

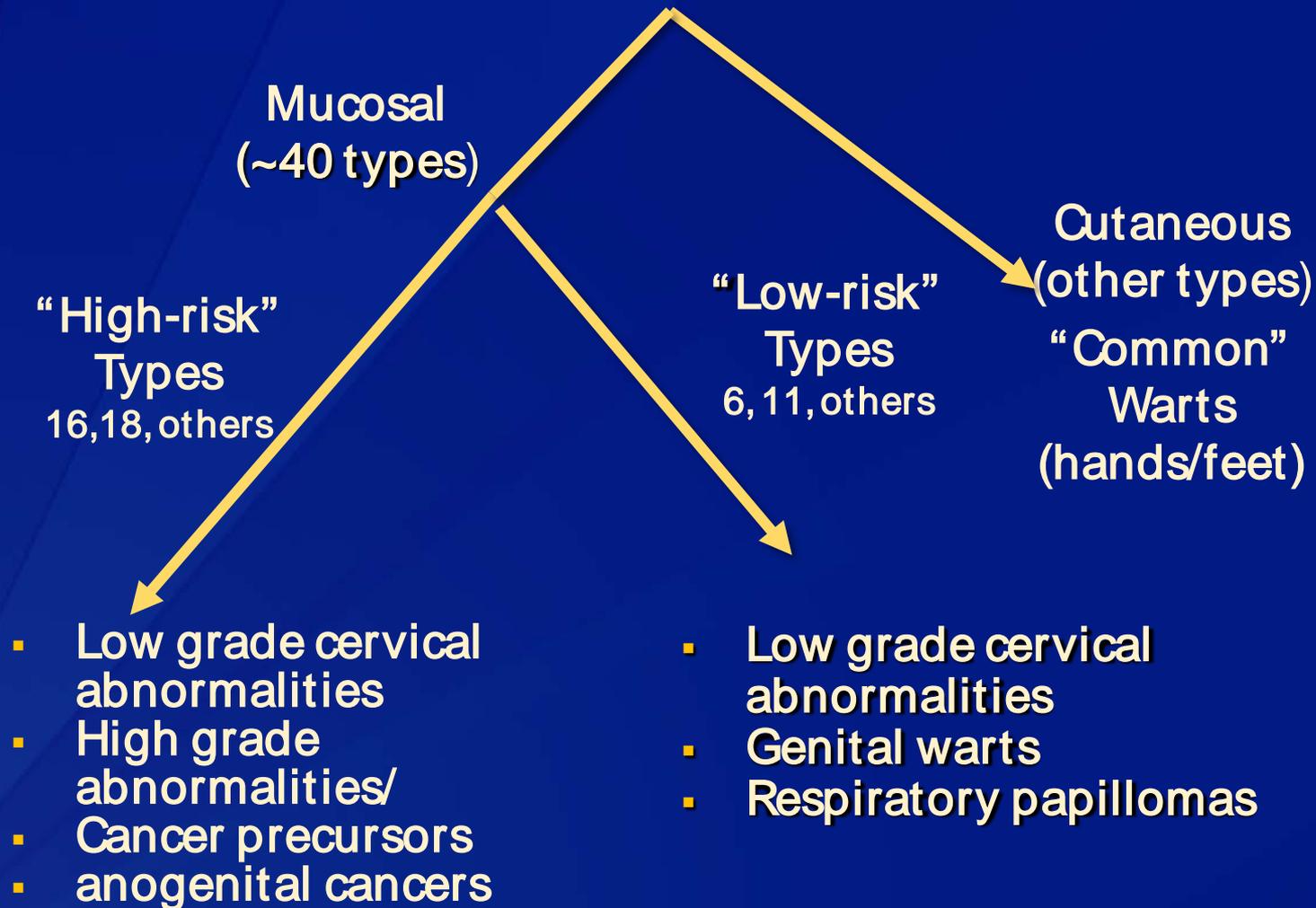
Human Papillomavirus and HPV Vaccines

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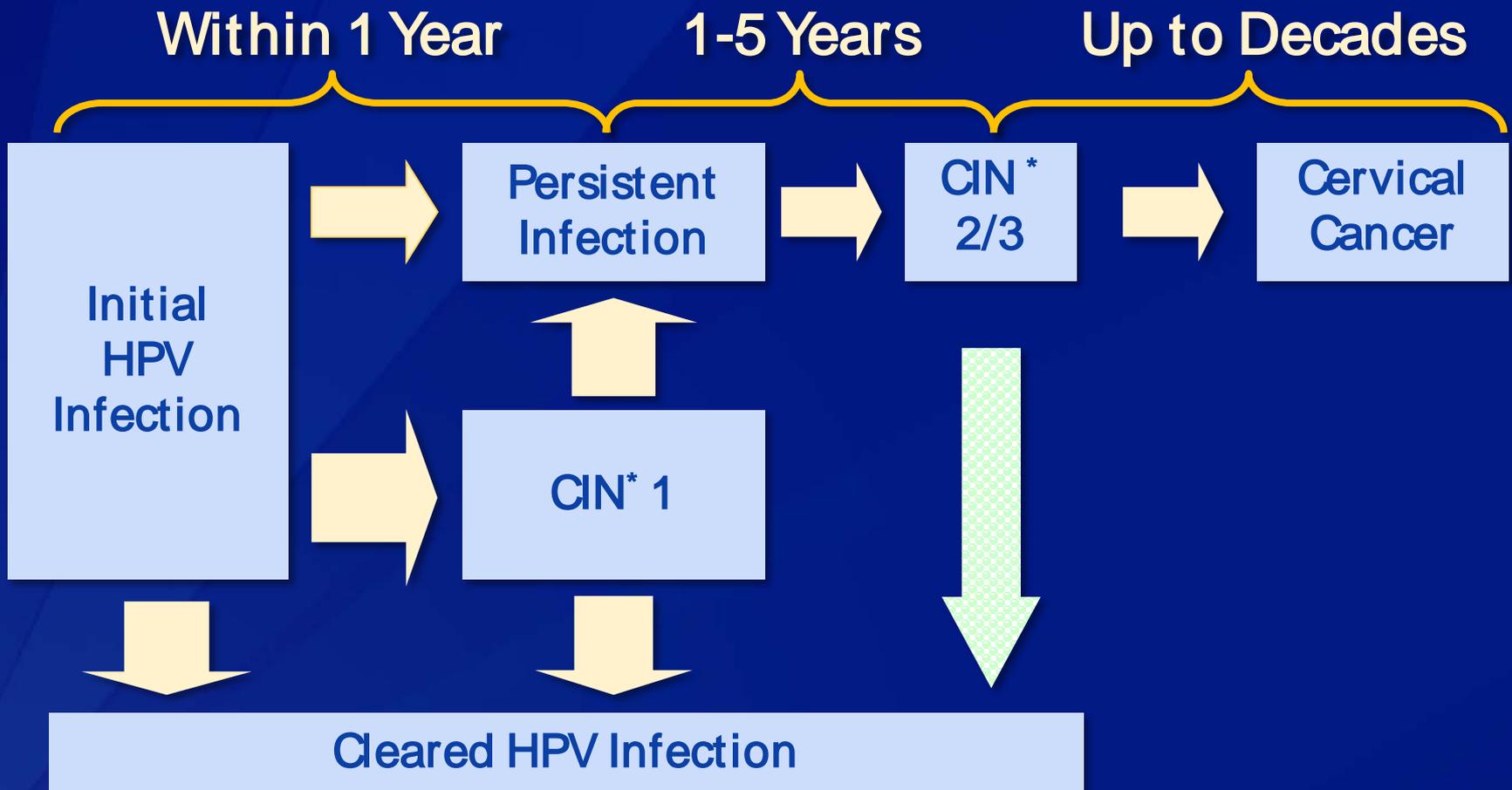
Human Papillomavirus (HPV) Disease

- ❑ 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



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).

Cancers Caused by HPV, U.S.

Cancer site	Average number of cancers per year probably caused by HPV [†]			Percentage per year
	Male	Female	Both Sexes	
Anus	1,400	2,600	4,000	91%
Cervix	0	10,400	10,400	91%
Oropharynx	7,200	1,800	9,000	72%
Penis	700	0	700	63%
Vagina	0	600	600	75%
Vulva	0	2,200	2,200	69%
TOTAL	9,300	17,600	26,900	

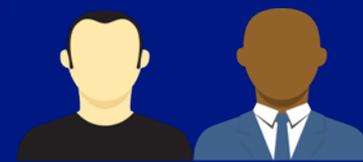
CDC, United States Cancer Statistics (USCS), 2006-2010

