EpiVac Pink Book Web-on-Demand Series

HPV–2020

Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
Atlanta, GA

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Learning Objectives

- 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.
- Describe an emerging immunization issue.
- Locate current immunization resources to increase knowledge of team's role in program implementation for improved team performance.
- Implement disease detection and prevention health care services (e.g., smoking cessation, weight reduction, diabetes screening, blood pressure screening, immunization services) to prevent health problems and maintain health.

Today's Agenda

EpiVac Pink Book Web-on-Demand Series: HPV–2020

Andrew Kroger, MD, MPH, Medical Officer, CDC/NCIRD

Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-092320
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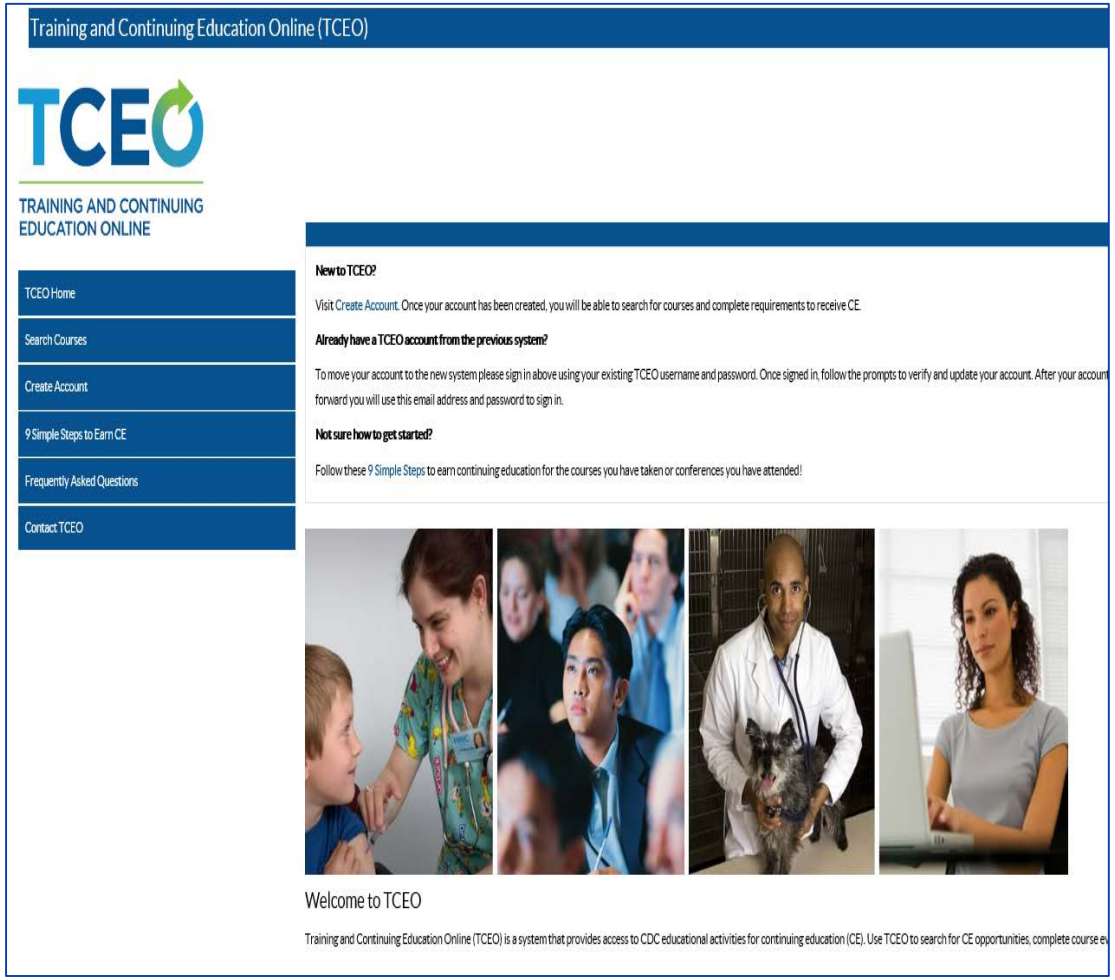

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Human Papillomavirus and Human Papillomavirus Vaccine

Pink Book Web-on-Demand Series 2020

Andrew Kroger, MD, MPH
Medical Officer/Medical Health Educator

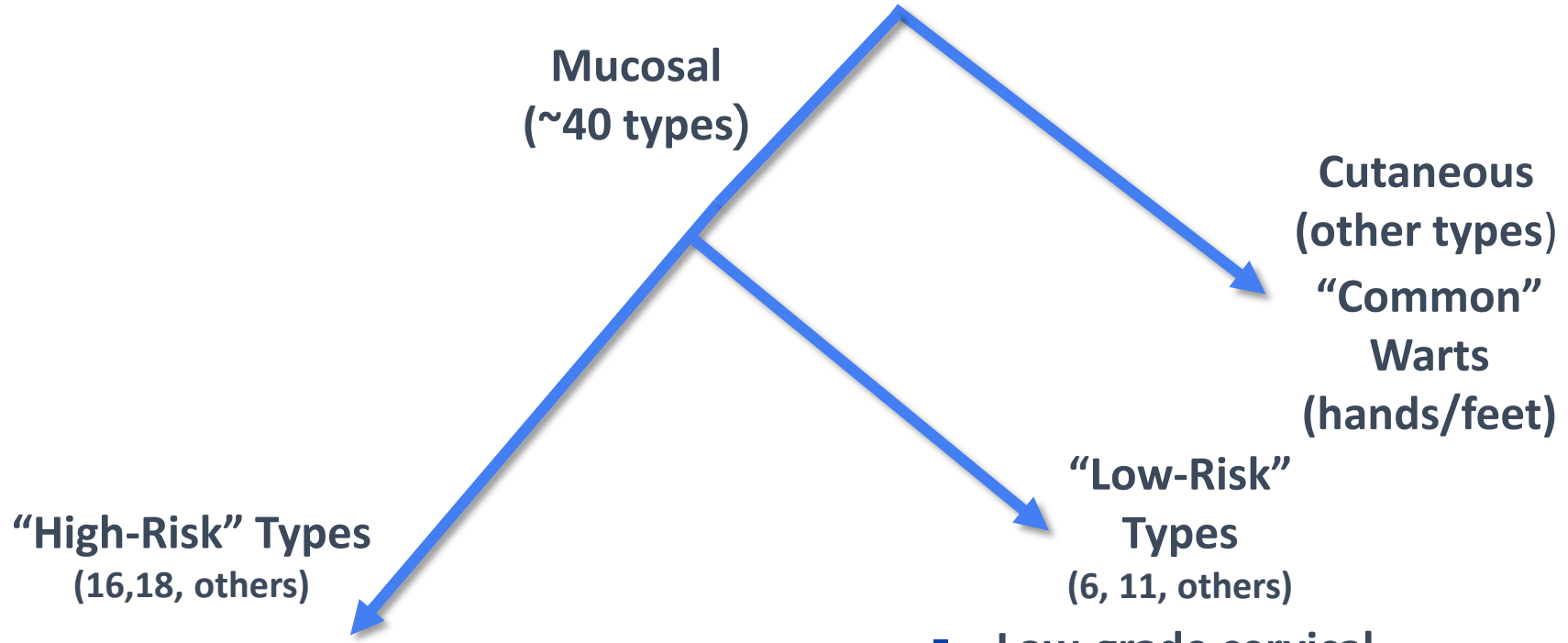
1

Disease

Human Papillomavirus (HPV) Disease

- Most common sexually transmitted infection in the U.S.
- Small DNA virus
- More than 150 types
- First vaccine was licensed in 2006

