Immunization Update 2017

Andrew Kroger MD, MPH
Medical Officer
Immunization Services Division

Wyoming Medical Society Annual Meeting
Jackson Hole, WY
June 2, 2017

Disclosures

- Andrew Kroger is a federal government employee with no financial interest or conflict with the manufacturer of any product named in this presentation
- Andrew Kroger will discuss the off-label use of Tdap, HPV, and MenACWY vaccines
- Andrew Kroger will not discuss a vaccine not currently licensed by the FDA

Overview

- **2017 immunization schedules**
- **Recent Advisory Committee on Immunization Practices Immunization updates**
  - MenACWY
  - MenB
  - Tdap
  - HPV
- **Immunization resources**

2017 Immunization Schedules

Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, 2017

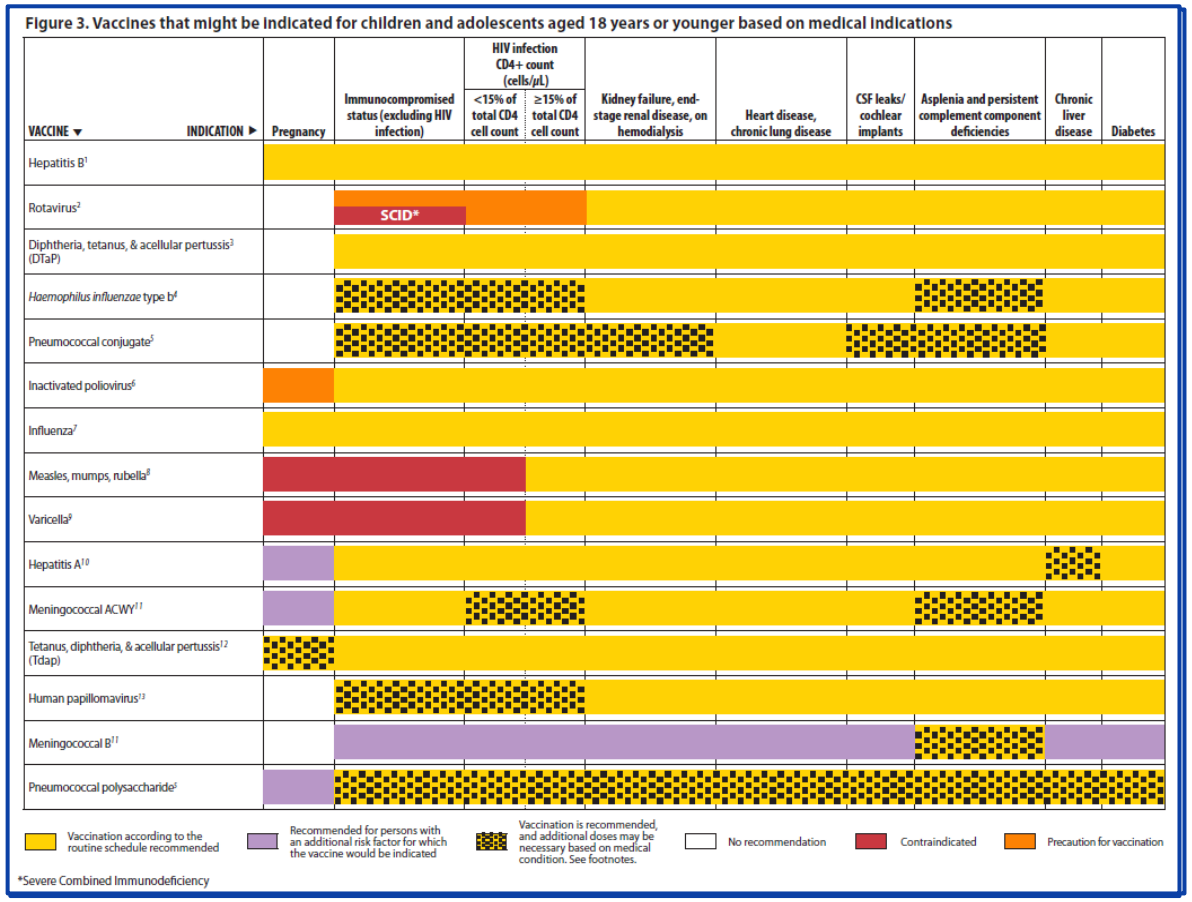


Figure 3. Vaccines that might be indicated for children and adolescents aged 18 years or younger based on medical indications

VACCINE ▼ INDICATION ▶	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count (cells/μL) <15% of total CD4 cell count	HIV infection CD4+ count (cells/μL) ≥15% of total CD4 cell count	Kidney failure, end-stage renal disease, on hemodialysis	Heart disease, chronic lung disease	CSF leaks/ cochlear implants	Asplenia and persistent complement component deficiencies	Chronic liver disease	Diabetes
Hepatitis B[1]										
Rotavirus[2]		SCID*								
Diphtheria, tetanus, & acellular pertussis[3] (DTaP)										
Haemophilus influenzae type b[4]										
Pneumococcal conjugate[5]										
Inactivated poliovirus[6]										
Influenza[7]										
Measles, mumps, rubella[8]										
Varicella[9]										
Hepatitis A[10]										
Meningococcal ACWY[11]										
Tetanus, diphtheria, & acellular pertussis[12] (Tdap)										
Human papillomavirus[13]										
Meningococcal B[11]										
Pneumococcal polysaccharide[5]										

Vaccination according to the routine schedule recommended

Recommended for persons with an additional risk factor for which the vaccine would be indicated

Vaccination is recommended, and additional doses may be necessary based on medical condition. See footnotes.

No recommendation

Contraindicated

Precaution for vaccination

*Severe Combined Immunodeficiency

- Figure 1 – Routinely recommended vaccines based on age
- Figure 2 – Catch-up schedule for children who start late or are more than 1 month be
- Figure 3 – Vaccines that might be indicated based on medical indications

New!

ACIP Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017

www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Childhood Immunization Schedule
Figure 3: Vaccines Based on Medical Indications

- Demonstrates most children with medical conditions can (and should) be vaccinated according to the routine immunization schedule

- Indicates when a medical condition is a precaution or contraindication

- Indicates when additional doses of vaccines may be necessary secondary to the child's/adolescent's medical condition

Recommended Immunization Schedule for Adults 19 Years of Age and Older

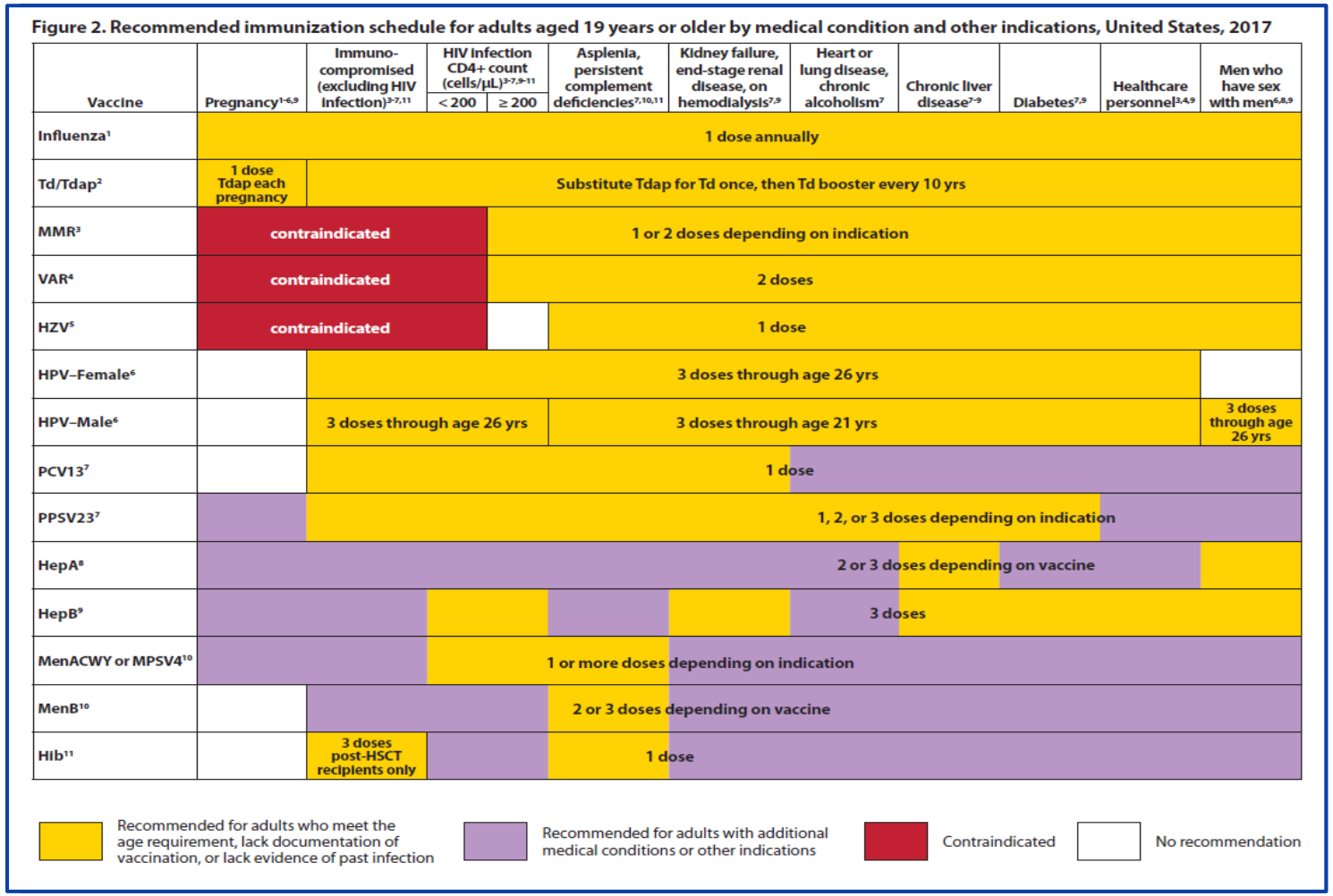


Figure 2. Recommended immunization schedule for adults aged 19 years or older by medical condition and other indications, United States, 2017