HPV-associated Disease

TYPE

WOMEN

MEN



16/18

70% of cervical cancers
60% of all anal/genital
cancers

70% of anal cancers

6/11

90% of genital warts
90% of RRP* lesions

90% of genital warts

90% of RRP lesions

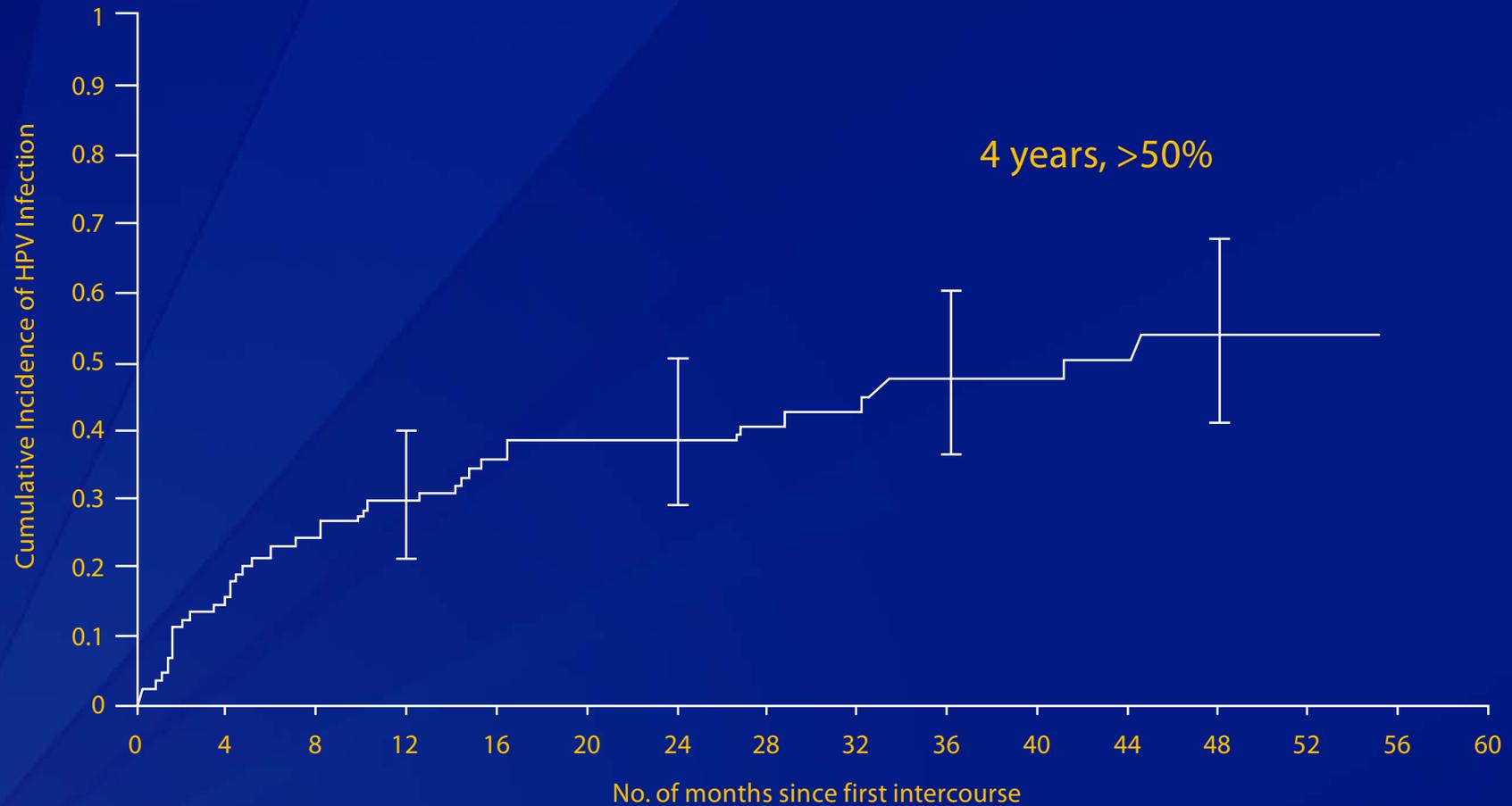
Transmission to women

* RRP = recurrent respiratory papillomatosis

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 2012.
- ❑ Screening should begin at age 21 years.
- ❑ Screen women 21 to 65 years of age with Pap test every 3 years.
- ❑ Co-testing (Pap and HPV testing) every 5 years in women 30 to 65 years of age.

Human Papillomavirus Vaccines

- ❑ 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 are noninfectious and nononcogenic.

Human Papillomavirus Vaccines

HPV Vaccines	Bivalent 2vHPV (Cervarix)	Quadrivalent 4vHPV (Gardasil)	9-Valent 9vHPV (Gardasil9)
L1 VLP Types	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Manufacturer	GSK	Merck	Merck
FDA Indications	Females (9-26 yrs): Cervical precancer and cancer	Females (9-26 yrs): Anal, cervical, vaginal, and vulvar precancer and cancer; genital warts	Females (9-26 yrs): Anal, cervical, vaginal, and vulvar precancer and cancer; genital warts
	Males Not approved for use in males	Males (9-26 yrs): Anal precancer and cancer; genital warts	Males (9-15 yrs): Anal precancer and cancer; genital warts

HPV Vaccine Efficacy

- ❑ High efficacy among females without evidence of infection with vaccine HPV types ($\geq 95\%$).
- ❑ 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 efficacy of the vaccine against other vaccine HPV types.

9vHPV (Gardasil 9)

- ❑ Licensed in the U.S. December 10, 2014.
 - Females 9-26 years, males 9-15 years.
 - Trials conducted with 3-dose schedule.
- ❑ Targets 5 additional high-risk types:
 - 6, 11, 16, 18, 31, 33, 45, 52, 58
- ❑ Males 16-26 yrs – not part of BLA submitted 2013.
 - SubBLA submitted to FDA.

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.

□ Non-inferior immunogenicity to 4vHPV.

□ Five additional types account for 11% of invasive cancers.

- Differences by gender: 14% for females; 5% for males.

□ 9vHPV can be administered at the same medical visit with MenACWY and Tdap.

□ Safety profile similar to 4vHPV across age, gender, race, ethnicity groups.

HPV 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.

Figure 1. Recommended immunization schedule for persons aged 0 through 18 years – United States, 2015.

(FOR THOSE WHO FALL BEHIND OR START LATE, SEE THE CATCH-UP SCHEDULE (FIGURE 2)).

These recommendations must be read with the footnotes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Figure 1. To determine minimum intervals between doses, see the catch-up schedule (Figure 2). School entry and adolescent vaccine age groups are shaded.