Human Papillomavirus Type and Disease Association

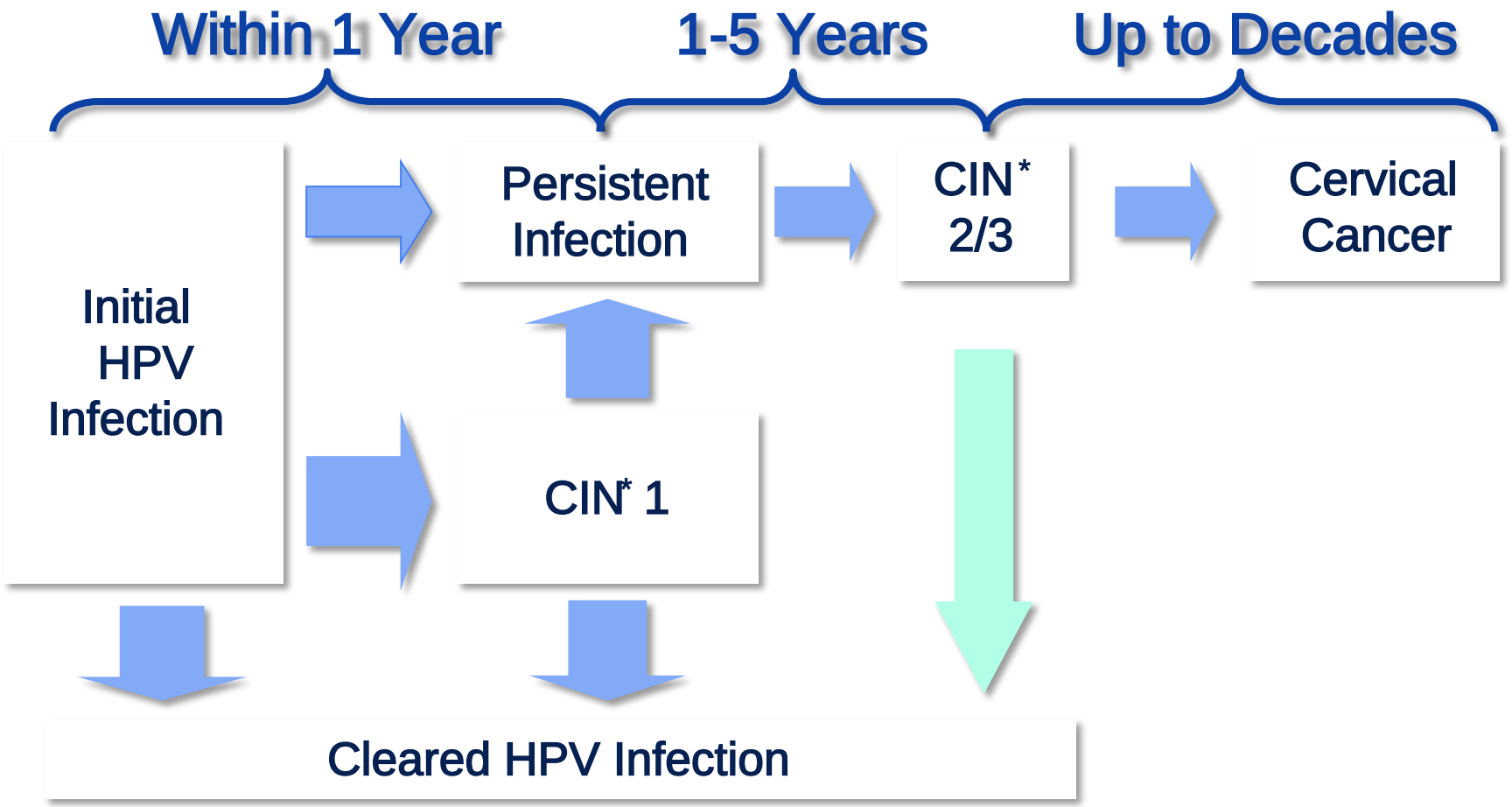


- Low-grade cervical abnormalities
- High-grade abnormalities
- Cancer precursors
- Anogenital cancers

- Low-grade cervical abnormalities
- Genital warts
- Respiratory papillomas

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2019-06/HPV-4-Chesson-508.pdf

Natural History of HPV Infection



*CIN = cervical intraepithelial neoplasia

HPV Clinical Features

- **Most HPV infections are asymptomatic and result in no clinical disease.**
- **Clinical manifestations of HPV infection include:**
  - Anogenital warts
  - Recurrent respiratory papillomatosis
  - Cervical cancer precursors (cervical intraepithelial neoplasia)
  - Cancer (cervical, anal, vaginal, vulvar, penile, and some oropharyngeal cancers)

TABLE 1. Average annual number and rate of human papillomavirus (HPV)—associated cancers and estimated percentage and annual number of cancers attributable to HPV, by HPV type, cancer type, and sex — United States,* 2012–2016

Cancer type	Reported HPV-associated cancers†		Estimated no.§ (%) of cancers attributable to HPV types¶		
	Total no.**	Rate††	9vHPV-targeted	Other HPV	HPV-negative
Cervix	12,015	7.2	9,700 (81)	1,200 (10)	1,100 (9)
Vagina	862	0.4	600 (73)	0 (2)	300 (25)
Vulva	4,009	2.1	2,500 (63)	300 (6)	1,200 (31)
Penis	1,303	0.8	700 (57)	100 (6)	500 (37)
Anus	6,810	1.8	6,000 (88)	200 (3)	600 (9)
Female	4,539	2.3	4,100 (90)	100 (2)	300 (8)
Male	2,270	1.3	1,900 (83)	100 (6)	300 (11)
Oropharynx	19,000	4.9	12,600 (66)	900 (5)	5,500 (29)
Female	3,460	1.7	2,100 (60)	100 (3)	1,300 (37)
Male	15,540	8.5	10,500 (68)	800 (5)	4,200 (28)
Total	**43,999**	**12.2**	**32,100 (73)**	**2,700 (6)**	**9,200 (21)**
Female	**24,886**	**13.7**	**19,000 (76)**	**1,700 (7)**	**4,200 (17)**
Male	**19,113**	**10.6**	**13,100 (69)**	**1,000 (5)**	**5,000 (26)**

Abbreviations: 9vHPV = 9-valent HPV vaccine; ICD-O-3 = *International Classification of Diseases for Oncology, Third Edition.*

* Compiled from population-based cancer registries that participate in the CDC National Program of Cancer Registries, and/or the National Cancer Institute's Surveillance, Epidemiology, and End Results Program and meet the criteria for high data quality for all years during 2012–2016, covering 100% of the U.S. population.