Vaccine	Pregnancy[1-6,9]	Immuno-compromised (excluding HIV infection)[3-7,11]	HIV infection CD4+ count (cells/μL)[3-7,9-11] < 200	HIV infection CD4+ count (cells/μL)[3-7,9-11] ≥ 200	Asplenia, persistent complement deficiencies[7,10,11]	Kidney failure, end-stage renal disease, on hemodialysis[7,9]	Heart or lung disease, chronic alcoholism[7]	Chronic liver disease[7-9]	Diabetes[7,9]	Healthcare personnel[3,4,9]	Men who have sex with men[6,8,9]
Influenza[1]	1 dose annually										
Td/Tdap[2]	1 dose Tdap each pregnancy	Substitute Tdap for Td once, then Td booster every 10 yrs									
MMR[3]	contraindicated	1 or 2 doses depending on indication									
VAR[4]	contraindicated	2 doses									
HZV[5]	contraindicated				1 dose						
HPV–Female[6]		3 doses through age 26 yrs									
HPV–Male[6]		3 doses through age 26 yrs			3 doses through age 21 yrs						3 doses through age 26 yrs
PCV13[7]		1 dose									
PPSV23[7]		1, 2, or 3 doses depending on indication									
HepA[8]		2 or 3 doses depending on vaccine									
HepB[9]		3 doses									
MenACWY or MPSV4[10]		1 or more doses depending on indication									
MenB[10]		2 or 3 doses depending on vaccine									
Hib[11]		3 doses post-HSCT recipients only			1 dose						

Recommended for adults who meet the age requirement, lack documentation of vaccination, or lack evidence of past infection

Recommended for adults with additional medical conditions or other indications

Contraindicated

No recommendation

Figure 1: Age-based recommendations

Figure 2: Recommendations based on medical and other indications

ACIP Recommended Immunization Schedule for Adults Aged 19 Years or Older, UNITED STATES, 2017

www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Footnotes

Footnotes — Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017

For further guidance on the use of the vaccines mentioned below, see: www.cdc.gov/vaccines/hcp/acip-recs/index.html.
For vaccine recommendations for persons 19 years of age and older, see the Adult Immunization Schedule.

Additional information

- For information on contraindications and precautions for the use of a vaccine and for additional information regarding that vaccine, vaccination providers should consult the ACIP General Recommendations on Immunization and the relevant ACIP statement, available online at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For purposes of calculating intervals between doses, 4 weeks = 28 days. Intervals of 4 months or greater are determined by calendar months.
- Vaccine doses administered ≤4 days before the minimum interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum interval or minimum age should not be counted as valid doses and should be repeated as age-appropriate. The repeat dose should be spaced after the invalid dose by the recommended minimum interval. For further details, see Table 1, *Recommended and minimum ages and intervals between vaccine doses, in MMWR, General Recommendations on Immunization and Reports / Vol. 60 / No. 2*, available online at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.
- Information on travel vaccine requirements and recommendations is available at wwwnc.cdc.gov/travel/.
- For vaccination of persons with primary and secondary immunodeficiencies, see Table 13, *Vaccination of persons with primary and secondary immunodeficiencies*, in *General Recommendations on Immunization* (ACIP), available at www.cdc.gov/mmwr/pdf/rr/rr6002.pdf.; and Immunization in Special Clinical Circumstances, (American Academy of Pediatrics). In: Kimberlin DW, Brady MT, Jackson MA, Long SS, eds. *Red Book: 2015 report of the Committee on Infectious Diseases. 30th ed.* Elk Grove Village, IL: American Academy of Pediatrics, 2015:68-107.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury petitions. Created by the National Childhood Vaccine Injury Act of 1986, it provides compensation to people found to be injured by certain vaccines. All vaccines within the recommended childhood immunization schedule are covered by VICP except for pneumococcal polysaccharide vaccine (PPSV23). For more information; see www.hrsa.gov/vaccinecompensation/index.html.

1. Hepatitis B (HepB) vaccine. (Minimum age: birth)

Routine vaccination:

At birth:

- Administer monovalent HepB vaccine to all newborns within 24 hours of birth.
- For infants born to hepatitis B surface antigen (HBsAg)-positive mothers, administer HepB vaccine and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth. These infants should be tested for HBsAg and antibody to HBsAg (anti-HBs) at age 9 through 12 months (preferably at the next well-child visit) or 1 to 2 months after completion of the HepB series if the series was delayed.
- If mother's HBsAg status is unknown, within 12 hours of birth, administer HepB vaccine regardless of birth weight. For infants weighing less than 2,000 grams, administer HBIG in addition to HepB vaccine within 12 hours of birth. Determine mother's HBsAg status as soon as possible and, if mother is HBsAg-positive, also administer HBIG to infants weighing 2,000 grams or more as soon as possible, but no later than age 7 days.

Doses following the birth dose:

- The second dose should be administered at age 1 or 2 months. Monovalent HepB vaccine should be used for doses administered before age 6 weeks.
- Infants who did not receive a birth dose should receive 3 doses of a HepB-containing vaccine on a schedule of 0, 1 to 2 months, and 6 months, starting as soon as feasible (see figure 2).
- Administer the second dose 1 to 2 months after the first dose (minimum interval of 4 weeks); administer the third dose at least 8 weeks after the second dose AND at least 16 weeks after the **first** dose. The final (third or fourth) dose in the HepB vaccine series should be administered **no earlier than age 24 weeks**.
- Administration of a total of 4 doses of HepB vaccine is permitted when a combination vaccine containing HepB is administered after the birth dose.

Catch-up vaccination:

- Unvaccinated persons should complete a 3-dose series.
- A 2-dose series (doses separated by at least 4 months) of adult formulation Recombivax HB is licensed for use in children aged 11 through 15 years.
- For other catch-up guidance, see Figure 2.

2. Rotavirus (RV) vaccines. (Minimum age: 6 weeks for both RV1 [Rotarix] and RV5 [RotaTeq])

Routine vaccination:

Administer a series of RV vaccine to all infants as follows:

1. If Rotarix is used, administer a 2-dose series at ages 2 and 4 months.
2. If RotaTeq is used, administer a 3-dose series at ages 2, 4, and 6 months.
3. If any dose in the series was RotaTeq or vaccine product is unknown for any dose in the series, a total of 3 doses of RV vaccine should be administered.

Catch-up vaccination:

- The maximum age for the first dose in the series is 14 weeks, 6 days; vaccination should not be initiated for infants aged 15 weeks, 0 days, or older.
- The maximum age for the final dose in the series is 8 months, 0 days.
- For other catch-up guidance, see Figure 2.

3. Diphtheria and tetanus toxoids and acellular pertussis (DTaP) vaccine. (Minimum age: 6 weeks. Exception: DTaP-IPV [Kinrix, Quadracel]: 4 years)

Routine vaccination:

- Administer a 5-dose series of DTaP vaccine at ages 2, 4, 6, 15 through 18 months, and 4 through 6 years. The fourth dose may be administered as early as age 12 months, provided at least 6 months have elapsed since the third dose.
- Inadvertent administration of fourth DTaP dose early: If the fourth dose of DTaP was administered at least 4 months after the third dose of DTaP and the child was 12 months of age or older, it does not need to be repeated.

Catch-up vaccination:

- The fifth dose of DTaP vaccine is not necessary if the fourth dose was administered at age 4 years or older.
- For other catch-up guidance, see Figure 2.

4. *Haemophilus influenzae* type b (Hib) conjugate vaccine. (Minimum age: 6 weeks for PRP-T [ActHIB, DTaP-IPV/Hib (Pentacel), Hiberix, and Hib-MenCY (MenHibrix)], PRP-OMP [PedvaxHIB])

Routine vaccination:

- Administer a 2- or 3-dose Hib vaccine primary series and a booster dose (dose 3 or 4, depending on vaccine used in primary series) at age 12 through 15 months to complete a full Hib vaccine series.
- The primary series with ActHIB, MenHibrix, Hiberix, or Pentacel consists of 3 doses and should be administered at ages 2, 4, and 6 months. The primary series with PedvaxHIB consists of 2 doses and should be administered at ages 2 and 4 months; a dose at age 6 months is not indicated.
- One booster dose (dose 3 or 4, depending on vaccine used in primary series) of any Hib vaccine should be administered at age 12 through 15 months.
- For recommendations on the use of MenHibrix in patients at increased risk for meningococcal disease, refer to the meningococcal vaccine footnotes and also to *MMWR* February 28, 2014 / 63(RR01):1-13, available at www.cdc.gov/mmwr/PDF/rr/rr6301.pdf.

Footnotes. Recommended Immunization schedule for adults aged 19 years or older, United States, 2017

1. Influenza vaccination

General Information

- All persons aged 6 months or older who do not have a contraindication should receive annual influenza vaccination with an age-appropriate formulation of inactivated influenza vaccine (IIV) or recombinant influenza vaccine (RIV).
- In addition to standard-dose IIV, available options for adults in specific age groups include: high-dose or adjuvanted IIV for adults aged 65 years or older, intradermal IIV for adults aged 18 through 64 years, and RIV for adults aged 18 years or older.
- Notes: Live attenuated influenza vaccine (LAIV) should not be used during the 2016–2017 influenza season. A list of currently available influenza vaccines is available at www.cdc.gov/flu/protect/vaccine/vaccines.htm.

Special populations

- Adults with a history of egg allergy who have only hives after exposure to egg should receive age-appropriate IIV or RIV.
- Adults with a history of egg allergy other than hives, e.g., angioedema, respiratory distress, lightheadedness, or recurrent emesis, or who required epinephrine or another emergency medical intervention, may receive age-appropriate IIV or RIV. The selected vaccine should be administered in an inpatient or outpatient medical setting and under the supervision of a healthcare provider who is able to recognize and manage severe allergic conditions.
- Pregnant women and women who might become pregnant in the upcoming influenza season should receive IIV.

2. Tetanus, diphtheria, and acellular pertussis vaccination

General Information

- Adults who have not received tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) or for whom pertussis vaccination status is unknown should receive 1 dose of Tdap followed by a tetanus and diphtheria toxoids (Td) booster every 10 years. Tdap should be administered regardless of when a tetanus or diphtheria toxoid-containing vaccine was last received.
- Adults with an unknown or incomplete history of a 3-dose primary series with tetanus and diphtheria toxoid-containing vaccines should complete the primary series that includes 1 dose of Tdap. Unvaccinated adults should receive the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second dose.
- Notes: Information on the use of Td or Tdap as tetanus prophylaxis in wound management is available at www.cdc.gov/mmwr/preview/mmwrhtml/rr5517a1.htm.