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	16–18 yrs
Hepatitis B ¹ (HepB)	1 st dose	← 2 nd dose →							← 3 rd dose →							
Rotavirus ² (RV) RV1 (2-dose series); RV5 (3-dose series)			1 st dose	2 nd dose	See footnote 2											
Diphtheria, tetanus, & acellular pertussis ³ (DTaP: <7 yrs)			1 st dose	2 nd dose	3 rd dose				← 4 th dose →			5 th dose				
Tetanus, diphtheria, & acellular pertussis ⁴ (Tdap: ≥7 yrs)														(Tdap)		
Haemophilus influenzae type b ⁵ (Hib)			1 st dose	2 nd dose	See footnote 5				← 3 rd or 4 th dose → See footnote 5							
Pneumococcal conjugate ⁶ (PCV13)			1 st dose	2 nd dose	3 rd dose				← 4 th dose →							
Pneumococcal polysaccharide ⁶ (PPSV23)																
Inactivated poliovirus ⁷ (IPV: <18 yrs)			1 st dose	2 nd dose					← 3 rd dose →			4 th dose				
Influenza ⁸ (IV; LAIV) 2 doses for some: See footnote 8							Annual vaccination (IV only) 1 or 2 doses				Annual vaccination (LAIV or IV) 1 or 2 doses			Annual vaccination (LAIV or IV) 1 dose only		
Measles, mumps, rubella ⁹ (MMR)						See footnote 9			← 1 st dose →			2 nd dose				
Varicella ¹⁰ (VAR)									← 1 st dose →			2 nd dose				
Hepatitis A ¹¹ (HepA)									← 2 nd dose →							
Human papillomavirus ¹² (HPV2: females only; HPV4: males and females)																(3-dose series)
Meningococcal ¹³ (Hib-MenCY ≥ 6 weeks; MenACWY-D ≥ 9 mos; MenACWY-CRM ≥ 2 mos)							See footnote 13							1 st dose		

Range of recommended ages for all children
Range of recommended ages for catch-up immunization
Range of recommended ages for certain high-risk groups
Range of recommended ages during which catch-up is encouraged and for certain high-risk groups
Not routinely recommended

This schedule includes recommendations in effect as of January 1, 2015. Any dose not administered at the recommended age should be administered at a subsequent visit, when indicated and feasible. The use of a combination vaccine generally is preferred over separate injections of its equivalent component vaccines. Vaccination providers should consult the relevant Advisory Committee on Immunization Practices (ACIP) statement for detailed recommendations, available online at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Clinically significant adverse events that follow vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) online (<http://www.vaers.hhs.gov>) or by telephone (800-822-7967). Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for vaccination, is available from CDC online (<http://www.cdc.gov/vaccines/recs/vac-admin/contraindications.htm>) or by telephone (800-CDC-INFO [800-232-4636]).

This schedule is approved by the Advisory Committee on Immunization Practices (<http://www.cdc.gov/vaccines/acip/>), the American Academy of Pediatrics (<http://www.aap.org>), the American Academy of Family Physicians (<http://www.aafp.org>), and the American College of Obstetricians and Gynecologists (<http://www.acog.org>).

NOTE: The above recommendations must be read along with the footnotes of this schedule.

Recommended Adult Immunization Schedule—United States - 2015

Note: These recommendations must be read with the footnotes that follow containing number of doses, intervals between doses, and other important information.

Figure 1. Recommended adult immunization schedule, by vaccine and age group¹

VACCINE ▼	AGE GROUP ►	19-21 years	22-26 years	27-49 years	50-59 years	60-64 years	≥ 65 years
Influenza ^{2,3}		1 dose annually					
Tetanus, diphtheria, pertussis (Td/Tdap) ^{3,4}		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs					
Measles ^{5,6}		2 doses					
Human papillomavirus (HPV) Female ^{5,7}		3 doses					
Human papillomavirus (HPV) Male ^{5,7}		3 doses					
Zoster ⁶						1 dose	
Measles, mumps, rubella (MMR) ^{7,8}		1 or 2 doses					
Pneumococcal 13-valent conjugate (PCV13) ^{8,9}		1-time dose					
Pneumococcal polysaccharide (PPSV23) ⁸		1 or 2 doses					1 dose
Meningococcal ⁹		1 or more doses					
Hepatitis A ¹⁰		2 doses					
Hepatitis B ¹¹		3 doses					
<i>Haemophilus influenzae</i> type b (Hib) ¹²		1 or 3 doses					

*Covered by the Vaccine Injury Compensation Program

 For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster

 Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indication)

 No recommendation

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 8:00 a.m. - 8:00 p.m. Eastern Time, Monday - Friday, excluding holidays.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), American College of Obstetricians and Gynecologists (ACOG) and American College of Nurse-Midwives (ACNM).

Figure 2. Vaccines that might be indicated for adults based on medical and other indications¹

VACCINE ▼	INDICATION ►	Pregnancy	Immuno-compromising conditions (excluding human immunodeficiency virus [HIV]) ^{4,6,7,8,11}		HIV infection CD4+ T lymphocyte count ^{4,6,7,8,11}		Men who have sex with men (MSM)	Kidney failure, end-stage renal disease, receipt of hemodialysis	Heart disease, chronic lung disease, chronic alcoholism	Asplenia (including elective splenectomy and persistent complement component deficiencies) ^{9,12}	Chronic liver disease	Diabetes	Healthcare personnel
			< 200 cells/ μ L	\geq 200 cells/ μ L	< 200 cells/ μ L	\geq 200 cells/ μ L							
Influenza ²			1 dose IIV annually				1 dose IIV or LAIV annually	1 dose IIV annually					1 dose IIV or LAIV annually
Tetanus, diphtheria, pertussis (Td/Tdap) ³		1 dose Tdap each pregnancy	Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs										
Varicella ⁴		Contraindicated				2 doses							
Human papillomavirus (HPV) Female ⁵		3 doses through age 26 yrs				3 doses through age 26 yrs							
Human papillomavirus (HPV) Male ⁵		3 doses through age 26 yrs				3 doses through age 21 yrs							
Zoster ⁶		Contraindicated				1 dose							
Measles, mumps, rubella (MMR) ⁷		Contraindicated				1 or 2 doses							
Pneumococcal 13-valent conjugate (PCV13) ⁸						1 dose							
Pneumococcal polysaccharide (PPSV23) ⁸						1 or 2 doses							
Meningococcal ⁹		1 or more doses											
Hepatitis A ¹⁰		2 doses											
Hepatitis B ¹¹		3 doses											
<i>Haemophilus influenzae</i> type b (Hib) ¹²		post-HSCT recipients only		1 or 3 doses									