† HPV-associated cancers were defined as invasive cancers at anatomic sites with cell types in which HPV DNA frequently is found. All cancers were histologically confirmed. Cervical cancers (ICD-O-3 site codes C53.0–C53.9) are limited to carcinomas (ICD-O-3 histology codes 8010–8671, 8940–8941). Vaginal (ICD-O-3 site code C52.9), vulvar (ICD-O-3 site codes C51.0–C51.9), penile (ICD-O-3 site codes C60.0–60.9), anal (ICD-O-3 site codes C20.9, C21.0–C21.9) and oropharyngeal (ICD-O-3 site codes C01.9, C02.4, C02.8, C05.1, C05.2, C09.0, C09.1, C09.8, C09.9, C10.0, C10.1, C10.2, C10.3, C10.4, C10.8, C10.9, C14.0, C14.2, and C14.8) cancer sites are limited to squamous cell carcinomas (ICD-O-3 histology codes 8050–8084, 8120–8131).

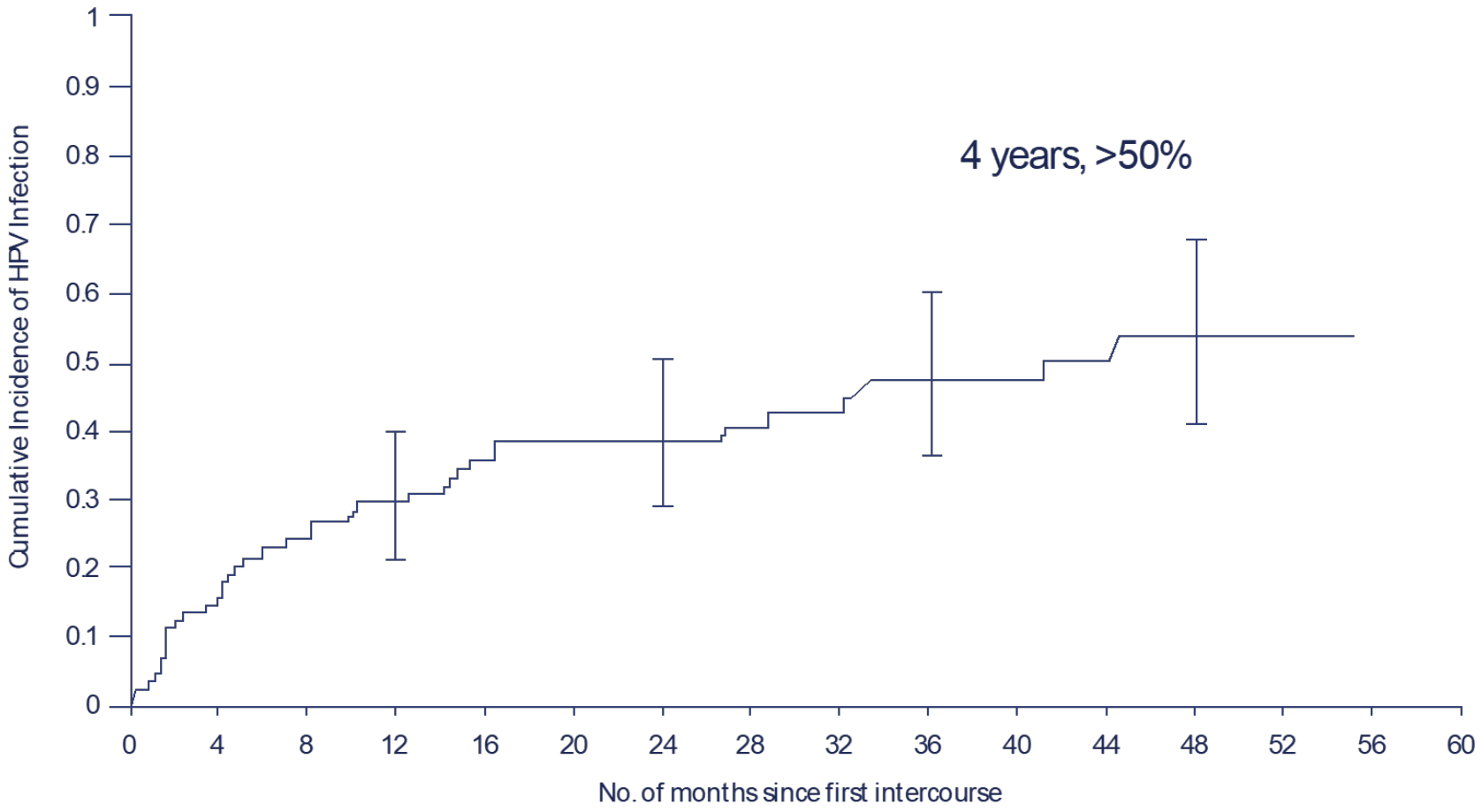
§ HPV-attributable cancers are cancers that are probably caused by HPV (https://academic.oup.com/jnci/article/107/6/djv086/872092). Estimates for attributable fraction were based on studies that used population-based data from cancer tissue studies to estimate the percentage of those cancers probably caused by HPV. The

https://www.cdc.gov/mmwr/volumes/68/wr/mm6833a3.htm?s_cid=mm6833a3_w

HPV Epidemiology

Reservoir	Human
Transmission	Direct contact (usually sexual)
Temporal pattern	None
Communicability	Presumed to be high

Cumulative Incidence of any HPV Infection Months after Sexual Initiation



Am J Epidemiol 2003;157(3):218–26

HPV Disease Burden in the U.S.

- **Estimated 79 million persons are infected**
  - ~14 million new infections annually
- **Common among adolescents and young adults**
  - 50% of new infections occur in persons 15–24 years of age.
- **About $8 billion spent annually on management of sequelae of HPV infections**

Cervical Cancer Screening

- Revised in 2018
- Screening should begin at age 21 years.
- Screen women 21 to 29 years of age with a Pap test every 3 years.
- Screen women 30 to 65 years of age with a Pap test every 3 years, an HPV test every 5 years, or co-testing (Pap and HPV testing) every 5 years.

https://www.cdc.gov/cancer/cervical/basic_info/screening.htm

2

Vaccine

Human Papillomavirus Vaccine

- HPV L1 major capsid protein of the virus is antigen used for immunization
- L1 protein produced using recombinant DNA technology
- L1 proteins self-assemble into virus-like particles (VLPs).
- VLPs are noninfectious and nononcogenic.

