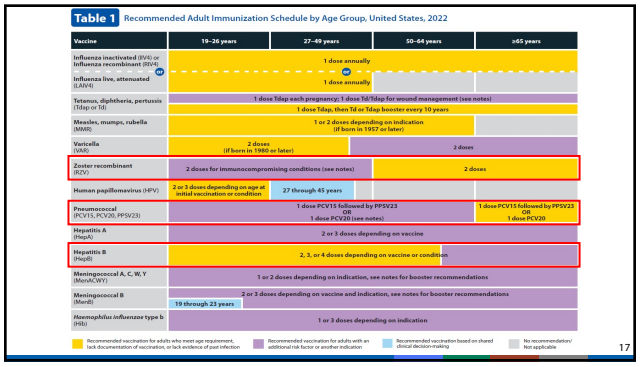

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Zoster

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18

Recombinant Zoster Vaccine in People with Altered Immunocompetence

- Persons with **altered immunocompetence** at higher risk of severe disease from zoster
- RZV **safety similar** to vaccine in immunocompetent individuals
- RZV **effective** in persons with altered immunocompetence

Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years: Recommendations of the Advisory Committee on Immunization Practices — United States, 2022

19

19

Updated Recommendations for Zoster Vaccine

- Two doses of recombinant zoster vaccine are recommended for the prevention of herpes zoster and its complications in adults 19 years of age or older who are or will be immunodeficient or immunosuppressed due to disease or therapy.

20

20

Zoster Vaccine Recommendations

Previous Recommendation	New Recommendation
Recombinant zoster vaccine (RZV) is recommended for the prevention of herpes zoster and related complications for: • Immunocompetent adults aged ≥50 years	Recombinant zoster vaccine (RZV) is recommended for the prevention of herpes zoster and related complications for: • Immunocompetent adults aged ≥50 years • Adults aged ≥19 years who are or will be immunodeficient or immunosuppressed due to disease or therapy

21

21

Zoster vaccine: Clinical Guidance

- 2 doses of RZV are needed, regardless of prior history of herpes zoster or receipt of zoster vaccine live
  - The 2nd RZV dose should typically be given 2–6 months after the first; may be administered 1-2 months after the 1st in people who are or will be immunosuppressed and who would benefit from a shorter vaccine schedule
- When possible, patients should be vaccinated before becoming immunosuppressed.
  - Otherwise, providers should consider timing vaccination when the immune response is likely to be most robust (i.e., during periods of lower immunosuppression and stable disease).
- RZV can be co-administered (at a different anatomic site) with other adult vaccines, including COVID-19 vaccines

22

22

RZV vaccination in special populations

- **Pregnant people:** Consider delaying RZV until after pregnancy.
- **Breastfeeding:** Consider vaccination without regard to breastfeeding status if RZV is otherwise indicated.
- **People with a history of herpes zoster:** Should receive RZV (herpes zoster can recur)
- **People who do not have a history of varicella, varicella vaccination, or herpes zoster**: Not recommended (as these people are not at risk for herpes zoster)

23

23

Pneumococcal

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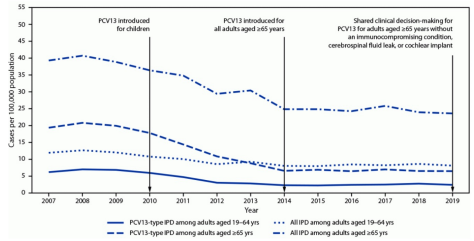
24

Incidence of invasive pneumococcal disease in adults, by type and age group – United States, 2007-2019



Kobayashi M, Farrar JL, Gierke R, et al. Use of 15-Valent Pneumococcal Conjugate Vaccine and 20-Valent Pneumococcal Conjugate Vaccine Among U.S. Adults: Updated Recommendations of the Advisory Committee on Immunization Practices — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:109-117.

