

Final Report

National HPV Vaccination Roundtable
Pharmacy-Located HPV Vaccination Pilot Project

University of Iowa, University of Kentucky,
Oregon Health & Science University in collaboration with the
Northwest Portland Area Indian Health Board

ACS Contract #32608 CFDA #93.733

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Introduction

Human papillomavirus (HPV) is the most common sexually transmitted infection, with 14 million infections in women and men in the United States (U.S.) annually.[1] HPV is responsible for approximately 30,700 cases of cancer each year, including virtually all cases of cervical cancer.[2] The HPV vaccine is recommended for adolescents beginning at 11 years of age, and consists of two doses administered over a course of six to twelve months, or three doses for those ages 15 and over.[3] In 2015, in the U.S., adolescent females were vaccinated against HPV with one dose at a rate of 62.8%, and adolescent boys at 49.8% showing HPV vaccination rates are well below the *Healthy People 2020* national goal of 80%.[4]

A common interest in the improvement of HPV immunization rates through the use of community-clinical linkages and alternative settings prompted a group of investigators from the Centers for Disease Control and Prevention (CDC)-funded Cancer Prevention Control Research Network (CPCRN)[5] to apply for the Pharmacy-located HPV Vaccination Pilot Project award. The investigators developed a common protocol, outlined below, for pharmacies to partner with local health care clinics to implement coordinated delivery of the three-dose HPV vaccine series in order to improve vaccine initiation and completion rates.

- Health clinic identifies patients ages 11-18 years in need of HPV vaccination
- Health clinic delivers first dose of HPV vaccine series, and transmits prescription orders for doses 2 and 3 to the partnering pharmacy
- Pharmacy schedules doses 2 and 3 (at 2 months and 6 months, respectively)
  - After three failed attempts to contact, notify health clinic of non-response
- Pharmacy documents the patient's receipt of HPV vaccination and gives record of immunization to the patient's healthcare provider via fax or electronic method. Pharmacy records the vaccination in the state immunization registry information system
- Pharmacy maintains patient log to track each vaccination. Data collected includes: date, name, gender, age, race/ethnicity, county of residence, insurance status, HPV dose number, patient reaction (if any), and pharmacist initials
- Pharmacy provides redacted data log to investigators
- Investigators collect evaluation feedback for final report

The above protocol was tailored as necessary by investigators at their respective institutions of the University of Iowa, University of Kentucky, and Oregon Health & Science University in collaboration with the Northwest Portland Area Indian Health Board (NPAIHB).

The purpose of this project was to document the front-line experiences during the implementation of the planned pharmacy-clinic linkage protocol. This report describes the experiences across three states with diverse populations, settings, and partnerships. Our participation in this important initiative provides valuable information for continued efforts to achieve national goals for initiation and completion of the HPV vaccination series.

Methods

The planned steps of recruitment, training, implementation, and evaluation are outlined below.

- Investigators approach pharmacist for recruitment
- Interested pharmacist provides contact information for a clinician or clinic they wish to partner with for HPV vaccine delivery
- Investigators contact clinician/clinic for recruitment
- Investigators schedule in-person training session for pharmacy-clinic partners
- Training session
  - Explanation of general project protocol, distribution of project binders
  - Distribution of publicly available HPV educational materials for providers, parents, adolescents, and young adults
  - Discussion and clarification of roles and responsibilities
  - Identify additional need for assistance from investigators
    - Enrollment in state Vaccines For Children (VFC) program
    - Additional HPV educational materials
    - Updating/testing compatibility of electronic medical record systems
- Investigators supervise project implementation, provide assistance as needed
- Pharmacists provide investigators with redacted data of HPV vaccine doses administered
- Number of patients and frequency of HPV vaccinations administered at pharmacies calculated from pharmacy data

Implementation

Collaboration of investigators across states with varying demographics provided learning experiences during project implementation. Activities completed at each of the three sites during the contract period are summarized as follows.