Human Papillomavirus Vaccine

HPV Vaccines	9-valent 9vHPV (Gardasil 9)
L1 VLP types	6, 11, 16, 18, 31, 33, 45, 52, 58
Manufacturer	Merck
Contraindications	Hypersensitivity to yeast
FDA indications	Females (9 through 45 yrs): Anal, cervical, vaginal, and vulvar precancer and cancer; genital warts
	Males (9 through 45 yrs): Anal precancer and cancer; genital warts

Only 9vHPV vaccine is available in the U.S.

Human Papillomavirus Vaccine
Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types (≥95%)

- No evidence of efficacy against disease caused by vaccine types participants were infected with at the time of vaccination

- Prior infection with one HPV type did not diminish the efficacy of the vaccine against other vaccine HPV types.

9vHPV (Gardasil 9)

- **Licensed by the FDA for males and females 9 through 45 years of age**
- **Trials conducted with 3-dose schedule**
- **Targets 5 additional high-risk types:**
  - 6, 11, 16, 18, **31, 33, 45, 52, 58**

https://www.fda.gov/media/117053/download

9vHPV (Gardasil 9)
Efficacy and Safety

- **Efficacy**
  - ~97% protection against 31-, 33-, 45-, 52-, 58-related outcomes
  - Similar protection against 6-, 11-, 16-, 18-related disease
- **Noninferior immunogenicity to 4vHPV**
- **5 additional types account for 11% of invasive cancers.**
  - Differences by gender: 14% for females, 4% for males
- **9vHPV can be administered at the same medical visit as MenACWY and Tdap.**
- **Safety profile similar to 4vHPV across age, gender, race, ethnic groups**

9vHPV (Gardasil 9)
Efficacy and Safety: 27 through 45 years

- Immunogenicity: 94 to 100%
- Safety–few serious adverse events and no vaccine-related deaths

https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf

Human Papillomavirus Vaccine
Duration of Immunity

- **The duration of immunity after a complete 3-dose schedule is not known:**
  - Available evidence indicates protection for at least 8 years for 4vHPV and at least 9 years for 2vHPV.
  - Multiple cohort studies are in progress to monitor the duration of immunity.

3

Clinical Considerations

Recommended Child and Adolescent Immunization Schedule for ages 18 years and younger, 2020.

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020

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). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19–23 mos	2–3 yrs	4–6 yrs	7–10 yrs	11–12 yrs	13–15 yrs	16 yrs	17–18 yrs
Hepatitis B (HepB)	1st dose	2nd dose			3rd dose												
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	See Notes												
Diphtheria, tetanus, acellular pertussis (DTaP <7 yrs)			1st dose	2nd dose	3rd dose			4th dose				5th dose					
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	See Notes		3rd or 4th dose, See Notes										
Pneumococcal conjugate (PCV13)			1st dose	2nd dose	3rd dose		4th dose										
Inactivated poliovirus (IPV <18 yrs)			1st dose	2nd dose	3rd dose							4th dose					
Influenza (IIV)					Annual vaccination 1 or 2 doses								Annual vaccination 1 dose only				
or													or				
Influenza (LAIV)											Annual vaccination 1 or 2 doses		Annual vaccination 1 dose only				
Measles, mumps, rubella (MMR)					See Notes		1st dose					2nd dose					
Varicella (VAR)							1st dose					2nd dose					
Hepatitis A (HepA)					See Notes		2-dose series, See Notes										
Tetanus, diphtheria, acellular pertussis (Tdap ≥7 yrs)																	
Human papillomavirus (HPV)													*	See Notes			
Meningococcal (MenACWY-D ≥9 mos, MenACWY-CRM ≥2 mos)			See Notes											1st dose		2nd dose	
Meningococcal B													See Notes				
Pneumococcal polysaccharide (PPSV23)											See Notes						

Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Range of recommended ages for certain high-risk groups

Recommended based on shared clinical decision-making or

No recommendation/ not applicable

https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf

Recommended Child and Adolescent Immunization Schedule for ages 18 years and younger, 2020.

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who are More than 1 month Behind, United States, 2020

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose.** Minimum age for the final dose is 24 weeks.		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days	**4 weeks**	**4 weeks** Maximum age for final dose is 8 months, 0 days.		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months**
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older. **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix) or unknown. **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose administered at younger than 15 months; OR if both doses were PRP-OMP (PedvaxHIB, Comvax) ***and*** were administered before the 1st birthday.	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after.	**No further doses needed** for healthy children if previous dose administered at age 24 months or older. **4 weeks** if current age is younger than 12 months and previous dose was administered at <7 months old. **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was given before age 12 months.	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before age 12 months or for children at high risk who received 3 doses at any age.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is < 4 years. **6 months (as final dose)** if current age is 4 years or older.	**6 months** (minimum age 4 years for final dose).	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 9 months MenACWY-D	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday. **6 months (as final dose)**	**6 months** if first dose of DTaP/DT was administered before the 1st birthday.	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose.**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older.			

Recommended Child and Adolescent Immunization Schedule for ages 18 years and younger, 2020.

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2020

Always use this table in conjunction with Table 1 and the notes that follow.

VACCINE	INDICATION										
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[1]		Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leaks or cochlear implants	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
			<15% and total CD4 cell count of <200/mm3	≥15% and total CD4 cell count of ≥200/mm3						
Hepatitis B										
Rotavirus		SCID[2]								
Diphtheria, tetanus, & acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
Influenza (IIV)										
or										
Influenza (LAIV)						Asthma, wheezing: 2–4yrs[3]				
Measles, mumps, rubella										
Varicella										
Hepatitis A										
Tetanus, diphtheria, &										
Human papillomavirus										
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										

- 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 Notes.
- Not recommended/ contraindicated—vaccine should not be administered
- Precaution—vaccine might be indicated if benefit of protection outweighs risk of adverse reaction
- Delay vaccination until after pregnancy if vaccine indicated
- No recommendation/ not applicable

1 For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote D) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2 Severe Combined Immunodeficiency
3 LAIV contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months.

Recommended Adult Immunization Schedule for ages 19 years or older, 2020.

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2020

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
Influenza inactivated (IIV) or Influenza recombinant (RIV)	1 dose annually			
or				
Influenza live, attenuated (LAIV)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV) *(preferred)*			2 doses	
or			or	
Zoster live			1 dose	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal conjugate (PCV13)	1 dose			65 years and older
Pneumococcal polysaccharide (PPSV23)	1 or 2 doses depending on indication			1 dose
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			
Hepatitis B (HepB)	2 or 3 doses depending on vaccine			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication, see notes for booster recommendations			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations			
	19 through 23 years			
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			

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

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

Recommended vaccination based on shared clinical decision-making

No recommendation/ Not applicable

Recommended Adult Immunization Schedule for ages 19 years or older, 2020.