¹Covered by the Vaccine Injury Compensation Program



For all persons in this category who meet the age requirements and who lack documentation of vaccination or have no evidence of previous infection; zoster vaccine recommended regardless of prior episode of zoster



Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)



No recommendation

Updated ACIP Recommendations

- ❑ Vaccinate males and females at 11-12 years.*
- ❑ Catch up those previously unvaccinated or missing doses:
 - Females age 13 through 26 years.
 - Males age 13 through 21 years.
 - High-risk males age 21 through 26 years.
 - Men who have sex with men and immunocompromised men (including HIV-infected persons).
- ❑ Use:
 - 2vHPV, 4vHPV, or 9vHPV for females.
 - 4vHPV or 9vHPV** for males.

*Vaccination series can be started at 9 years of age

** ACIP off-label recommendation MMWR2015;64:300-4

Updated ACIP Recommendations Administration

- ❑ **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 (24 weeks) after dose 1.
- ❑ **There is NO maximum interval between HPV vaccine doses.**
- ❑ **If the vaccination schedule is interrupted, the series does not need to be restarted.**

*ACIP off-label recommendation MMWR2015;64(29):300-4

HPV Vaccine Administration

- ❑ Administer at the same medical visit as other vaccines.
- ❑ IM injection.
- ❑ Pre-vaccination testing is not recommended:
 - Pap.
 - HPV.
 - Pregnancy.
- ❑ No therapeutic effect on HPV infection, genital warts, cervical lesions.

HPV Vaccine Interchangeability

- ❑ No data on schedules that include 2vHPV and 4vHPV and/or 9vHPV.
- ❑ Response to types 16 and 18 likely to be similar when 2vHPV, 4vHPV, or 9vHPV used in the same series.
- ❑ Protection against types other than 16 and 18 is probably reduced if fewer than 3 doses of 4vHPV or 9vHPV received.
- ❑ Use same vaccine for all 3 doses whenever possible.

Updated ACIP Recommendations Interchangeability*

- ❑ If immunization providers do not know or do not have available the HPV vaccine product previously administered or are in settings transitioning to 9vHPV for protection against HPV 16 and 18:
 - Females: Any HPV vaccine product may be used to continue or complete the series.
 - Males: 4vHPV or 9vHPV* may be used to continue or complete the series.

* ACIP off-label recommendation MMWR2015;64(29):300-4

9vHPV Vaccination for Persons who Completed other HPV Vaccination Series

- ❑ Manufacturer did not seek indication for 9vHPV vaccination in previously vaccinated persons.
- ❑ One study evaluated 9vHPV in prior 4vHPV vaccinees:
 - >98% of prior 4vHPV recipients seroconverted to 5 new types after 3 doses of 9vHPV.
 - Acceptable safety profile in these subjects.
 - Serologic geometric mean titers to 5 additional types were lower (25%-63%) in females who received prior 4vHPV compared to other study subjects.

Clinical Considerations

- ❑ The majority of all HPV-associated cancers that can be prevented by vaccination are due to HPV 16 and 18.
- ❑ The benefit of protection against the 5 additional types targeted by 9-valent HPV vaccination is mostly limited to females for prevention of cervical cancers and precancers.
- ❑ Available data show no serious safety concerns in persons who were vaccinated with 9-valent HPV vaccine after having received a 3-dose series of quadrivalent HPV vaccine.
- ❑ Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.

Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV vaccine <http://www.cdc.gov/vaccines/who/teens/downloads/9vHPV-guidance.pdf>

What is the cost effectiveness of 3 additional doses of 9-valent HPV vaccine for persons who already have received a complete 3-dose HPV vaccination series?

- The estimated cost per quality-females aged 13-18 years who
- The potential benefit would be males of any age.
- In contrast, models have estim: saving, compared with routine

References

1. Food and Drug Administration. 9-valent vaccine, recombinant [Drug Administration]; 2014. Available at: <https://www.fda.gov/oc/ohrt/ucm42645>
2. Joura EA, Giuliano AR, Iversen C, et al. NEJM 2015;372:711-20.
3. Van Damme P, Olsson S, Block S. 2015;136:e28-39.
4. Vesikari T, Brodzski N, van Dam and safety of a 9-valent human old girls. *Pediatr Infect Dis J* 2011;50:100-105.
5. Markowitz LE, Dunne EF, Saraiya Committee on Immunization P.
6. Petrosky E, Bocchini J, Hairei S, et al. *Vaccination Recommendations*

- Otherwise, the safety profiles of 9-valent vaccine given to HPV vaccine naïve persons and 9-valent vaccine given to persons who had previously completed a 3-dose series were generally similar.

Information for persons who previously co

Is additional vaccination with 9-valent HPV vaccine rec series of either quadrivalent or bivalent HPV vaccine?