Iowa

- IRB determined not human subjects research in February
- Finalized collaborative protocol, gathered existing educational materials on HPV for training binder
- Initiated contact with four pharmacists with previous collaborations with investigators
  - Towncrest Pharmacy, locally owned in Iowa City joined project in April
  - Osterhaus Pharmacy, locally owned in Maquoketa joined project in May
  - Two pharmacies declined due to time constraint, not enough staff, lack of interest from pharmacists and potential clinic partners
- Pharmacists provided contact information for proposed partnering clinic
  - Investigators contacted suggested partners via email
- Southeast Iowa City Clinic partnered with Towncrest Pharmacy (Team 1) in May
  - Family practice clinic run by the University of Iowa Hospitals and Clinics
- Training/teambuilding session conducted with Team 1 in June
  - Team was given training binder, CDC posters for display in English and Spanish
  - Proposed start date August 1, started September 1
- Medical Association of Maquoketa PC partnered with Osterhaus in June (Team 2)
  - Family practice clinic – town population of 6,000

- Training/teambuilding session conducted with Team 2 in late June
  - Team was given training binder, CDC posters for display in English and Spanish
  - Proposed start date August 15, started September 15
- Status update from Osterhaus Pharmacy: 1 patient, unable to bill commercial insurance for vaccine
- Towncrest Pharmacy requested text reminder system in August
  - Created "Oh, don't forget account" in September, for $0.02/text
  - Use preferred method stated by guardian for reminders: phone, text or email
- Merck Scientific Department provided Towncrest with education and training materials
  - Pharmacists conducted training for staff in August
- Status update from Towncrest Pharmacy
  - Received prescriptions for 17 patients
    - 7 patients scheduled for 2nd dose
    - 4 patients to be scheduled for 2nd dose
    - 4 patients scheduled for 3rd dose
    - 2 patients have completed the series

Kentucky

- Initial meeting with Total Care Pharmacy staff in January
- IRB determined not human subjects research in February
- TCP pharmacists' HPV vaccination continuing education (CE) training in March
- TCP declined to participate in state Vaccines for Children (VFC) program due to time constraints / programmatic requirements in May
- District health department signed on as medical provider for the HPV vaccine protocol at TCP in June
- UK College of Pharmacy collaborator delivered HPV vaccination CE presentation at annual state pharmacy association meeting in June (25 pharmacists, 11 PharmD students)
- Funding processed and received at University of Kentucky accounting in July

Activities Completed July-September

- Printed, stamped, and delivered 430+ letters regarding the project and the Immunization Action Council (IAC) FAQ flyer for parents and young adults to TCP for mailing to local customers
- Printed and delivered CDC posters to TCP
- Scheduled 30-second radio ads through three local stations (WIVY, WQHY, and WMKY) for a total of 237 ads running August-October
- Recorded 1-minute news segment for WQHY
  - Featured on air, station website and Facebook page. Link to news segment: http://q95fm.net/2016/08/national-immunization-month-robin-vanderpool-discusses-hpv-vaccination/
- Collaborated with public school system to advertise pilot project at back-to-school event
  - Attended by approximately 100 families
- Printed bi-weekly 8" ads in *The Morehead News*, a local newspaper (designed by staff at UK Markey Cancer Center)
- Additional advertisement in local community magazine and digital advertising screens located throughout Morehead
- Connected with Student Health Services at Morehead State University

  - Printed and delivered 8 HPV posters (from CDC) for the health services office and 50 flyers for students (IAC FAQ for adolescents)
- Dr. Robin Vanderpool presented an overview of HPV vaccination at regional immunization conference in September (Northeast KY Area Health Education Center)
- 3 HPV vaccine doses delivered
  - Additional 3 turned away due to insurance not paying in the pharmacy setting