25

25

Two Newly Licensed Pneumococcal Conjugate Vaccines

23-valent pneumococcal polysaccharide vaccine (PPSV23)	Pneumovax23®, Merck
13-valent pneumococcal conjugate vaccine (PCV13)	Prevnar13®, Pfizer
15-valent pneumococcal conjugate vaccine (PCV15)	Vaxneuvance™, Merck
20-valent pneumococcal conjugate vaccine (PCV20)	Prevnar20™, Pfizer

Adapted from slide prepared by M. Kobayashi

26

26

Pneumococcal vaccine recommendations

- Adults **65 years of age or older** who have not previously received any pneumococcal vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15).
  - If PCV15 is used, this should be followed by a dose of PPSV23.

- Adults ages **19 through 64 years with certain underlying medical conditions** or other risk factors* who have not previously received any pneumococcal vaccine or whose previous vaccination history is unknown should receive a pneumococcal conjugate vaccine (either PCV20 or PCV15).
  - If PCV15 is used, this should be followed by a dose of PPSV23.

27

27

Pneumococcal: Underlying Medical Conditions or Other Risk Factors*

- Alcoholism
- Chronic heart/liver/lung disease
- Chronic renal failure
- Cigarette smoking
- Cochlear implant
- Congenital or acquired asplenia
- CSF leak
- Diabetes mellitus
- Generalized malignancy
- Human immunodeficiency virus
- Hodgkin disease
- Immunodeficiency
- Iatrogenic immunosuppression
- Leukemia, lymphoma, multiple myeloma
- Nephrotic syndrome
- Sickle cell disease or other hemoglobinopathies
- Solid organ transplant

28

28

Use of PCV15 vaccine followed by PPSV23

- When PCV15 is used, the recommended interval between administration of PCV15 and PPSV23 is ≥1 year.
- To minimize the risk for invasive pneumococcal disease caused by serotypes unique to PPSV23, a minimum interval of 8 weeks between PCV15 and PPSV23 can be considered for adults with:
  - An immunocompromising condition
  - Cochlear implant
  - Cerebrospinal fluid leak

29

29

Pneumococcal vaccine recommendations

Adults 19 through 64 years	Previous Recommendation	New Recommendation
None of the conditions listed below	No recommendation	No recommendation
Chronic medical conditions**	PPSV23	PCV20 OR PCV15 and PPSV23
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions	Both PCV13* and PPSV23, repeat PPSV23 after 5 years	

Adults 65 years or older	Previous Recommendation	New Recommendation
None of the conditions listed below	PCV13* based on shared clinical decision making; PPSV23 for all	PCV20 OR PCV15 and PPSV23
Chronic medical conditions**	PCV13* based on shared clinical decision making; PPSV23 for all	
Cochlear implant, CSF leak	Both PCV13* and PPSV23	
Immunocompromising conditions	Both PCV13* and PPSV23	

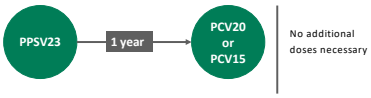
*If not previously administered; **Examples include alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking

30

30

Adults with Previous PPSV23 Only

- May receive one dose of PCV20 or PCV15 ≥1 year after their last PPSV23 dose.
  - When PCV15 is used, no need to be followed by another dose of PPSV23



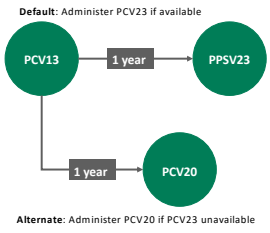
Adapted from slide prepared by M. Kobayashi

31

31

Adults Who Have Already Received PCV13

- Any adult who has received PCV13, and is recommended for PPSV23, may receive PCV20 as a substitute for PPSV23 if PPSV23 is not available.
- If PPSV23 is available, it should be administered
  - 1-year interval
  - Exceptions: 8-week interval for people with functional and anatomic asplenia, immunosuppression, chronic renal disease, CSF leak, cochlear implant



32

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Pneumococcal vaccine: Clinical Guidance

- At this time, CDC does not have recommendations for repeating doses of PCV15 or PCV20.
- PCV15, PCV20, PPSV23 can be co-administered (at a different anatomic site) with a quadrivalent influenza vaccine.
  - No data are available on coadministration with other vaccines
  - Evaluation of coadministration of PCV15, PCV20, or PPSV23 with COVID-19 vaccines is ongoing.