- There is no ACIP recommendation for routine additional completed a quadrivalent or bivalent vaccination series

If a person desires protection against the 5 additional t completed a 3-dose series of quadrivalent HPV vaccine

- The majority of all HPV-associated cancers that can be p are the HPV types prevented by all three vaccines: bival
- The benefit of protection against the 5 additional types limited to females for prevention of cervical cancers and HPV-associated cancers in males is due to the 5 addition
- Available data show no serious safety concerns in perso having completed a 3-dose quadrivalent HPV vaccinac
- Cervical cancer screening is recommended beginning a both vaccinated and unvaccinated women.

What data are available on efficacy and immunogeni after a complete 3-dose series of another HPV vaccine j

- In an immunogenicity and safety clinical trial, 3 doses of given to females who had completed a 3-dose quadriva vaccine was administered 12 to 36 months after comple
 - After 3 doses, over 98% of vaccinees developed antib measured after the first dose of 9-valent HPV vaccine; antibody against all 5 additional types. Antibody tite dose. Antibody was not measured after the second d
 - In a cross study comparison, geometric antibody titer 3 doses of 9-valent HPV vaccine after 3 doses of quad who received 3 doses of 9-valent HPV vaccine witho antibody titers is not known because there is no imm
- An immunogenicity trial of 2 doses of 9-valent HPV vacc be available within a year. In this trial, the 2 doses are se
 - Results from this trial will not directly address additio quadrivalent HPV vaccine.

What data are available on the safety of 9-valent HPV v 3-dose series of another HPV vaccine product?

- In a randomized trial, 9-valent HPV vaccine was compar previously received 3 doses of quadrivalent HPV vaccin there was an acceptable safety profile.
- Compared to persons in other studies who were vacci any HPV vaccination, those who received 9-valent HPV v higher rates of injection site swelling and redness.
- Otherwise, the safety profiles of 9-valent vaccine given 1 to persons who had previously completed a 3-dose seri

If a 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 the 3-dose series?

- The current recommended HPV vaccination schedule is for the second dose to be given 1-2 months after the first dose and the third dose 4 months after the second; maximum intervals between HPV doses.
- Antibody titers have not been found to be diminished a from a few studies of bivalent and quadrivalent HPV vac doses were administered at an interval of 6 months com is evaluating 2 doses of 9-valent HPV vaccine in 9-14 ye

If a person desires protection against the 5 additional t started a series with another HPV vaccine product, wh

- The majority of all HPV-associated cancers that can be p are the HPV types prevented by all three vaccines: bival
- The benefit of protection against the 5 additional types to females for prevention of cervical cancers and precan associated cancers in males is due to the 5 additional ty
- Available data show no serious safety concerns in perso having received a 3-dose series of quadrivalent HPV vac
- Cervical cancer screening is recommended beginning a both vaccinated and unvaccinated women.

What data are available on the number of doses of 9-v 5 additional types for a series started with quadrivalen vaccine?

- There are no data on efficacy or immunogenicity of 1, 2 have received 1 or 2 doses of quadrivalent HPV vaccine.
- In an immunogenicity and safety clinical trial, 3 doses of given to females who had completed a 3-dose quadriva vaccine was administered 12 to 36 months after comple
 - After 3 doses, over 98% of vaccinees developed antib measured after the first dose of 9-valent HPV vaccine; antibody against all 5 additional types. Antibody tite dose. Antibody was not measured after the second d
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- An immunogenicity trial of 2 doses of 9-valent HPV vacc ongoing; results are expected to be available within a yr 6 or 12 months.
 - Results from this trial will not directly address additio quadrivalent HPV vaccine.

What data are available on the safety of 9-valent HPV v vaccine product?

- In a randomized trial, 9-valent HPV vaccine was compar previously received 3 doses of quadrivalent HPV vaccin vaccine, there was an acceptable safety profile.
- Compared to persons in other studies who were vacci any HPV vaccination, those who received 9-valent HPV v higher rates of injection site swelling and redness.

Supplemental information and guidance for vaccination providers regarding use of 9-valent HPV vaccine

A 9-valent human papillomavirus (HPV) vaccine (Gardasil 9, Merck & Co., Inc) was licensed for use in females and males in the United States in December 2014.^{1,2,3,4} 9-valent HPV vaccine is the third HPV vaccine licensed by the Food and Drug Administration (FDA); the other vaccines are bivalent HPV vaccine, licensed for use in females, and quadrivalent HPV vaccine, licensed for use in females and males.⁵ In February 2015, the Advisory Committee on Immunization Practices (ACIP) recommended 9-valent HPV vaccine as one of 3 HPV vaccines that can be used for routine vaccination of females and one of 2 HPV vaccines for routine vaccination of males. A Policy Note was published in the MMWR in March 2015.⁶ The information below summarizes some of the recommendations included in the Policy Note and provides additional guidance for issues that were not addressed in the Policy Note but are likely to arise during the transition from quadrivalent HPV vaccine to 9-valent HPV vaccine.

Information about the vaccines

What are some of the similarities and differences in the characteristics of the three licensed HPV vaccines?

- Each of the three currently licensed HPV vaccines is a noninfectious, virus-like particle (VLP) vaccine.
- Bivalent, quadrivalent and 9-valent HPV vaccines each target HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-associated cancers in both women and men in the United States. 9-valent HPV vaccine also targets five additional cancer causing types (HPV 31, 33, 45, 52, 58) which account for about 15% of cervical cancers. Quadrivalent and 9-valent HPV vaccines also protect against HPV 6 and 11, types that cause anogenital warts.
- Quadrivalent and 9-valent HPV vaccines are licensed for use in females and males; bivalent HPV vaccine is licensed for use in females.