Special populations

- Pregnant women should receive 1 dose of Tdap during each pregnancy, preferably during the early part of gestational weeks 27–36, regardless of prior history of receiving Tdap.

3. Measles, mumps, and rubella vaccination

General Information

- Adults born in 1957 or later without acceptable evidence of immunity to measles, mumps, or rubella (defined below) should receive 1 dose of measles, mumps, and rubella vaccine (MMR) unless they have a medical contraindication to the vaccine, e.g., pregnancy or severe immunodeficiency.
- Notes: Acceptable evidence of immunity to measles, mumps, or rubella in adults is: born before 1957, documentation of receipt of MMR, or laboratory evidence of immunity or disease. Documentation of healthcare provider-diagnosed disease without laboratory confirmation is not acceptable evidence of immunity.

Special populations

- Pregnant women who do not have evidence of immunity to rubella should receive 1 dose of MMR upon completion or termination of pregnancy and before discharge from the healthcare facility; non-pregnant women of childbearing age without evidence of rubella immunity should receive 1 dose of MMR.
- Adults with primary or acquired immunodeficiency including malignant conditions affecting the bone marrow or lymphatic system, systemic immunosuppressive therapy, or cellular immunodeficiency should not receive MMR.
- Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≥200 cells/μl for at least 6 months who do not have evidence of measles, mumps, or rubella immunity should receive 2 doses of MMR at least 28 days apart. Adults with HIV infection and CD4+ T-lymphocyte count <200 cells/μl should not receive MMR.
- Adults who work in healthcare facilities should receive 2 doses of MMR at least 28 days apart; healthcare personnel born before 1957 who are unvaccinated or lack laboratory evidence of measles, mumps, or rubella immunity, or laboratory confirmation of disease should be considered for vaccination with 2 doses of MMR at least 28 days apart for measles or mumps, or 1 dose of MMR for rubella.
- Adults who are students in postsecondary educational institutions or plan to travel internationally should receive 2 doses of MMR at least 28 days apart.
- Adults who received inactivated (killed) measles vaccine or measles vaccine of unknown type during years 1963–1967 should be revaccinated with 1 or 2 doses of MMR.
- Adults who were vaccinated before 1979 with either inactivated mumps vaccine or mumps vaccine of unknown type who are at high risk for mumps infection, e.g., work in a healthcare facility, should be considered for revaccination with 2 doses of MMR at least 28 days apart.

4. Varicella vaccination

General Information

- Adults without evidence of immunity to varicella (defined below) should receive 2 doses of single-antigen varicella vaccine (VAR) 4–8 weeks apart, or a second dose if they have received only 1 dose.
- Persons without evidence of immunity for whom VAR should be emphasized are: adults who have close contact with persons at high risk for serious complications, e.g., healthcare personnel and household contacts of immunocompromised persons; adults who live or work in an environment in which transmission of varicella zoster virus is likely, e.g., teachers, childcare workers, and residents and staff in institutional settings; adults who live or work in environments in which varicella transmission has been reported, e.g., college students, residents and staff members of correctional institutions, and military personnel; non-pregnant women of childbearing age; adolescents and adults living in households with children; and international travelers.
- Notes: Evidence of immunity to varicella in adults is: U.S.-born before 1980 (for pregnant women and healthcare personnel, U.S.-born before 1980 is not considered evidence of immunity); documentation of 2 doses of VAR at least 4 weeks apart; history of varicella or herpes zoster diagnosis or verification of varicella or herpes zoster disease by a healthcare provider; or laboratory evidence of immunity or disease.

Special populations

- Pregnant women should be assessed for evidence of varicella immunity. Pregnant women who do not have evidence of immunity should receive the first dose of VAR upon completion or termination of pregnancy and before discharge from the healthcare facility, and the second dose 4–8 weeks after the first dose.
- Healthcare institutions should assess and ensure that all healthcare personnel have evidence of immunity to varicella.
- Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic immunosuppressive therapy, should not receive VAR.
- Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count ≥200 cells/μl may receive 2 doses of VAR 3 months apart. Adults with HIV infection and CD4+ T-lymphocyte count <200 cells/μl should not receive VAR.

5. Herpes zoster vaccination

General Information

- Adults aged 60 years or older should receive 1 dose of herpes zoster vaccine (HZV), regardless of whether they had a prior episode of herpes zoster.

Special populations

- Adults aged 60 years or older with chronic medical conditions may receive HZV unless they have a medical contraindication, e.g., pregnancy or severe immunodeficiency.
- Adults with malignant conditions, including those that affect the bone marrow or lymphatic system or who receive systemic immunosuppressive therapy, should not receive HZV.
- Adults with human immunodeficiency virus (HIV) infection and CD4+ T-lymphocyte count <200 cells/μl should not receive HZV.

6. Human papillomavirus vaccination

General Information

- Adult females through age 26 years and adult males through age 21 years who have not received any human papillomavirus (HPV) vaccine should receive a 3-dose series of HPV vaccine at 0, 1-2, and 6 months. Males aged 22 through 26 years may be vaccinated with a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.
- Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received 2 doses at least 5 months apart are considered adequately vaccinated and do not need an additional dose of HPV vaccine.
- Adult females through age 26 years and adult males through age 21 years (and males aged 22 through 26 years who may receive HPV vaccination) who initiated the HPV vaccination series before age 15 years and received only 1 dose, or 2 doses less than 5 months apart, are not considered adequately vaccinated and should receive 1 additional dose of HPV vaccine.
- Notes: HPV vaccination is routinely recommended for children at age 11 or 12 years. For adults who had initiated but did not complete the HPV vaccination series, consider their age at first HPV vaccination (described above) and other factors (described below) to determine if they have been adequately vaccinated.

Special populations

- Men who have sex with men through age 26 years who have not received any HPV vaccine should receive a 3-dose series of HPV vaccine at 0, 1-2, and 6 months.
- Adult females and males through age 26 years with immunocompromising conditions (described below), including those with human immunodeficiency virus (HIV) infection, should receive a 3-dose series of HPV vaccine at 0, 1–2, and 6 months.
- Pregnant women are not recommended to receive HPV vaccine, although there is no evidence that the vaccine poses harm. If a woman is found to be pregnant after initiating the HPV vaccination series, delay the remaining doses until after the pregnancy. No other intervention is needed. Pregnancy testing is not needed before administering HPV vaccine.
- Notes: Immunocompromising conditions for which a 3-dose series of HPV vaccine is indicated are primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, e.g., B-lymphocyte antibody deficiencies, complete or partial T-lymphocyte defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease, and immunosuppressive therapy.

ACIP Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017

www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

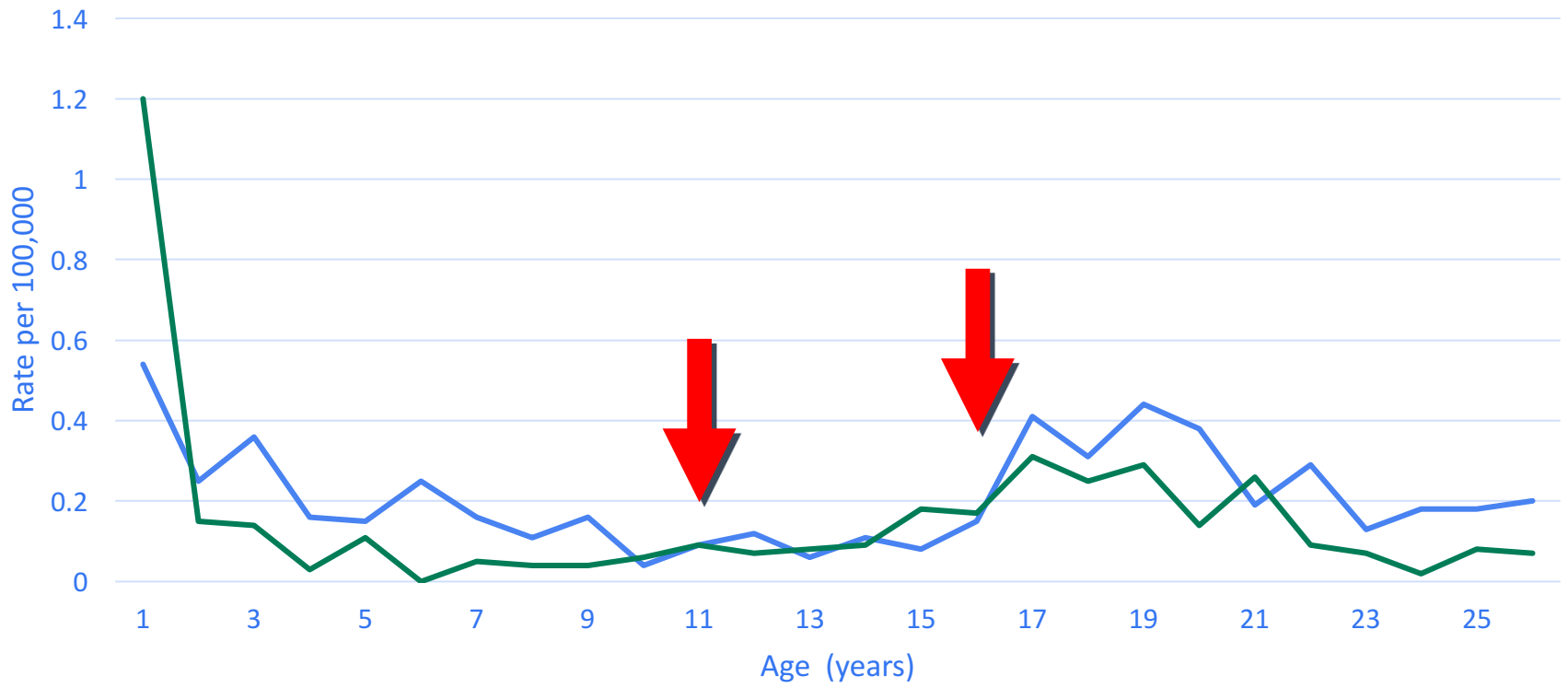
ACIP Recommended Immunization Schedule for Adults Aged 19 Years or Older, UNITED STATES, 2017

www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Advisory Committee on Immunization Practices (ACIP) Updates and MMWR Publications

Meningococcal Vaccines

Rates of Meningococcal Disease (C and Y) by Age, 1999-2008



Active Bacterial Core surveillance (ABCs), 1998-2008

MenACWY Recommendations*

- Administer MenACWY at age 11 or 12 years with a booster dose at 16 years of age
- Administer 1 dose at age 13 through 15 years if not previously vaccinated
- For persons vaccinated at age 13 through 15 years, administer a one-time booster dose, preferably at or after 16 through 18 years of age

*ACIP off-label recommendation

MMWR 2013;62(RR-2):10-11

Why Do We Give a Booster Dose of MenACWY?