Adapted from slide prepared by M. Kobayashi

33

33

Summary of pneumococcal recommendations across the lifespan

- PCV13 recommended for pediatric vaccination
  - Licensure of PCV15 and PCV20 in children anticipated in 2022-2023
- PCV15 or PCV20 recommended for all adults aged ≥65 and adults aged 19-64 years with certain medical conditions and risk factors
- PPSV23 recommended for children with certain medical conditions and for adults who receive PCV15

CDC recommends **PCV13** for:

- All babies and children younger than 2 years old
- Children 2 through 18 years old with certain medical conditions

CDC recommends **PCV15 or PCV20** for:

- Adults 65 years or older
- Adults 19 through 64 years old with certain medical conditions or risk factors

CDC recommends **PPSV23** for:

- Children 2 through 18 years old with certain medical conditions
- Adults 19 years or older who get PCV15

34

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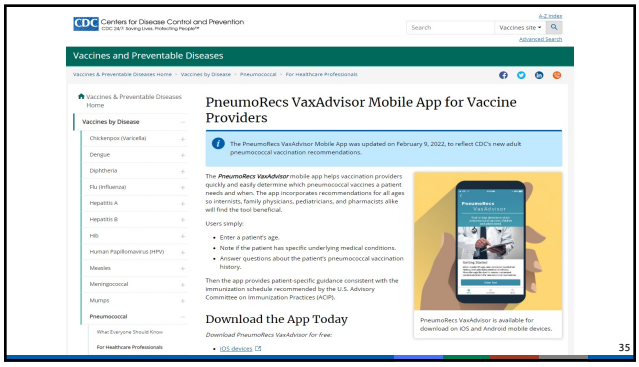

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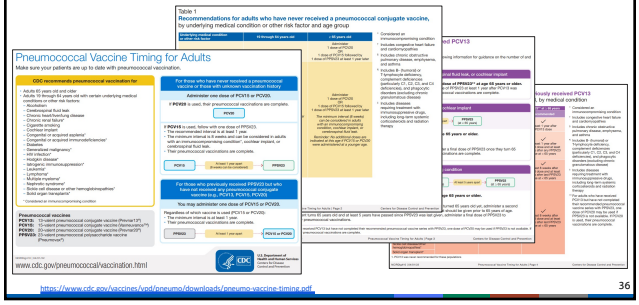
Timing Resource



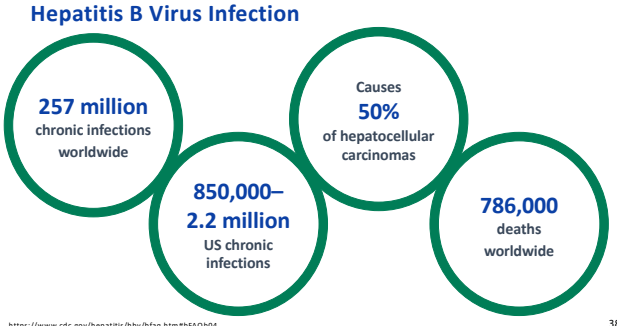
36

Hepatitis B

37

37

Hepatitis B Virus Infection



https://www.cdc.gov/hepatitis/hbv/bfaq.htm#bFAQb04

38

38

Updated Hepatitis B vaccine recommendations for adults

- People who **should** receive hepatitis B vaccines:
  - Adults 19 through 59 years of age
  - Adults 60 years of age or older with risk factors for hepatitis B infection
- People who **may** receive hepatitis B vaccines:
  - Adults 60 years of age or older without known risk factors for hepatitis B infection