What percent of HPV-associated cancers in females and males are caused by the 5 additional types in the 9-valent HPV vaccine?

- About 14% of HPV-associated cancers in females (approximately 2800 cases annually) and 4% of HPV-associated cancers in males (approximately 550 cases annually) are caused by the 5 additional types in the 9-valent HPV vaccine.

Information for persons who started an HPV vaccination series with quadrivalent or bivalent HPV vaccine

If a series was started with quadrivalent HPV vaccine or bivalent HPV vaccine, can it be completed with 9-valent HPV vaccine?

- Yes, ACIP recommendations state that 9-valent HPV vaccine may be used to continue or complete a series started with a different HPV vaccine product.

Are additional 9-valent HPV vaccine doses recommended for a person who started a series with quadrivalent or bivalent HPV vaccine and completed the series with one or two doses of 9-valent HPV vaccine?

- There is no ACIP recommendation for additional 9-valent HPV vaccine doses for persons who started the series with quadrivalent or bivalent HPV vaccine and completed the series with 9-valent HPV vaccine.



HPV Vaccine Special Situations

- ❑ Administer vaccine to:
 - Females who:
 - Have equivocal or abnormal Pap test.
 - Have positive HPV DNA test.
 - Are breastfeeding.
 - Males and females who:
 - Have genital warts.
 - Are immunosuppressed.

HPV Vaccine

Contraindications and Precautions

❑ Contraindication

- Severe allergic reaction to a vaccine component or following a prior dose.
 - HPV2 prefilled syringe contains latex.

❑ Precaution

- Moderate or severe acute illnesses (defer until symptoms improve).

HPV Vaccination during 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 vaccination 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 closed.
 - Telephone numbers are in the package inserts.

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

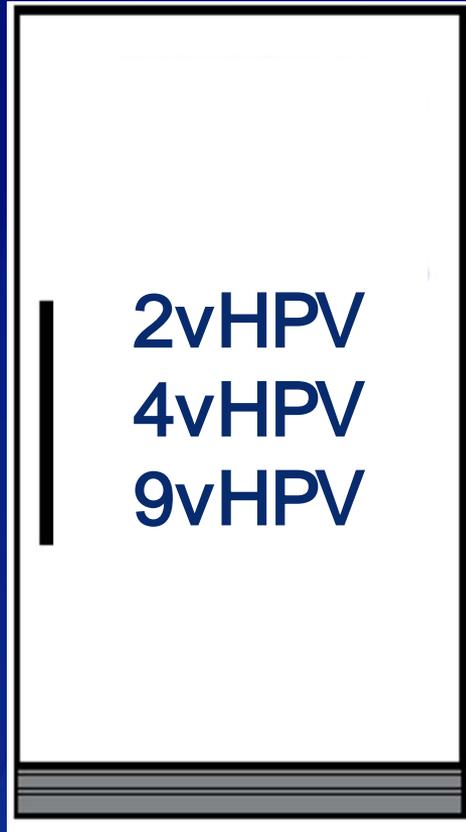
Syncope Following Vaccination

- ❑ 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 11-18 years.
- ❑ Serious injuries have resulted.
- ❑ ACIP recommends providers strongly consider observing patients for 15 minutes after they are vaccinated.

Human Papillomavirus Vaccine Safety Summary

- ❑ Only local reactions occur more frequently among vaccine recipients than among placebo recipients.
- ❑ Serious adverse reactions have been reported following HPV vaccine.
 - Most do not appear to have been caused by the vaccine (i.e., the reactions are coincidental to vaccination).
- ❑ Syncope precautions should be observed when vaccinating adolescents and young adults.
- ❑ Monitoring and evaluation of reports will continue.

Storage and Handling



- ❑ Store between in the refrigerator between 35° – 46°F (2° – 8° C).
- ❑ Protect from light.

HPV Immunization Rates

Females 13-17 Years of Age, 2014

HPV Vaccine	U.S.	
	Females	Males
1 or more doses*	60%	41.7%
3-dose series completion**	69.3%	57.8%

*Percentages \geq human papillomavirus vaccine, either HPV4 or HPV2

**Percentage who received 3 or more HPV doses, either HPV4 or HPV2

*MMWR*2015;64 (No.29):784-92

Why HPV Vaccine Coverage Matters

- ❑ Currently, there are 26 million girls under 13 years of age in the United States.
- ❑ If none are vaccinated, 168,400 will develop cervical cancer and 54,100 will die from it.

Why HPV Vaccine Coverage Matters

- ❑ Continuing 30% coverage among 12-year-old girls would prevent 45,500 of these cases and 14,600 deaths.
- ❑ Vaccinating 80% would prevent 98,800 cases and 31,700 deaths.
- ❑ For each year we stay at 30% coverage instead of achieving 80%, 4,400 future cervical cancer cases and 1,400 cervical cancer deaths will occur.

HPV Vaccine Communications During the Healthcare Encounter

- ❑ HPV vaccine is often presented as optional, whereas other adolescent vaccines are recommended.
- ❑ Some 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 teen is not at risk for HPV and vaccination can be delayed until older.