- In most cases, meningococcal infection progresses rapidly, with fulminant disease occurring within 1-4 days after invasion of normally sterile body sites
- There's little time for immune memory cells to ramp up production of antibodies
- Manufacturer serologic data show significant decline in antibody 3-5 years after vaccination, although few breakthrough cases have been reported
- While vaccine-induced immunologic memory might be protective against infection with other disease-causing encapsulated bacteria, the presence of detectable circulating antibody appears to be important for protection against *N. meningitides*

MMWR 2009;58(No. 37):1042-3

MenACWY Adolescent Vaccination Recommendations

- **A booster dose is not recommended for healthy persons if the first dose is administered at or after 16 years of age**

- **A booster dose is not recommended for healthy persons after 21 years of age if they are not at increased risk of exposure**
  - A booster dose is not recommended for healthy persons 22 years of age and older even if the first dose was administered at 11-15 years of age

Meningococcal ACWY Recommendations for HIV-infected Persons

- **Accumulating evidence indicates that HIV infection increases the risk of invasive meningococcal disease**

- **At the June 2016 meeting ACIP voted to recommend routine MenACWY vaccination for all HIV-infected persons age 2 months and older**

- **Number of doses depends on age**
  - Persons 2 years and older should receive 2 doses separated by 8 weeks

MMWR 2016:65(43);1189–1194

Use of 2- and 3-Dose Schedules of MenB-FHbp (Trumenba) Meningococcal Serogroup B Vaccine

- **Current ACIP Recommendations for Serogroup B Meningococcal (MenB) Vaccines**
  - Certain persons aged ≥10 years who are at increased risk for meningococcal disease should receive MenB vaccine (Category A)[1]
  - A MenB vaccine series may be administered to adolescents and young adults aged 16–23 years to provide short-term protection against most strains of serogroup B meningococcal disease (Category B)[2]

[1]*MMWR* 2015 64(22); 608-612

[2]*MMWR* 2015 64(41); 1171-1176

Use of 2- and 3-Dose Schedules of MenB-FHbp (Trumenba) Meningococcal Serogroup B Vaccine

- **Changes to the dosage and administration section for MenB-FHbp approved by FDA on April 14, 2016**

- **Original FDA approved schedule:**
  - 3 doses – 0, 2, and 6 months

- **Additional schedule:**
  - 2 dose schedule – 0 and 6 months

Recommended schedule is based on the risk of exposure and the patient's susceptibility to meningococcal serogroup B disease

https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6619a6.pdf

Use of 2- and 3-Dose Schedules of MenB-FHbp (Trumenba) Meningococcal Serogroup B Vaccine

- **Administer 3 doses to persons at increased risk for meningococcal disease and during serogroup B outbreaks**
  - 3 doses of MenB-FHbp should be administered at 0, 1-2, 6 months intervals

- **Administer 2 doses to healthy adolescents who are not at increased risk for meningococcal disease**
  - 2 doses of MenB-FHbp should be administered at 0 and 6 months intervals

Tdap Vaccine

Tdap Update

- **Children aged 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose may be given at age 11 through 12 years**
  - Consistent with guidance when Tdap is inadvertently administered to children in this age group

12. Tetanus and diphtheria toxoids and acellular pertussis (Tdap) vaccine. (Minimum age: 10 years for both Boostrix and Adacel)

Routine vaccination:

- Administer 1 dose of Tdap vaccine to all adolescents aged 11 through 12 years.
- Tdap may be administered regardless of the interval since the last tetanus and diphtheria toxoid-containing vaccine.
- Administer 1 dose of Tdap vaccine to pregnant adolescents during each pregnancy (preferably during the early part of gestational weeks 27 through 36), regardless of time since prior Td or Tdap vaccination.

Catch-up vaccination:

- Persons aged 7 years and older who are not fully immunized with DTaP vaccine should receive Tdap vaccine as 1 dose (preferably the first) in the catch-up series; if additional doses are needed, use Td vaccine. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years may be administered.
- Persons aged 11 through 18 years who have not received Tdap vaccine should receive a dose, followed by tetanus and diphtheria toxoids (Td) booster doses every 10 years thereafter.

ACIP Recommended Immunization Schedule for Children and Adolescents Aged 18 Years or Younger, UNITED STATES, 2017
www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

Tdap and Pregnancy

- **Maternal antibodies from women immunized before pregnancy waned quickly (Healy 2012)**
  - Concentration of maternal antibodies unlikely high enough to provide passive protection to infants
- **A single dose of Tdap during one pregnancy is insufficient to provide protection for subsequent pregnancies**

Tdap in Pregnancy

- **Infants of Tdap vaccinated mothers were born with significantly higher anti-pertussis antibodies compared to infants of unvaccinated mothers**

- **Within the 27– 36 weeks administration "window"**
  - Concentration of anti-pertussis antibodies in infant cord blood were higher when mothers were vaccinated earlier
  - Longer exposure to vaccine allows for higher vaccine induced antibody levels produced by mother and transferred to infant

- **The tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) footnote for vaccination of pregnant adolescents/adults between gestational weeks 27–36 has been updated to reflect a preference for vaccination earlier during this period**

ACIP meeting October 2016
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2016-10/pertussis-02-liang.pdf

Bottom Line

An infant's first dose of pertussis vaccine is the one you administer to his/her mom!

Human Papillomavirus Vaccine

Human Papillomavirus Vaccine
Routine Recommendations

- **Routinely vaccinate boys and girls at 11 – 12 years of age***
- **Catch-up those previously unvaccinated or are missing doses including:**
  - Females age 13 through 26 years
  - Males age 13 through 21 years
  - High-risk males age 22 through 26 years
    - Men who have sex with men and immunocompromised men (including HIV-infected men)
- **Males aged 22 through 26 years of age may be vaccinated**

***Vaccination series can be started at 9 years of age**

****9vHPV is the only product available through Vaccines For Children program 5/2/2016**

***MMWR* 2015;64:300-4**

ACIP HPV Immunization Recommendations
Previously Unvaccinated Adolescents

- **Administer 2 doses of HPV vaccine to healthy adolescents starting the series at 9 through 14 years of age**
- **Follow the routine 2-dose schedule**
  - Administer dose 2 6-12 months after the 1st dose
- **If a 2nd dose is inadvertently administered prior to 6 months default to a 3-dose series**

MMWR 2016;65(49):1405-08

ACIP Immunization Recommendations
Previously Unvaccinated Adolescents

- **Administer 3 doses of HPV vaccine to adolescents starting the series on or after the 15th birthday**
- **Routine 3-dose schedule: 0, 1-2, 6 months**
  - Dose #2: Administer at least 1 to 2 months after dose 1
  - Dose #3: Administer at least:
    - 12 weeks after dose 2 AND
    - 6 months (5 months) after dose 1
- **An accelerated schedule using minimum intervals is not recommended**

MMWR 2016;65(49):1405-08

ACIP Immunization Recommendations
Persons with an Incomplete Series

- **Adolescents who initiated vaccination with 9vHPV, 4vHPV, or 2vHPV**
  - Before their 15th birthday, are fully vaccinated if they received
    - 2 doses at the recommended dosing schedule (0, 6-12 month), OR
    - 3 doses at the recommended dosing schedule (0, 1-2, 6 month)
  - On or after the 15th birthday are fully vaccinated if they received,
    - 3 doses at the recommended dosing schedule (0, 1-2, 6 month)
- **All doses do not have to 9vHPV**
- **No additional doses are recommended, regardless of their current age**

MMWR 2016;65(49):1405-08

ACIP HPV Immunization Recommendations
Medical Condition Considerations

- **ACIP recommends HPV vaccination for immunocompromised females and males aged 9 through 26 years with 3 doses of HPV vaccine (0, 1-2, 6 months)**

- **Administer a 3-dose series to immunocompromised persons including those with:**
  - Primary or secondary immunocompromising conditions that might reduce cell-mediated or humoral immunity, such as B lymphocyte antibody deficiencies, T lymphocyte complete or partial defects, HIV infection, malignant neoplasm, transplantation, autoimmune disease or immunosuppressive therapy

MMWR 2016;65(49):1405-08

ACIP HPV Immunization Recommendations
Schedule Considerations

- **Number of recommended doses is based on:**
  - Age at administration of the first dose OR
  - Health status – immunosuppression
- **Series does not need to be restarted if interrupted**
  - There is NO maximum interval between HPV vaccine doses
- **HPV vaccine can be administered during the same clinical visit other vaccines**
- **9vHPV may be used to continue or complete a series started with 4vHPV or 2vHPV regardless of the dosing schedule**

MMWR 2016;65(49):1405-08

CDC HPV 2-Dose FAQs for Clinicians

Clinician FAQ: CDC Recommendations for HPV Vaccine 2-Dose Schedules

After the October 2016 ACIP meeting, CDC now recommends that 11 or 12 year olds receive 2 doses of HPV vaccine instead of 3. Parents may have questions about this change. This resource helps explain the reasons for changing the HPV vaccine recommendation, and provides tips for talking with the parents of your patients about the change.

What has changed in the new HPV vaccine recommendations?

In October 2016, CDC updated HPV vaccination recommendations regarding dosing schedules. CDC now recommends 2 doses of HPV vaccine for people starting the vaccination series before the 15th birthday. Three doses of HPV vaccine are recommended for people starting the vaccination series on or after the 15th birthday and for people with certain immunocompromising conditions.

CDC continues to recommend routine vaccination for girls and boys at age 11 or 12 years. The vaccination series can be started at age 9 years. CDC also recommends vaccination through age 26 years for females and through age 21 years for males. Males age 22–26 years may be vaccinated.

What is the recommended 2-dose HPV vaccination schedule?