39

39

People with risk factors for Hepatitis B infection

- **Persons at risk for infection by sexual exposure**
  - Sex partners of hepatitis B surface antigen (HBsAg)–positive persons
  - Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than one sex partner during the previous 6 months)
  - Persons seeking evaluation or treatment for a sexually transmitted infection
  - Men who have sex with men
- **Persons at risk for infection by percutaneous or mucosal exposure to blood**
  - Current or recent injection-drug users
  - Household contacts of HBsAg-positive persons
  - Residents and staff of facilities for developmentally disabled persons
  - Health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
  - Hemodialysis patients and predialysis, peritoneal dialysis, and home dialysis patients
  - Persons with diabetes aged 19–59 years; persons with diabetes aged ≥60 years at the discretion of the treating clinician
- **Others**
  - International travelers to countries with high or intermediate levels of endemic hepatitis B virus (HBV) infection (HBsAg prevalence of ≥2%)
  - Persons with hepatitis C virus infection
  - Persons with chronic liver disease (including, but not limited to, persons with cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and an alanine aminotransferase [ALT] or aspartate aminotransferase [AST] level greater than twice the upper limit of normal)
  - Persons with HIV infection
  - Incarcerated persons

40

40

Hepatitis B vaccine

Previous Recommendation	New Recommendation
Hepatitis B vaccine (HepB) is recommended for the prevention of hepatitis B virus infection and related complications for: • All infants • Unvaccinated children aged <19 years • Adults at risk	Hepatitis B vaccine (HepB) is recommended for the prevention of hepatitis B virus infection and related complications for: • All infants • Unvaccinated children aged <19 years • Adults 19 through 59 years of age • Adults aged ≥60 years at risk*

*Anyone age 60 years or older who does not meet risk-based recommendations may still receive Hepatitis B vaccination (No need to identify or disclose risk)

41

41

COVID-19 Vaccines

42

42

COVID-19 vaccine recommendations

- A COVID-19 vaccine primary series and booster dose is recommended for **everyone ages 5 years and older**
- Some people are eligible and recommended to receive a **2nd booster dose**
- In most situations, an **mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna)** is preferred over the Janssen COVID-19 Vaccine for primary and first booster vaccination
  - Only mRNA vaccines can be used for 2nd booster

43

43

Updated recommendations for COVID-19 vaccines: Children ages 5–11 years

Children who are **not** moderately or severely immunocompromised

Children who **are** moderately or severely immunocompromised

44

44

2nd COVID-19 Vaccine Booster Doses

- CDC updated its COVID-19 vaccination guidance around second **booster doses** using an mRNA COVID-19 vaccine **at least 4 months** after the first booster dose

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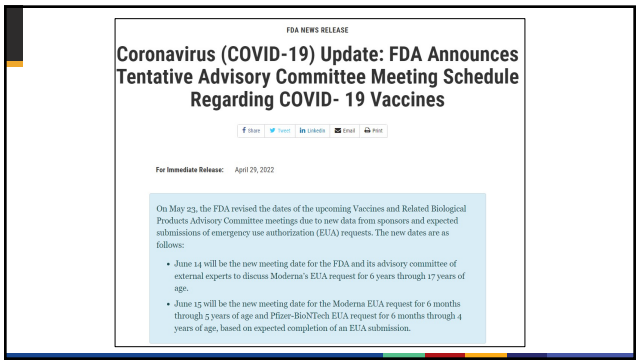

FDA NEWS RELEASE

Coronavirus (COVID-19) Update: FDA Announces Tentative Advisory Committee Meeting Schedule Regarding COVID- 19 Vaccines

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For Immediate Release: April 29, 2022

On May 23, the FDA revised the dates of the upcoming Vaccines and Related Biological Products Advisory Committee meetings due to new data from sponsors and expected submissions of emergency use authorization (EUA) requests. The new dates are as follows:

- June 14 will be the new meeting date for the FDA and its advisory committee of external experts to discuss Moderna's EUA request for 6 years through 17 years of age.
- June 15 will be the new meeting date for the Moderna EUA request for 6 months through 5 years of age and Pfizer-BioNTech EUA request for 6 months through 4 years of age, based on expected completion of an EUA submission.