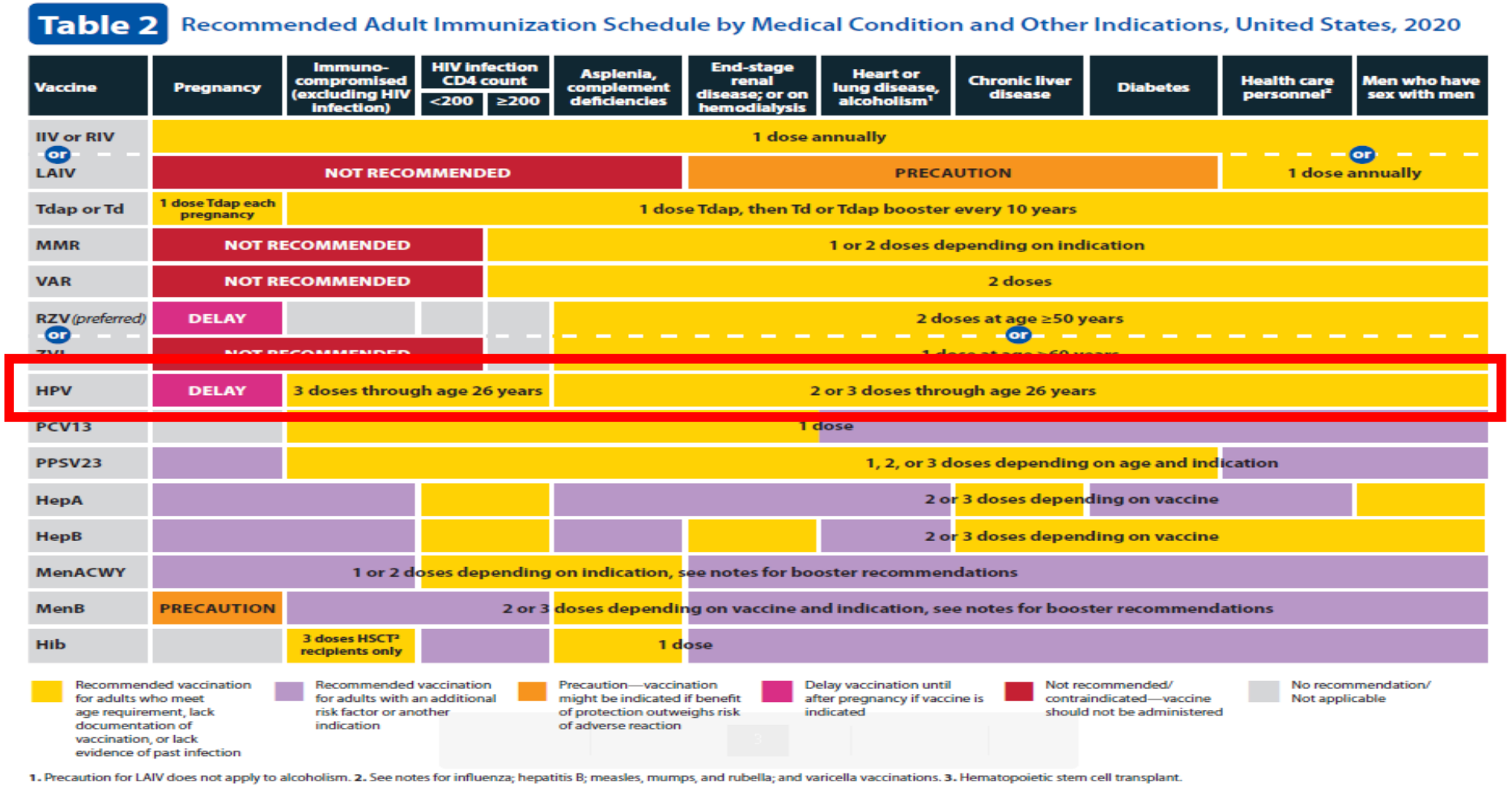


Table 2 Recommended Adult Immunization Schedule by Medical Condition and Other Indications, United States, 2020

Vaccine	Pregnancy	Immuno-compromised (excluding HIV infection)	HIV infection CD4 count <200	HIV infection CD4 count ≥200	Asplenia, complement deficiencies	End-stage renal disease; or on hemodialysis	Heart or lung disease, alcoholism[1]	Chronic liver disease	Diabetes	Health care personnel[2]	Men who have sex with men
IIV or RIV	1 dose annually										
or										or	
LAIV	NOT RECOMMENDED						PRECAUTION			1 dose annually	
Tdap or Td	1 dose Tdap each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	NOT RECOMMENDED	1 or 2 doses depending on indication									
VAR	NOT RECOMMENDED	2 doses									
RZV *(preferred)*	DELAY				2 doses at age ≥50 years						
or					or						
ZVL	NOT RECOMMENDED				1 dose at age ≥60 years						
HPV	DELAY	3 doses through age 26 years			2 or 3 doses through age 26 years						
PCV13		1 dose									
PPSV23		1, 2, or 3 doses depending on age and indication									
HepA		2 or 3 doses depending on vaccine									
HepB		2 or 3 doses depending on vaccine									
MenACWY	1 or 2 doses depending on indication, see notes for booster recommendations										
MenB	PRECAUTION	2 or 3 doses depending on vaccine and indication, see notes for booster recommendations									
Hib		3 doses HSCT[3] recipients only			1 dose						

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

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

Precaution—vaccination might be indicated if benefit of protection outweighs risk of adverse reaction

Delay vaccination until after pregnancy if vaccine is indicated

Not recommended/ contraindicated—vaccine should not be administered

No recommendation/ Not applicable

1. Precaution for LAIV does not apply to alcoholism. **2.** See notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations. **3.** Hematopoietic stem cell transplant.

Human Papillomavirus Vaccine Routine Recommendations

- **Routinely vaccinate boys and girls at 11 through 12 years of age.***
- **Catch up those who are unvaccinated or who are missing doses, including:**
  - Females and males age 13 through 26 years

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

MMWR 2015;64:300–4

HPV Vaccination Schedules

- FDA has approved a 2-dose schedule for 9vHPV (Gardasil 9).
- ACIP reviewed data on 2-dose schedules, including studies of immune response, vaccine effectiveness, and duration of protection. Specifically:

HPV Vaccination Schedules

- Data from clinical trials showed 2 doses of HPV vaccine given in younger adolescents (9 through 14 years) produced an immune response similar or higher than the response in young adults (16 through 26 years) who received 3 doses.
- Data available to date show that a 3-dose schedule in older adolescents and young adults provides long-lasting protection.
- Study data suggest that a 2-dose schedule given to younger adolescents will also provide long-lasting protection.