For girls and boys starting the vaccination series before the 15th birthday, the recommended schedule is 2 doses of HPV vaccine. The second dose should be given 6–12 months after the first dose (0, 6–12 month schedule).

Answering parents' questions: *We now recommend 2 doses of HPV vaccine for your son or daughter, instead of 3, if your child starts the series before their 15th birthday. I still recommend your child start the vaccination series by age 11 or 12 years for best protection against HPV. He or she will need a second dose 6-12 months after the first dose.*

Who should still receive a 3-dose schedule?

CDC continues to recommend a 3-dose schedule for persons starting the HPV vaccination series on or after the 15th birthday, and for persons with certain immunocompromising conditions. The second dose should be given 1–2 months after the first dose, and the third dose should be given 6 months after the first dose (0, 1–2, 6 month schedule).

Answering parents' questions: *If your child starts the series after his or her 15th birthday or has certain health problems that weaken his or her immune system, he or she will still need the 3-dose series. We will give the second dose 1–2 months after the first, and the last dose 6 months after the first dose.*

Why did CDC make the recommendation change to a 2-dose schedule?

Over the past year, CDC and the Advisory Committee on Immunization Practices (ACIP) have been reviewing data on 2-dose schedules, including results from studies of HPV vaccines that compared the antibody responses after 2 doses and 3 doses. These studies showed that the antibody response after 2 doses given at least 6 months apart to 9–14 year-olds was as good or better than the antibody response after 3 doses given to older adolescents and young adults, the age group in which efficacy was demonstrated in clinical trials.

Answering parents' questions: *CDC and ACIP (a group of experts that make vaccine recommendations) have been reviewing data on 2-dose HPV vaccination schedules for several months. The evidence showed that 2 doses of HPV vaccine given at least 6 months apart in younger adolescents were as good or better than 3 doses. These updated recommendations are an example of using the latest available evidence to provide your child with the best possible protection against serious diseases.*

Answering parents' questions: *Since your child received his/her first dose of the HPV vaccine before he/she was 15 years old, we'll only need to give 1 more dose.*

National Center for Immunization and Respiratory Diseases
Office of the Director
CS HCVG1S-PTT-106 11/30/2016

Why is the 2-dose schedule change recommended only for girls and boys age 9–14 years?

ACIP makes recommendations based on the best available scientific evidence. Immunogenicity studies have shown that 2 doses of HPV vaccine given to 9–14 year-olds at least 6 months apart were as good, or better, than 3 doses given to older adolescents and young adults. Studies have not been done to show this in adolescents age 15 years or older.

Answering parents' questions: *The data we currently have from scientific studies (clinical trials) showed that 2 doses of HPV vaccine given at least 6 months apart were as good or better than 3 doses in children 9–14 years of age. Older adolescents haven't been studied in the same way, so we don't have information available for that age group. For that reason, the recommendation for number of doses has not been changed for older adolescents.*

What is the recommendation for persons with immunocompromising conditions?

CDC recommends 3 doses of HPV vaccine (0, 1–2, 6 months) for immunocompromised people age 9 through 26 years. People whose immune responses might be lower, for example due to HIV infection, cancer, autoimmune disease, or taking immunosuppressant medications, should receive 3 doses to make sure they get the most benefit. However, children with asthma, diabetes, and other conditions that would not suppress immune response to HPV vaccination can receive a 2-dose schedule.

Answering parents' questions: *Even though CDC has recommended just 2 doses of HPV for kids under 15 years, we'll need to give your child 3 doses because he/she has a health problem that weakens his or her immune system.*

If a HPV vaccine series was started with quadrivalent HPV vaccine or bivalent HPV vaccine and will be completed with 9-valent HPV vaccine, what are the intervals for the remaining doses in a 3-dose or 2-dose series?

If the first dose of any vaccine was given before the 15th birthday, vaccination should be completed according to a 2-dose schedule. In a 2-dose series, the second dose is recommended 6–12 months after the first dose (0, 6–12 month schedule).

If the first dose of any vaccine was given on or after the 15th birthday, vaccination should be completed according to a 3-dose schedule. In a 3-dose series, the second dose is recommended 1–2 months after the first dose, and the third dose is recommended 6 months after the first dose (0, 1–2, 6 month schedule

If a vaccination schedule is interrupted, vaccine doses do not need to be repeated.

If a girl or boy received 2 doses of HPV vaccine less than 5 months apart, do they need a third HPV vaccine dose?

Yes. In a 2-dose schedule of HPV vaccine, the recommended interval is 6–12 months, and the minimum interval is 5 months between the first and second dose. If the second dose is given earlier than 5 months, a third dose should be administered.

Answering parents' questions: *The recommended schedule is 2 doses given 6 to 12 months apart. The minimum amount of time between those doses is 5 months. Because your child received 2 doses less than 5 months apart, we'll need to give your child a third dose.*

If someone is age 15 years or older and started the vaccination series at age 11 but only received 1 dose, how many more doses do they need?

This person needs 1 more dose to complete a 2-dose series, which is recommended because the vaccination was started before turning 15 years old. In a 2-dose series, the second dose is recommended 6–12 months after the first dose. In this case, the first dose was given several years ago, so the second dose can be given right away.

Is the 9-valent HPV vaccine approved by FDA for use as a 2-dose schedule?

Yes, in October 2016, FDA approved a 2-dose schedule (0, 6–12 months) of 9-valent HPV vaccine for use in girls and boys age 9–14 years in the United States.

What HPV vaccines are currently available in the United States?

Three HPV vaccines are licensed for use in the United States: 9-valent HPV vaccine, quadrivalent HPV vaccine, and bivalent HPV vaccine. However, after the end of 2016, only 9-valent HPV vaccine will be sold in the United States.

CDC Clinician FAQ: CDC Recommendations for HPV Vaccine 2-Dose Schedules https://www.cdc.gov/hpv/downloads/hcvg15-ptt-hpv-2dose.pdf

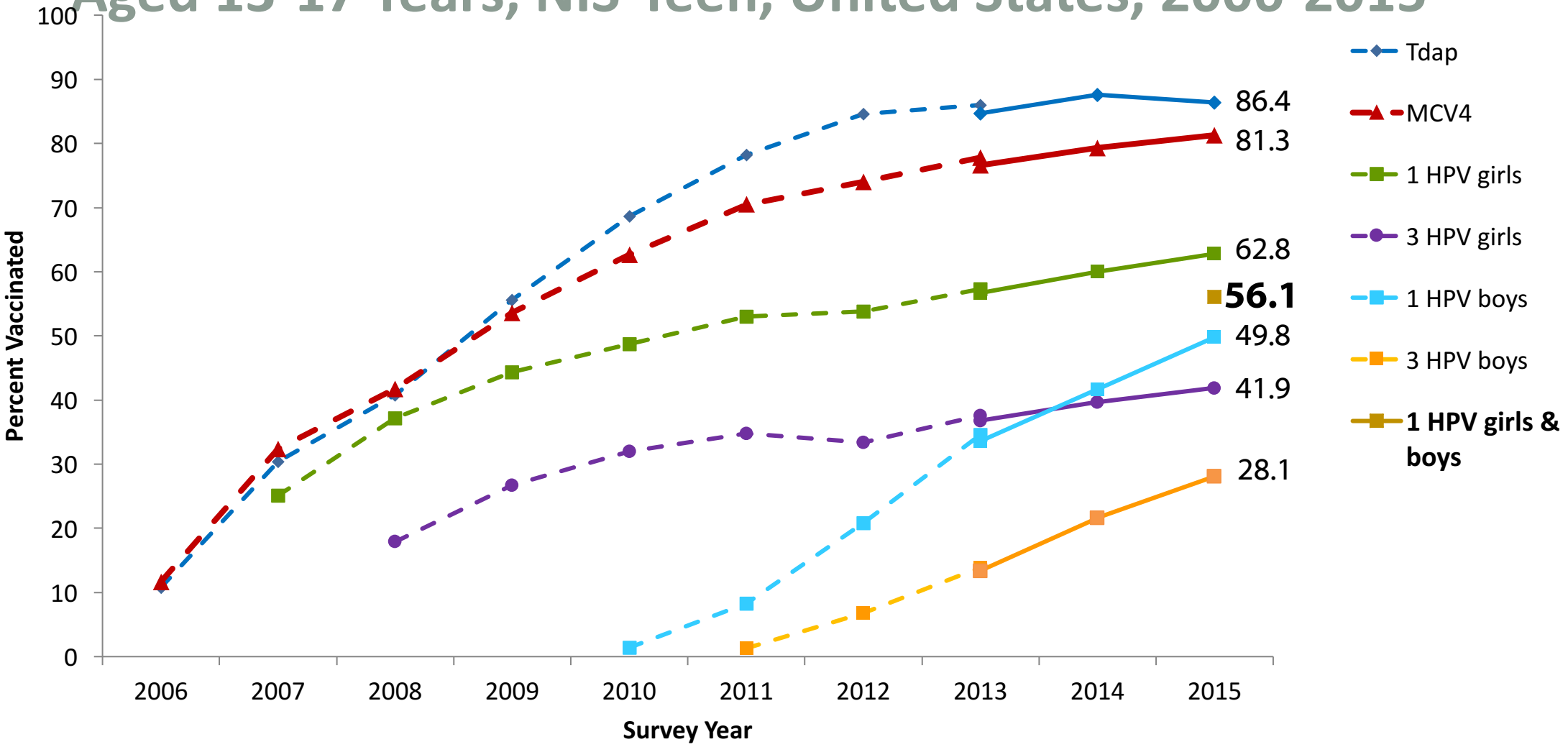
HPV Vaccines

- 2vHPV and 4vHPV vaccines are no longer being distributed in the United States
- All available doses of 2vHPV expired at the end of 2016
- All available doses of 4vHPV expired May 27, 2017

ACIP HPV Immunization Recommendations
Additional Considerations

- **For persons who have completed a series of 4vHPV or 2vHPV, there is no ACIP recommendation for additional vaccination with 9vHPV**
- **No therapeutic effect on HPV infection, genital warts, cervical lesions**
- **Prevaccination assessments not recommended**
  - HPV
  - Pregnancy

Estimated HPV Vaccination Coverage among Adolescents Aged 13-17 Years, NIS-Teen, United States, 2006-2015



Source: Reagan-Steiner, et al. MMWR; August 26, 2016 / 65(33);850–858

Lack of provider motivation and skill

Lack of parental acceptance

Barriers

Lack of provider motivation and skill

Lack of parental acceptance

Barriers

Why Is HPV Vaccine Coverage So Low?