Goff S, et al. *Vaccine* 2011;10:7343-9

Hughes C, et al. *BMC Pediatrics* 2011;11:74

Strategies for Increasing HPV Vaccination Rates 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.
 - Immunize at every opportunity.
 - Use standing orders.
- ❑ **Reminder and recall.**
- ❑ **Tools for improving uptake of HPV at www.cdc.gov/vaccines/teens**

HPV Vaccination Resources for HCP

CDC Home
 Centers for Disease Control and Prevention
 CDC 24/7: Saving Lives. Protecting People.™

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Preteen and Teen Vaccines

Vaccines Home
Vaccines & **I**mmunizations

Vaccines Home > Specific Groups > Preteen and Teen Home > For HCPs

HPV Vaccine Resources for Healthcare Professionals


HPV YOU ARE THE KEY TO CANCER PREVENTION

Contact Us:

- Centers for Disease Control and Prevention
 1600 Clifton Rd
 Atlanta, GA 30333
- 800-CDC-INFO
 (800-232-4636)
 TTY: (888) 232-6348
[Contact CDC-INFO](#)

HPV Vaccine is Cancer Prevention

Overview | Tools for Your Practice | Handouts to Give to Patients & Parents

- HPV is so common that almost everyone will be infected with HPV at some point in their lives; however most people will never know they have been infected.
- HPV exposure can occur with any type of intimate sexual contact.
- In the U.S., HPV causes about 17,000 cancers in women, and about 9,000 cancers in men each year.

Low HPV vaccination rates are leaving another generation of

Resource Spotlight




Tips and Time-savers for Talking with Parents about HPV Vaccine



Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. For example, you can say "Your child needs these shots today," and name all of the vaccines recommended for the child's age. Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents' questions helps you save time and give an effective response. CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver.

- CDC RESEARCH SHOWS:** The "HPV vaccine is cancer prevention" message resonates strongly with parents. In addition, studies show that a strong recommendation from you is the single best predictor of vaccination.
- TRY SAYING:** HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That's why I'm recommending that your daughter/son receive the first dose of HPV vaccine today.
- CDC RESEARCH SHOWS:** Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against.
- TRY SAYING:** HPV can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men. There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine. There are also many more precancerous conditions requiring treatment that can have lasting effects.
- CDC RESEARCH SHOWS:** Parents want a concrete reason to understand the recommendation that 11–12 year olds receive HPV vaccine.
- TRY SAYING:** We're vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity. We vaccinate people well before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children well before they get exposed to HPV.
- CDC RESEARCH SHOWS:** Parents may be concerned that vaccinating may be perceived by the child as permission to have sex.
- TRY SAYING:** Research has shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.
- CDC RESEARCH SHOWS:** Parents might believe their child won't be exposed to HPV because they aren't sexually active or may not be for a long time.
- TRY SAYING:** HPV is so common that almost everyone will be infected at some point. It is estimated that 79 million Americans are currently infected with 14 million new HPV infections each year. Most people infected will never know. So even if your son/daughter waits until marriage to have sex, or only has one partner in the future, he/she could still be exposed if their partner has been exposed.
- CDC RESEARCH SHOWS:** Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision.
- TRY SAYING:** I strongly believe in the importance of this cancer-preventing vaccine, and I have given HPV vaccine to my son/daughter/grandchild/niece/nephew/friend's children. Experts (like the American Academy of Pediatrics, cancer doctors, and the CDC) also agree that this vaccine is very important for your child.
- CDC RESEARCH SHOWS:** Understanding that the side effects are minor and emphasizing the extensive research that vaccines must undergo can help parents feel reassured.
- TRY SAYING:** HPV vaccine has been carefully studied by medical and scientific experts. HPV vaccine has been shown to be very effective and very safe. Like other shots, most side effects are mild, primarily pain or redness in the arm. This should go away quickly, and HPV vaccine has not been associated with any long-term side effects. Since 2006, about 57 million doses of HPV vaccine have been distributed in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.
- CDC RESEARCH SHOWS:** Parents want to know that HPV vaccine is effective.
- TRY SAYING:** In clinical trials of boys and girls, the vaccine was shown to be extremely effective. In addition, studies in the U.S. and other countries that have introduced HPV vaccine have shown a significant reduction in infections caused by the HPV types targeted by the vaccine.
- CDC RESEARCH SHOWS:** Many parents do not know that the full vaccine series requires 3 shots. Your reminder will help them to complete the series.
- TRY SAYING:** I want to make sure that your son/daughter receives all 3 shots of HPV vaccine to give them the best possible protection from cancer caused by HPV. Please make sure to make appointments on the way out, and put those appointments on your calendar before you leave the office today!



U.S. Department of Health and Human Services
 Centers for Disease Control and Prevention



www.cdc.gov/vaccines/teens | PreteenVaccines@cdc.gov

www.cdc.gov/vaccines/YouAreTheKey

HPV Resources

- ❑ ACIP HPV Recommendations web page

www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hpv.html

- ❑ CDC HPV Infection web page

www.cdc.gov/hpv/

- ❑ CDC HPV Vaccination web page

www.cdc.gov/vaccines/vpd-vac/hpv/default.htm

- ❑ Immunization Action Coalition HPV web page

www.immunize.org/hpv/

- ❑ Children's Hospital of Philadelphia Vaccine Education Center HPV web page

www.chop.edu/service/vaccine-education-center/a-look-at-each-vaccine/hpv-vaccine.html

Required PHS Act Statement

- ❑ Correct and consistent condom use may have a protective effect on HPV acquisition, reduce the risk for HPV-associated diseases, and mitigate the adverse consequences of infection with HPV.

This statement is required by section 317 of the Public Health Service Act, 42 U.S.C., 243.