ACIP HPV Immunization Recommendations Previously Unvaccinated Adolescents

- **Administer 2 doses of HPV vaccine to adolescents starting the series at 9 through 14 years of age.**
- **Follow the routine 2-dose schedule:**
  - Administer the second dose 6-12 months after the first dose.
- **If a second dose is inadvertently administered prior to 5 months, default to a 3-dose series.**

https://www.cdc.gov/vaccines/pubs/pinkbook/supplement.html

ACIP HPV Immunization Recommendations Previously Unvaccinated Adolescents

- **Administer 3 doses to adolescents starting the series on or after the 15th birthday, or to immunosuppressed or autoimmune persons of any age.**
- **Routine 3-dose schedule*: 0, 1 through 2, 6 months**
  - Dose #2 should be administered at least 1 through 2 months after dose 1.
  - Dose #3: Administer at least:
    - 12 weeks after dose 2 AND
    - 6 months (24 weeks) after dose 1
- **An accelerated schedule using minimum intervals is not recommended.**

MMWR 2016;65(49):1405–08

ACIP HPV 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 through 12 months) OR
    - 3 doses at the recommended dosing schedule (0, 1 through 2, 6 months)
  - On or after the 15th birthday are fully vaccinated if they received:
    - 3 doses at the recommended dosing schedule (0, 1 through 2, 6 months)
- **All of the doses do not have to be 9vHPV.**
- **No additional doses are recommended, regardless of the current age of the vaccine recipient.**

MMWR 2016;65(49):1405–08

ACIP HPV Immunization Recommendations
Medical Condition Considerations

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

MMWR 2016;65(49):1405–08

HPV Vaccination of Adults 27 through 45 Years of Age

- Shared clinical decision-making is recommended for adults 27 through 45 years of age.
- Shared clinical decision-making includes adults who may have received doses prior to the 27th birthday.
- Criteria for making the shared clinical decision-making available in box at https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf

Box: https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf

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.

Box: https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6832a3-H.pdf

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.

Human Papillomavirus Vaccine Administration

- **Administer HPV vaccine via intramuscular (IM) injection:**
  - Needle size: 1- through 1½-inch, 22- to 25-gauge
  - Site: Deltoid muscle in the upper arm
- **Follow proper injection practices:**
  - Use aseptic technique.
  - Use a new needle and syringe for each injection.
- **Administer HPV vaccine at the same medical visit as other vaccines.**

ACIP HPV Immunization Recommendations Additional Considerations

- **No therapeutic effect on HPV infection, genital warts, cervical lesions**
- **Prevaccination assessments not recommended**
  - HPV
  - Pregnancy

Human Papillomavirus Vaccine Special Situations

- **Administer vaccine to:**
  - Females who:
    - Have equivocal or abnormal Pap test
    - Have positive HPV DNA test
    - Are breast-feeding
  - Males and females who:
    - Have genital warts
    - Are immunosuppressed

MMWR 2014;63(No. 5):1–30
MMWR 2015;64(29):300–4

Human Papillomavirus Vaccine and Pregnancy

- **Initiation of the vaccine series should be delayed until after completion of pregnancy.**
- **If a woman is found to be pregnant after initiating the vaccine series, remaining doses should be delayed until after the pregnancy.**
- **If a vaccine dose has been administered during pregnancy, there is no indication for intervention.**
- **Women vaccinated during pregnancy should be reported to the respective manufacturer.**
  - Active pregnancy registry for 9vHPV established; others are closed
  - Contact information is in the package insert.

MMWR 2014;63(No. 5):1–30
MMWR 2015;64(29):300–4

Human Papillomavirus Vaccine
Contraindications and Precautions

- **Contraindication**
  - Severe allergic reaction to a vaccine component or following a prior dose
- **Precaution**
  - Moderate or severe acute illnesses (defer until symptoms improve)

Adverse Events Following any Dose of HPV Vaccine Among Females*

Adverse Event	2vHPV	4vHPV	9vHPV
Pain	92%	84%	89%
Swelling	44%	29%	40%
Erythema	48%	25%	34%
Fever	13%	13%	5%
Nausea	7%	GI 28%**	4%
Headache	12%	55%	11%

*FDA product approval data

**GI = Gastrointestinal symptoms, including nausea, vomiting, diarrhea, and/or abdominal pain

Adverse Events Following any Dose of HPV Vaccine Among Females*

- Postural orthostatic tachycardia syndrome (POTS)
- Guillain-Barré syndrome (GBS)
- Complex regional pain syndrome (CRPS)

https://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html#A10

Syncope Following Vaccination

- **An increase in the number of reports of syncope has been detected by the Vaccine Adverse Event Reporting System (VAERS).**
  - Most of the increase among females 11 to 18 years
- **Serious injuries have resulted.**
- **ACIP recommends providers strongly consider observing patients for 15 minutes after they are vaccinated.**

Knowledge Check

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

A) Yes

B) No

Answer

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

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**

9vHPV (Gardasil 9)

Ages: 9 years through 45 years

Recommended ages: 11 years or 12 years

Catch-up ages: 13 years through 26 years

Shared clinical decision-making ages: 27 through 45 years

Route: Intramuscular (IM) injection

Vaccine storage label example
Available at www.cdc.gov/vaccines/hcp/admin/storage/guide/vaccine-storage-labels.pdf

HPV Vaccination Coverage
Females 13 through 17 Years of Age, 2018

HPV Vaccine	U.S.	
	Females	Males
1 or more doses*	69.9%	66.3%
HPV UTD**	53.7%	48.7%

Percentages ≥1 human papillomavirus vaccine, either 4vHPV or 2vHPV

**HPV UTD includes those with ≥3 doses and those with 2 doses when the first HPV vaccine dose was initiated before age 15 years and time between the first and second dose was at least 5 months minus 4 days.

https://www.cdc.gov/vaccines/imz-managers/coverage/teenvaxview/data-reports/hpv/dashboard/2018.html

HPV Vaccine Communications during the Health Care Encounter

- HPV vaccine is often presented as optional, whereas other adolescent vaccines are recommended.
- Some providers expressed mixed or negative opinions about relatively new vaccines and concerns over safety and efficacy.
- When parents express reluctance, providers are hesitant to engage in discussion.
- Some providers share parents' views that a teen is not at risk for HPV and vaccination can be delayed until the teen is older.