Parents

- Parents are not offered vaccination
- Parents perceive vaccine as optional or unnecessary at that time
- Parents perceive that their providers discouraged vaccination
- Parents want information about vaccine safety
- Parents do not understand the reason to vaccinate at 11 to 12 years of age

Providers

- Providers are reluctant to give multiple shots at one visit
- Providers introduce HPV vaccination at age 11 years but do not recommend it strongly
- Providers recommend vaccination based on their estimation of sexual activity
- Providers have limited experience with HPV and underestimate risk
- Providers perceive HPV as more emotionally charged than other vaccines
- Delaying vaccination leads to nonvaccination

Both providers and parents know they are often unaware of the timing of sexual debut.

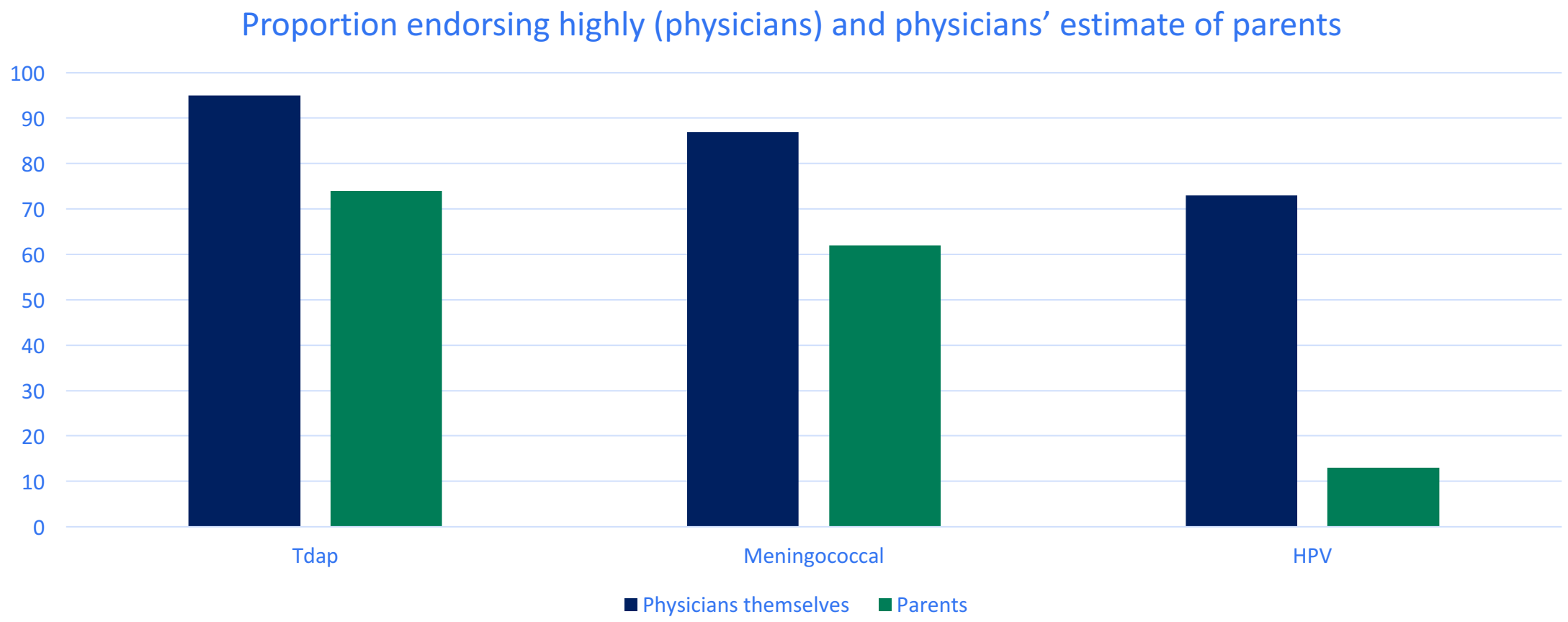
Perkins RB et al. Pediatrics 2014;134:e666-e674

Reasons for Not Vaccinating Adolescents with HPV Vaccine, Unvaccinated Adolescents* Aged 13-17 Years, NIS-Teen, United States, 2015

Parents of Girls		Parents of Boys	
	% (95% CI)		% (95% CI)
Not needed/necessary	19.6 (16.8-22.8)	**Not needed/necessary**	20.6 (18.2-23.3)
Not sexually active	13.9 (10.7-17.8)	**Not recommended**	17.7 (15.3-20.3)
Safety concerns/ side effects	13.4 (11.3-15.8)	**Lack of knowledge**	12.9 (11.2-15.0)
Lack of knowledge	11.7 (9.2-14.8)	**Safety concerns/ side effects**	9.3 (7.7-11.1)
Not recommended	9.5 (7.7-11.6)	**Not sexually active**	8.3 (7.0-9.9)

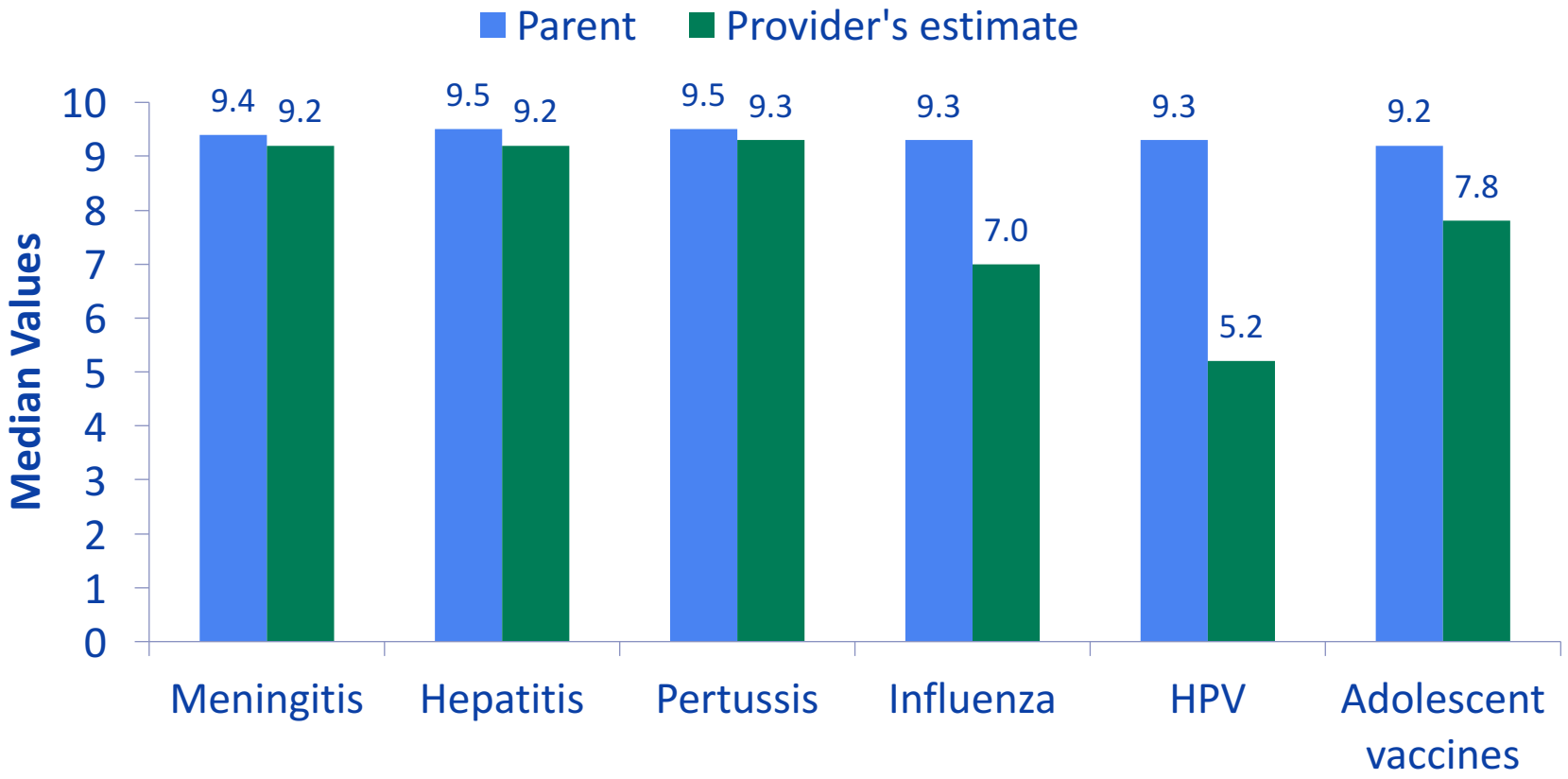
* Analysis limited to adolescents with zero HPV vaccine doses, whose parents reported that they were not likely to seek HPV vaccination for their adolescent in the next 12 months

Physicians' Perceptions of Adolescent Vaccine Endorsement for Patients Ages 11-12, 2014



Gilkey MB et al, Preventive Medicine 2015;77:181-185

Parent opinions on the importance of vaccines and provider estimates of parental responses



Adapted from Healy et al. Vaccine. 2014;32:579-584.