Oregon

- Initial meeting with the Northwest Portland Area Indian Health Board (NPAIHB) immunization coordinator, cancer prevention coordinator and clinical application coordinator/pharmacist in February
  - Compiled list of the six tribes that have pharmacies in Oregon
- Completed budget and narrative for University of Iowa in February
- Complications with funding delayed receipt at NPAIHB
  - Iowa funding receipt delayed due to complications with legal language, unable to distribute funds to OR and KY according to timeline
  - NPAIHB legal language: initially hesitant to accept funding because contract does not allow use for indirect cost, vaccine payment
- IRB submission delayed: IRB requires award funding before allowing submission

Activities completed April-September

- Scheduled meetings with tribes to discuss project participation. Printed and delivered CDC posters about HPV for display in clinics and pharmacies
  - Tribe 1: Pharmacist was not interested, although one nurse was interested in increasing male immunizations for tribal members
  - Tribe 2: previous collaborating pharmacist was out with injury, moved to another clinic after recovery. Clinical director didn't want to take this on right now, suggested later date when pharmacy is more settled
  - Tribe 3: recent turnover; requested August meeting but then cancelled because medical director and PHN absent. Feel their issue with HPV vaccination is provider-related, want to schedule provider training for later in the fall
  - Tribe 4: focus on women's health. New pharmacist, only wanted information at the time but seemed open to later involvement
  - Tribe 5: pharmacist too busy doing other projects: DPP and tobacco cessation
  - Tribe 6: health committee expressed interest, requested HPV educational materials. Most interested in doing "media blitz" to improve raise vaccine awareness, but future partnership seemed promising

Challenges

Limited time proved to be the most significant challenge encountered during the pilot project, caused by the short contract period and a delay in funding disbursement. Delayed receipt of funding impeded the ability of investigators to commence the project activities as originally projected. Additional challenges included site recruitment, concerns from clinicians over potential revenue loss, and vaccine payment at pharmacies. The team efficiently developed protocols and gathered existing educational resources at the beginning of the grant period in February, although encountered some difficulty upon initiation of recruitment of local pharmacy-clinic partnerships. NPAIHB in particular felt a disproportionate amount of their time was spent attempting to generate interest and locate viable partners in the community.

Iowa successfully recruited two pharmacy-clinic teams who both have previous experience in collaborative public health initiatives and familiarity with the University of Iowa. The Iowa team encountered some reluctance from one clinic due to concerns about clinic revenue loss caused by transference of vaccine series completion to pharmacies. This concern was expressed by a physician, but was alleviated when the clinic manager said they would like to participate in the pilot project. The clinical team was appreciative of the availability of English and Spanish versions of CDC materials about HPV, but were disappointed they could not accommodate the increasing number of patients who speak French and Swahili. Although the CDC materials were not available in these languages, Vaccine Information Statements from the IAC written in French and Swahili were provided upon vaccination. In working with the second pharmacy-clinic team in Iowa, the main challenge encountered by investigators was their location in a rural town with a population of 6,000, resulting in a smaller pool of eligible adolescents available for participation.

The participating pharmacy in Kentucky was not enrolled in VFC, and was deterred from doing so by the perceived amount of time and effort required to do so. Securing a clinical partner was also difficult despite several personal introductions being provided by a key physician stakeholder in the community. However, the regional health department was extremely helpful in facilitating the pharmacy vaccination protocol. Again, recruitment proved difficult, due to factors including lack of pharmacist time, the possible perception of HPV vaccination as a low priority by pharmacists, and the routine experience of high turnover in some pharmacies, particularly pharmacy interns from the university.

In Oregon, the process was generally slowed by the involvement of additional stakeholders and requirements for IRB submission. The NPAIHB consists of 45 tribal representatives from Northwest tribes, and their decisions are driven by perceived potential benefit directly to tribes by any proposed project. Funding is required to be in place before an IRB is submitted, further slowing project progress. Finally, the availability of potential partners was small, with a total of six pharmacies. All pharmacies share their location with a partnering clinic, so the refusal of one party left the investigators with no alternatives to pursue.