Goff S, et al. *Vaccine* 2011;10:7343–9
Hughes C, et al. *BMC Pediatrics* 2011;11:74

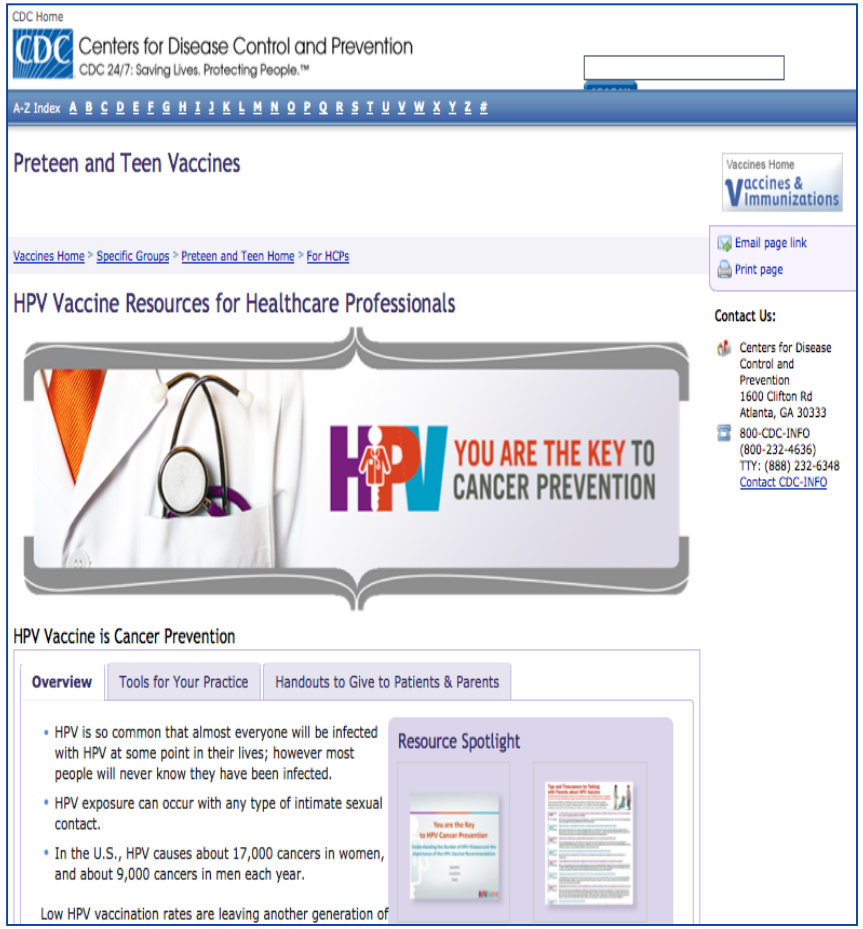
Strategies for Increasing HPV Vaccination Coverage in Clinical Practices

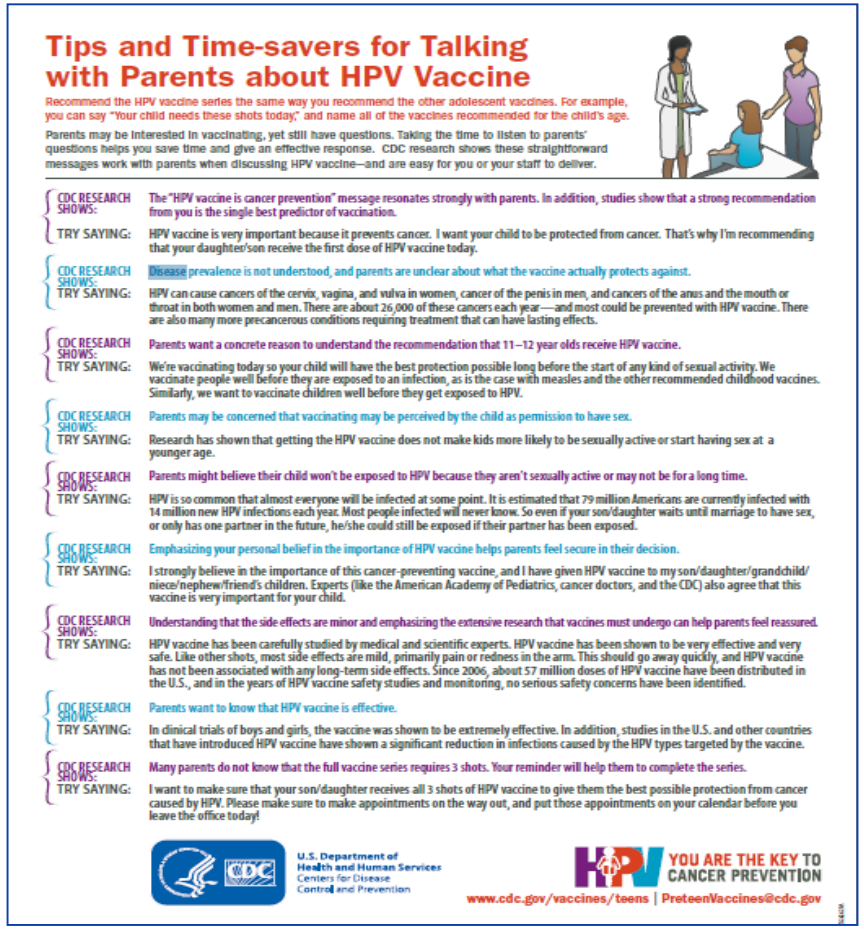
- **Recommend HPV vaccine!**
  - Include HPV vaccine when discussing other recommended vaccines.
- **Integrate standard procedures supporting vaccination:**
  - Assess for needed vaccines at every clinical encounter.
  - Vaccinate at every opportunity.
  - Use standing orders.
- **Reminder and recall**
- **Tools for improving uptake of HPV vaccine at www.cdc.gov/vaccines/teens**