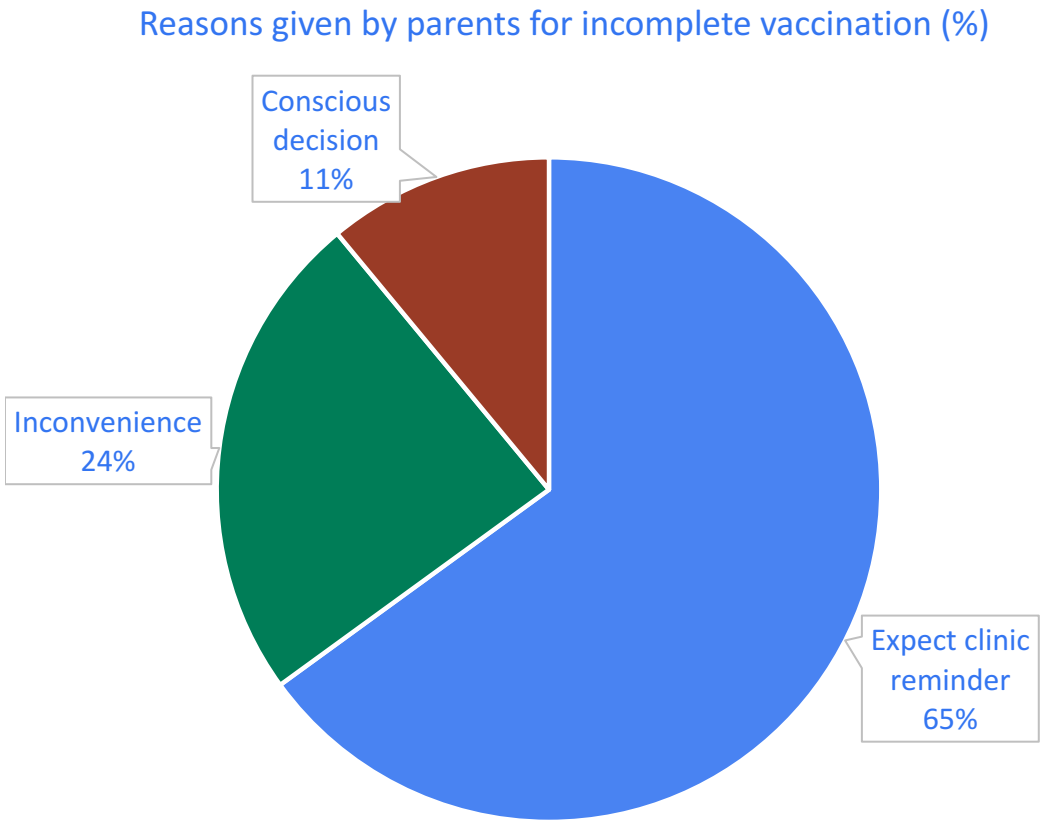
“optional”

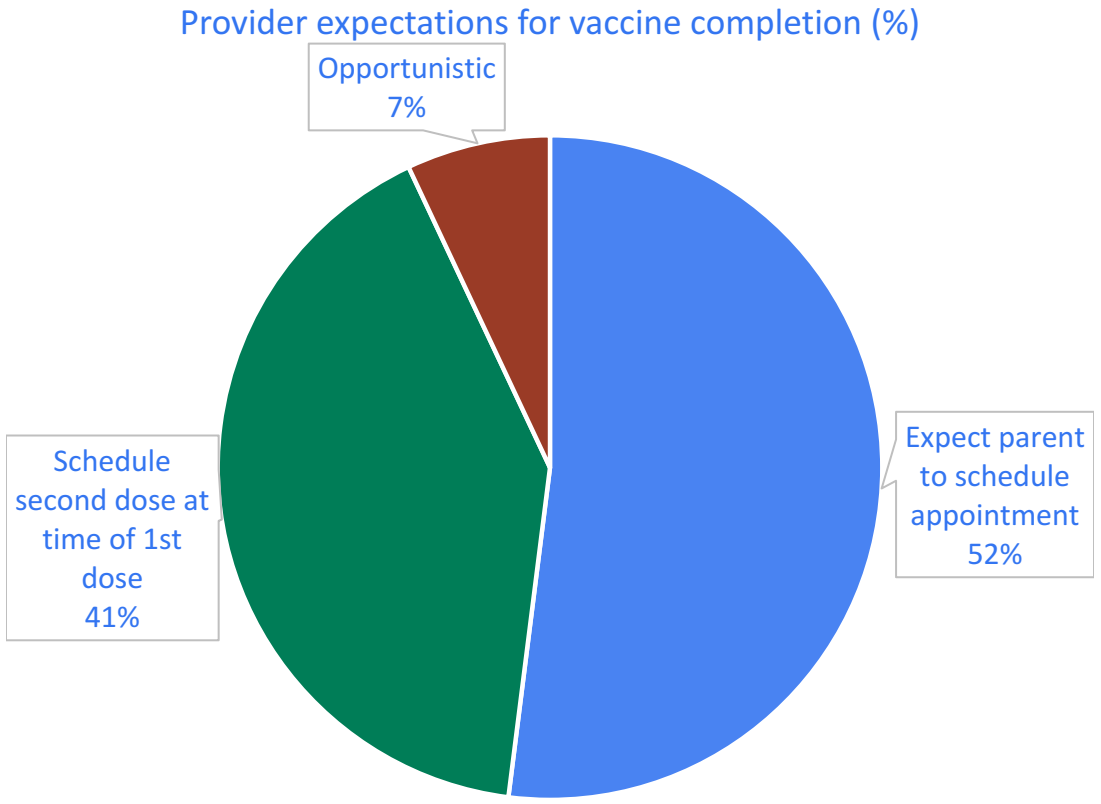
“new vaccine”

“not at risk”

“you can wait”

Why don’t adolescents finish the HPV vaccine series?





Perkins RB et al. Human Vaccines and Immunotherapeutics, 2016

What can we do about it?

HPV Vaccination: What Works

Parents

- Parents want to prevent cancer
- Parents trust their provider's recommendation
- Parents think benefits outweigh risks
- Parents want a strong recommendation

Providers

- Providers emphasize cancer prevention
- Providers normalize the HPV vaccine and coadminister with other vaccines
- Providers give a strong recommendation

Perkins RB et al. Pediatrics 2014;134:e666-e674

What Can Healthcare Providers Do?

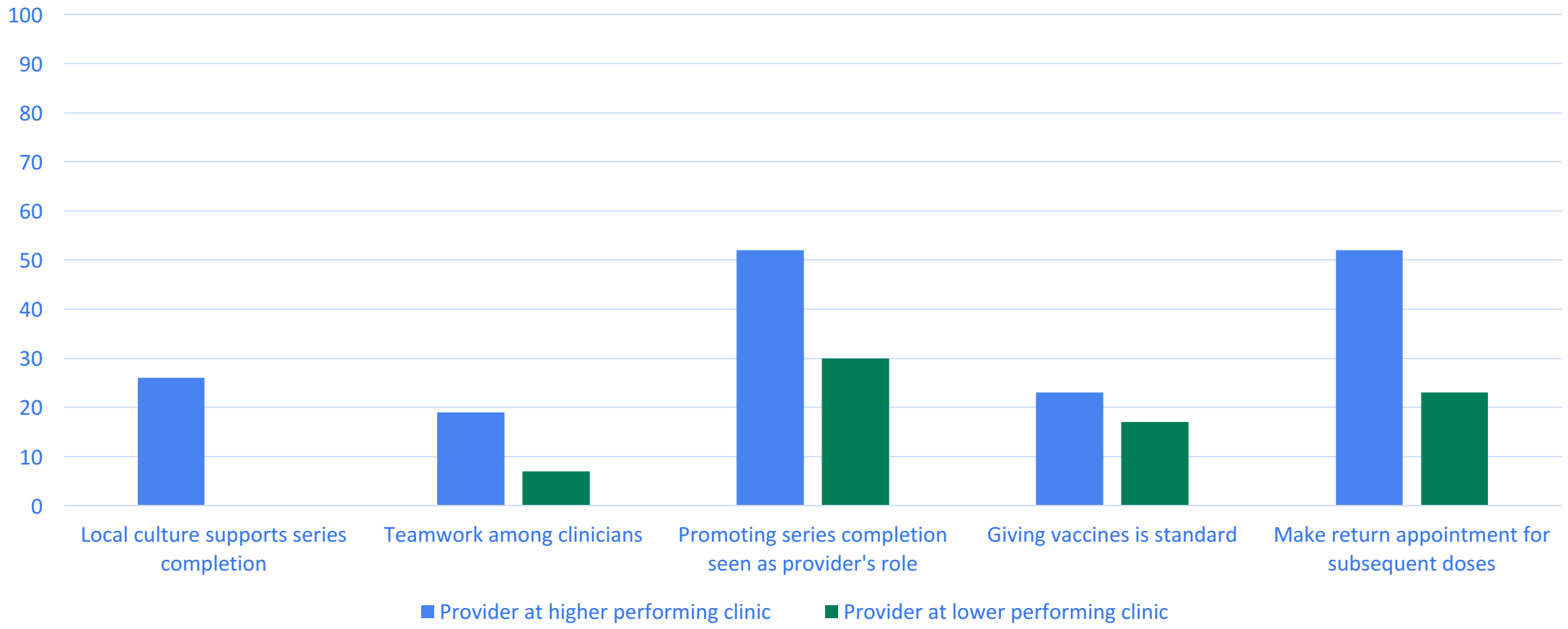
- Make an effective recommendation for HPV vaccination as cancer prevention for every 11- or 12-year-old patient
- Assess HPV vaccine coverage for each provider in your practice and develop an office-wide strategy to improve it
- Engage the entire practice – not just healthcare providers – in committing to improve HPV vaccine coverage
- Implement systems strategies to improve HPV vaccine coverage

“

Now that Sophia is 11, she is due for three vaccines. These will help protect her from meningitis, HPV cancers, and pertussis. We’ll give those shots today at the end of the visit.