46

Shared Clinical Decision-Making

47

47

Vaccines included on the CDC immunization schedule with shared clinical decision-making recommendations*

- Serogroup B meningococcal vaccine in people 16-23 year of age
- HPV vaccine in people 27-45 years of age

*ACIP recommends other vaccines based on shared clinical decision-making (e.g., JYNNEOS orthopoxvirus vaccine, Tick-Borne Encephalitis vaccine in some travelers)

48

48

How do shared clinical decision-making recommendations differ from other ACIP recommendations?

- With shared clinical decision-making recommendations, the vaccine is not recommended for everyone in a particular age or risk group
- ACIP makes this type of recommendation when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.
- Decision on whether to vaccinate may be informed by:
  - Best available evidence of who may benefit from vaccination
  - Individual's characteristics, values, and preferences
  - Healthcare provider's clinical discretion
  - Characteristics of vaccine being delivered

49

49

Considerations for shared clinical decision-making regarding MenB vaccination of adults 16-23 years old

- the serious nature of meningococcal infections, with high rates of death and permanent sequelae in those who develop invasive disease;
- the low number of serogroup B meningococcal disease cases (average of 34 serogroup B cases annually among persons aged 16–23 years in the United States during 2015–2018);
- the increased risk among college students, especially those who are freshmen, attend a 4-year university, live in on-campus housing, or participate in sororities and fraternities;
- the protection provided by MenB vaccines against most strains of serogroup B *N. meningitidis;*
- the estimated relatively short duration of MenB protection (antibody waning within 1–2 years postcompletion of the primary series); and
- the evidence to date suggesting that MenB vaccination has no effect on meningococcal carriage (i.e., MenB vaccines might provide individual protection against serogroup B disease but herd protection is unlikely).

https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

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Considerations for shared clinical decision-making regarding HPV vaccination of adults 27-45 years

Ideally, HPV vaccination should be given in early adolescence because vaccination is most effective before exposure to HPV through sexual activity. For adults aged 27 through 45 years who are not adequately vaccinated,* clinicians can consider discussing HPV vaccination with persons who are most likely to benefit. HPV vaccination does not need to be discussed with most adults aged >26 years.

- HPV is a very common sexually transmitted infection. Most HPV infections are transient and asymptomatic and cause no clinical problems.
- Although new HPV infections are most commonly acquired in adolescence and young adulthood, some adults are at risk for acquiring new HPV infections. At any age, having a new sex partner is a risk factor for acquiring a new HPV infection.
- Persons who are in a long-term, mutually monogamous sexual partnership are not likely to acquire a new HPV infection.
- Most sexually active adults have been exposed to some HPV types, although not necessarily all of the HPV types targeted by vaccination.
- No clinical antibody test can determine whether a person is already immune or still susceptible to any given HPV type.
- HPV vaccine efficacy is high among persons who have not been exposed to vaccine-type HPV before vaccination.
- Vaccine effectiveness might be low among persons with risk factors for HPV infection or disease (e.g., adults with multiple lifetime sex partners and likely previous infection with vaccine-type HPV), as well as among persons with certain immunocompromising conditions.
- HPV vaccines are prophylactic (i.e., they prevent new HPV infections). They do not prevent progression of HPV infection to disease, decrease time to clearance of HPV infection, or treat HPV-related disease.

* Dosing schedules, intervals, and definitions of persons considered adequately vaccinated have not changed.

https://www.cdc.gov/mmwr/volumes/68/wr/mm6832a3.htm

51

51