4

Resources

HPV Vaccination Resources for HCP





www.cdc.gov/vaccines/YouAreTheKey

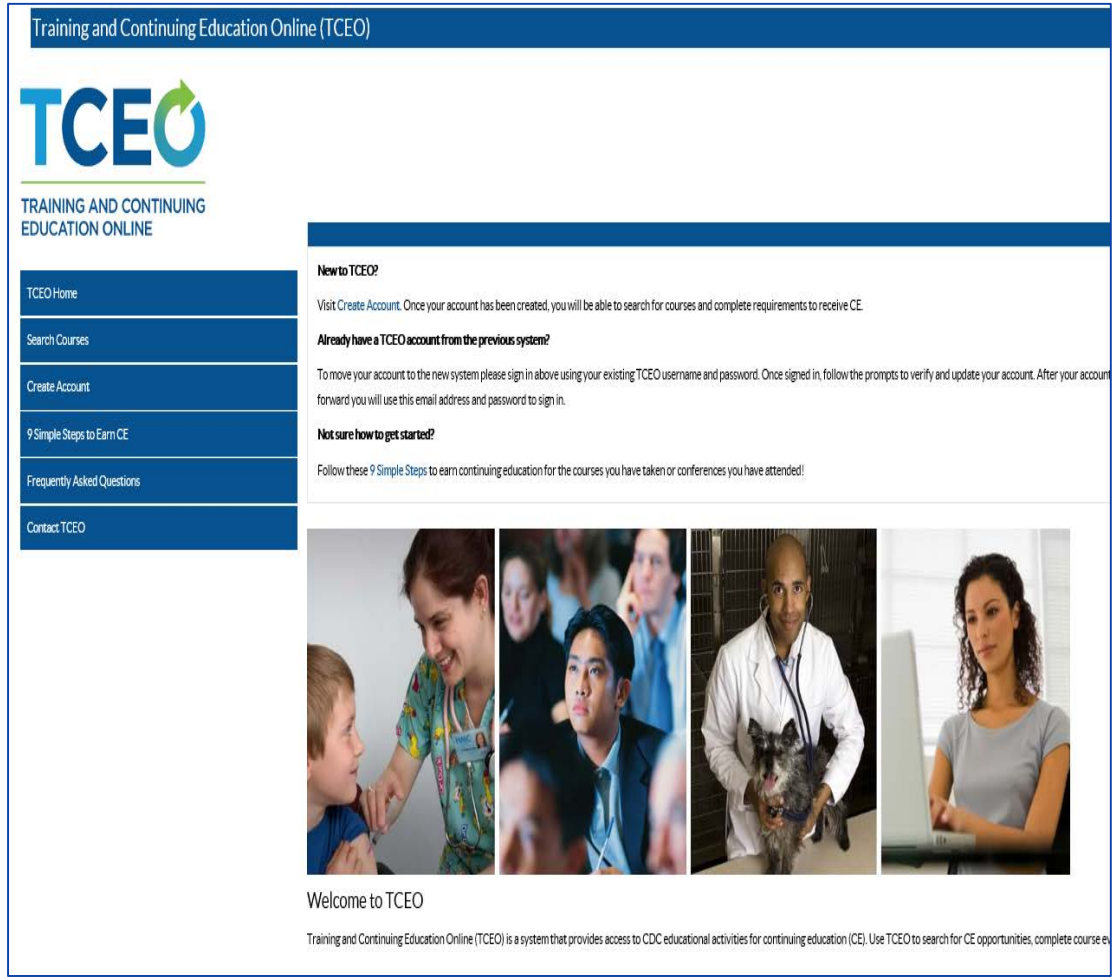
Human Papillomavirus Vaccine Resources

- **Human papillomavirus resource pages at www.cdc.gov/vaccines/ed/webinar-epv/**
- **Includes information for:**
  - Health care providers on:
    - Disease and treatment
    - Vaccine administration, storage, and handling
  - Parents and patients on:
    - Disease
    - Vaccine safety
  - Partners and programs
    - Print, matte articles, online, video and audio resources

Questions

Continuing Education Information

- CE credit, go to: www.cdc.gov/GetCE
- Search course number: WD4344-092320
- CE credit expires: July 1, 2022
- CE instructions are available on the EpiVac Pink Book Web-on-Demand Series web page
- Questions and additional help with the online CE system, e-mail CE@cdc.gov



E-mail Your Immunization Questions to Us

NIPINFO@cdc.gov

Write “Web-on-Demand–HPV” in the subject line

EpiVac Pink Book Web-on-Demand Resources

- Comprehensive list of resources for ALL sessions
- Located on the web page for this web-on-demand session at www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Additional materials located on this webpage include:
  - HPV slide set
  - Web-on-demand questions and answers
  - Transcript of this session
  - Continuing education instructions

COURSE RESOURCES

Epidemiology and Prevention of Vaccine-Preventable Diseases

- Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) Supplement: www.cdc.gov/vaccines/pubs/pinkbook/supplement.html

Overall Resources

- Current childhood and adult immunization schedules: www.cdc.gov/vaccines/schedules/index.html
- CDC Vaccine Schedules App for Health Care Providers: www.cdc.gov/vaccines/schedules/hcp/schedule-app.html
- Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- CDC General Best Practice Guidelines for Immunization: www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- CDC Continuing Education Information: www.cdc.gov/vaccines/ed/ce-credit-how-to.html
- Health Care Personnel Vaccination Recommendations: www.immunize.org/catg.d/p2017.pdf
- Pink Book Webinar Series: www.cdc.gov/vaccines/ed/webinar-epv/index.html
- Vaccines Licensed for Use in the United States Package Inserts: www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm
- You Call the Shots: www.cdc.gov/vaccines/ed/youcalltheshots.html

Course Intro and Objectives

- What is the Advisory Committee on Immunization Practices (ACIP)?: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-acip-color-office.pdf
- CDC Immunization Resources for You and Your Patients: www.cdc.gov/vaccines/hcp/admin/downloads/Resource-Booklet.pdf
- Parents' Guide to Childhood Immunizations: www.cdc.gov/vaccines/parents/tools/parents-guide/index.html
- Order Information for Free CDC Immunization Materials for Providers and Patients: www.cdc.gov/pubs/CDCInfoOnDemand.aspx

Principles of Vaccination

- Immune System Research: www.niaid.nih.gov/research/immune-system-research
- What is the Immune System?: www.vaccines.gov/basics/work/prevention
- Understanding How Vaccines Work: www.cdc.gov/vaccines/hcp/conversations/downloads/vacsafe-understand-color-office.pdf
- Vaccines Work: www.vaccines.gov/basics/work/index.html
- Vaccine Basics: How Vaccines Work: www.vaccineinformation.org/how-vaccines-work/
- The History of Vaccines: How Vaccines Work: www.historyofvaccines.org/content/how-vaccines-work

General Best Practice Guidelines

- Ask the Experts-Scheduling Vaccines FAQs: www.immunize.org/askexperts/scheduling-vaccines.asp
- Ask the Experts-Combination Vaccines FAQs: www.immunize.org/askexperts/experts_combo.asp
- Ask the Experts-Precautions and Contraindications FAQs: www.immunize.org/askexperts/precautions-contraindications.asp
- Foreign Language Vaccine-Preventable Disease Terms: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/foreign-products-tables.pdf
- Guide to Contraindications and Precautions to Commonly Used Vaccines: www.immunize.org/catg.d/p3072a.pdf
- Guidelines for Vaccinating Pregnant Women: www.cdc.gov/vaccines/pregnancy/hcp/guidelines.html
- IDSA 2013 Clinical Practice Guideline for Vaccination of the Immunocompromised Host: www.idsociety.org/Guidelines/Patient_Care/IDSA_Practice_Guidelines/Vaccination_of_the_Immunocompromised_Host/
- Interval Between Antibody-Containing Products and Measles- and Varicella-Containing Vaccines: www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/a/mmr_ig.pdf

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Centers for Disease Control and Prevention

Thank You From Atlanta!