”

Factors that May Impact HPV Vaccine Series Completion in Clinics with Higher and Lower Series Completion: Pro-HPV Vaccination Culture



Hudson SM et al. Vaccine 2016

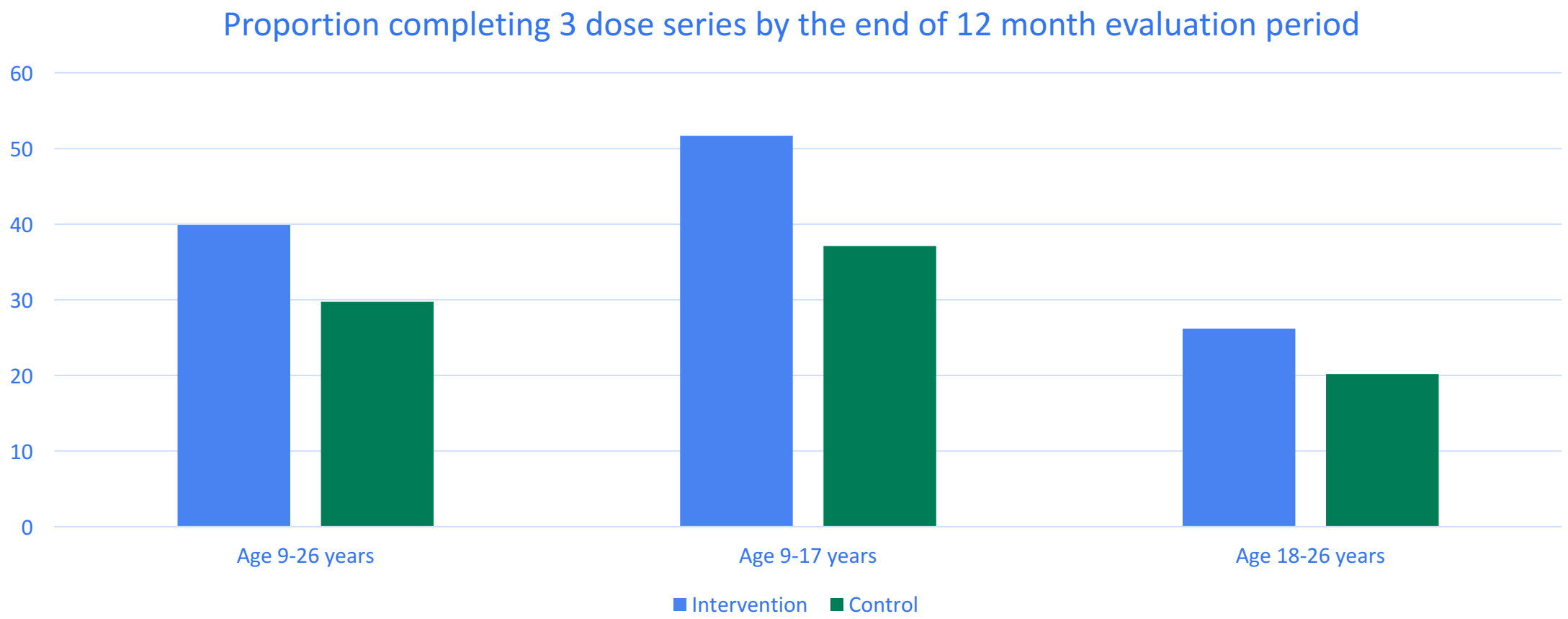
What Can Healthcare Providers Do?

- Make an effective recommendation for HPV vaccination as cancer prevention for every 11- or 12-year-old patient
- Assess HPV vaccine coverage for each provider in your practice and develop an office-wide strategy to improve it
- Engage the entire practice – not just healthcare providers – in committing to improve HPV vaccine coverage
- Implement systems strategies to improve HPV vaccine coverage

Systems Strategies to Improve HPV Vaccine Coverage

- Establish standing orders for HPV vaccination beginning at age 11-12 years in your practice
- Conduct reminder/recall beginning at 11-12 years of age
- Assess HPV vaccine coverage at every visit and prompt clinical staff to give HPV vaccine at that visit
- Schedule return visit for next dose before the patient leaves the office
- Document each dose in the child's medical record and the state's immunization information system

Impact of a Mailed Reminder Letter on HPV Series Completion in Girls and Young Women



Chao C et al, Journal of Adolescent Health 2015;56:85-90

What Can Community- and State-Level Organizations Do?

- Convene and commit to implementing effective strategies
- Immunization programs: AFIX focused on adolescent immunization
- Provider organizations: help members develop the motivation and skills to make an effective recommendation for HPV vaccination
- Cancer programs: motivate immunization providers to prevent cancers caused by HPV in their patients
- Health care payers: use HPV vaccine coverage as a quality measure
- All organizations: increase public awareness and support for HPV vaccination as cancer prevention
- All organizations: promote or implement systems strategies to improve HPV vaccine coverage

Selected NCIRD-Supported Activities to Improve HPV Vaccine Coverage, 2013-2016

- **Partner with national provider and quality improvement organizations**
- **National HPV Vaccination Roundtable (with DCPC)**
- **Multi-component intervention to improve HPV vaccine coverage in 22 jurisdictions**
- **Technical assistance to selected states to**
  - support stakeholder engagement
  - develop of state-wide plans
  - Implement effective strategies
- **NACCHO partnership**
- **Support health services research in large health systems**
- **Communications campaigns targeting both providers and parents of pre-teen children**

HEDIS Measures for HPV Vaccination Coverage

- **CDC partnered with the National Committee for Quality Assurance (NCQA) to develop a HEDIS measure for HPV vaccination coverage of girls**
  - Proportion of girls who have received three doses of HPV vaccine by their 13th birthday
- **The measure was first publicly reported in HEDIS 2014 (MMWR 2015)**
- **The NCQA/HEDIS measure was included in the Core Set of Children's Health Care Quality Measures for Medicaid and CHIP in FY2014**
- **CDC partnered with NCQA to include receipt of 3 doses of HPV vaccine by age 13 in the Adolescent Immunization measure for HEDIS 2017**

Performance Rates on Adolescent Immunization: Medicaid/CHIP Children's Health Care Quality Measures, FY2014

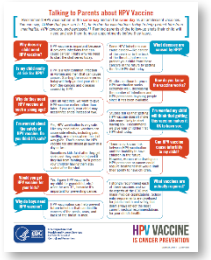
Measure	# of states reporting	Mean	25th percentile	75th percentile
1 dose Tdap + 1 dose meningococcal vaccine by 13 years	35	64.9	52.6	79.7
3 doses HPV by 13 years	32	17.2	12.9	22.9

HHS. 2015 Annual Report on the Quality of Care for Children in Medicaid and CHIP. February 2016.

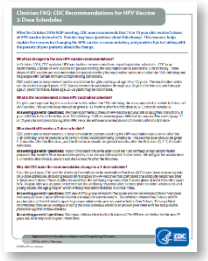
Improving HPV Vaccine Coverage in the United States

- **Provider-level interventions are effective, but difficult to bring to scale**
- **Ongoing engagement and coalition-building at the national, state, and local level continues to be important**
- **Updated Adolescent Immunization measure in HEDIS 2017 provides an opportunity for systems interventions**
  - State level: encouraging state planning efforts to include major payers and health systems, including Medicaid managed care organizations
  - National level: including HPV vaccine coverage in conversations with national payers, health systems, and Medicaid

HPV Resources: Clinicians



- The newly updated Tips and Timesavers for Talking with Parents about HPV vaccine addresses common questions parents may have



- Clinician FAQ: Consult this factsheet for explanations on the new 2-dose HPV vaccine recommendation

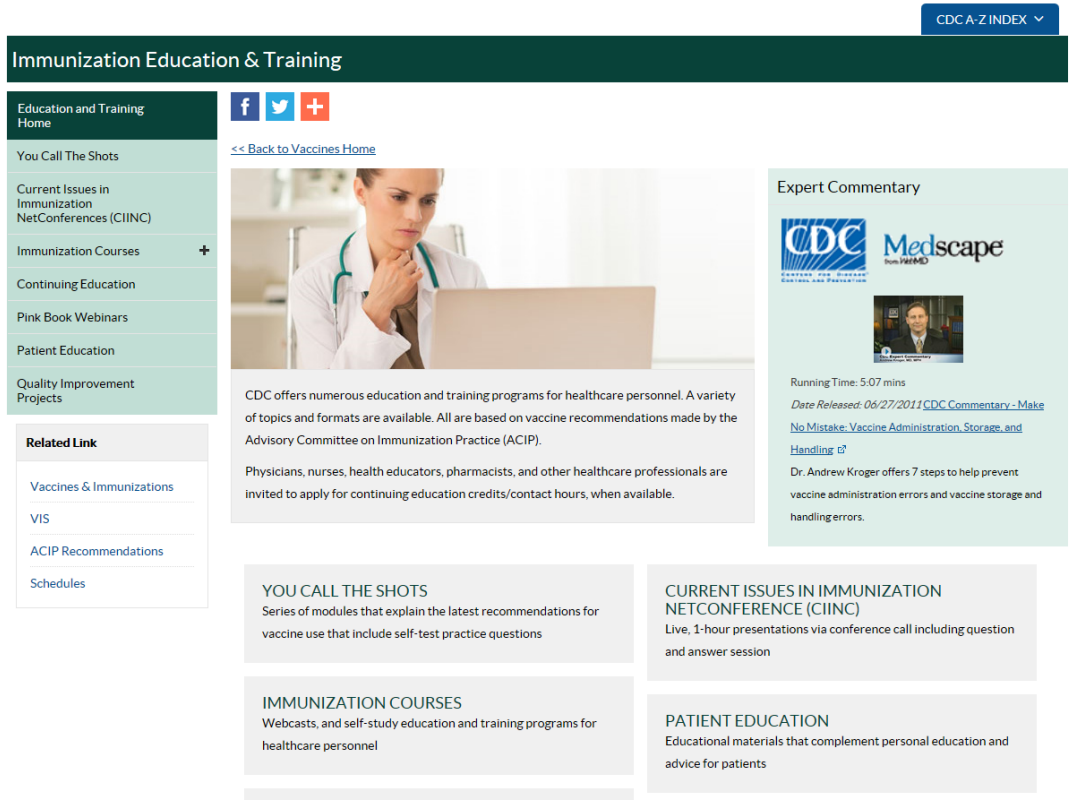
- Visit the HPV Clinician Webpage for more HPV facts, how to promote vaccination, and how to successfully communicate with parents

Tips and Timesavers: https://www.cdc.gov/hpv/hcp/for-hcp-tipsheet-hpv.pdf
2-dose HPV Vaccine Factsheet: https://www.cdc.gov/hpv/downloads/hcvg15-ptt-hpv-2dose.pdf
HPV Clinician Webpage: https://www.cdc.gov/hpv/hcp/index.html

Immunization Resources

CDC Resources for Staff Education

- **Competency-based education for staff is critical**
- **Multiple education products available free through the CDC website:**
  - Immunization courses (webcasts and online self-study)
  - Netconferences
  - You Call the Shots self-study modules
- **Continuing education credits available**



https://www.cdc.gov/vaccines/ed/index.html

CDC Vaccine and Immunization Resources

Questions? Email CDC

Providers	nipinfo@cdc.gov
Parents and patients	www.cdc.gov/cdcinfo
Website	www.cdc.gov/vaccines
Twitter	@DrNancyM_CDC
Influenza	www.cdc.gov/flu
Vaccine Safety	www.cdc.gov/vaccinesafety

Additional slides- just in case