Lessons Learned

During the course of the pilot project, the investigators learned valuable lessons that will inform and guide the future implementation of similar initiatives.

Pharmacists were the first group approached by investigators during the recruitment process, and proved to be knowledgeable and well-equipped to identity collaborative opportunities in their communities. Those who participated in the pilot project and were strongly committed had existing relationships with the recruiting team member. Iowa partnered with two independent locally owned pharmacies, and Kentucky partnered with a pharmacy belonging to a local chain with six locations. The familiarity and engagement of local pharmacists within their respective communities, along with relatively small staff sizes, proved beneficial to investigators during the recruitment and training process.

The existence of relationships between pharmacists and clinicians proved beneficial in varying degrees when securing commitment for participation. While the two clinicians suggested by Iowa pharmacists accepted immediately, the Kentucky team found that provider groups declined initial outreach efforts, despite having a personal introduction by a colleague. In future interactions with successful and sustainable partnerships, it would be useful to examine in more detail the establishment of mutual benefit and the facilitators and barriers of buy-in from individuals and organizations.

In the process of developing a protocol and gathering materials for use in team trainings, the investigators easily found helpful educational materials about HPV vaccination for a range of target populations, including practitioners, parents, young adults, and adolescents. The investigators also utilized posters and flyers available on the CDC website for commercial printing for display at clinics and pharmacies. As mentioned above, one improvement that could be made to the available educational and promotional materials focused on HPV vaccination would be an increased availability of versions in various languages.

The importance of community engagement was increasingly apparent in the effort to increase project awareness and promote vaccination. The Kentucky site instigated an impressive array of advertisements delivered through diverse modalities including radio, newspapers, digital advertisement, and social networking sites. Observations of positive initial reactions of those introduced to the pilot project support a need for expansion of advertising across all research sites. In Iowa, multiple parents and guardians were surprised to learn of the existence of the partnership and remarked on its convenience. Additional advertising would increase community awareness and feasibly improve HPV immunization rates through increased consumer demand. It is also helpful to consider strategic placement to effectively reach the target audience of parents and adolescents, such as the back-to-school event in Kentucky attended by approximately 100 families.

Finally, the investigators agree that multi-site collaboration is feasible and promising. The opportunity to implement the general protocol of a pilot project at multiple sites with varying demographics in different states greatly increased the team's ability to understand and adapt to the various situations and contexts such a project can encounter.

Discussion

The closing of the contract period led to the contemplation of several key questions, listed below with answers compiled from the project teams in the three states.

If you had the project to do over again, what would you do the same? What would you do differently?

If we were starting the project over now, we would conduct activities in much the same way; however, we wish there had been more time to implement the project. A more efficient process of funding receipt and disbursement at the University of Iowa would improve our ability to complete IRB submissions and begin work in the field faster. Although constrained by the ACS vendor contract, we wish there had been more opportunity to conduct formative interviews with the pharmacists, area healthcare providers, and community members.

We did a nice job with advertisements and raising community awareness, particularly at the Kentucky site, and we would expand these efforts at all sites. Increased public knowledge about HPV and greater demand for the vaccine would support our efforts to recruit pharmacy-clinic teams for participation.

If you had another 18 months, what would you put in place now?

If granted additional time, we would continue and expand our efforts, focusing on a more extensive outreach in all states for team recruitment, increasing advertising and presence at community events, and pursuing promising opportunities presented during the pilot project. In Oregon, for example, the lead investigator received a reference from a pharmacist for a tribal immunization coordinator who was interested in increasing HPV vaccination in boys. Additionally, we would pursue possible expansion of the pilot project, for instance to the five additional pharmacy chain sites located in Kentucky. Finally, we would increase advertising and focus on targeting adolescents and their parents through the public school system and other youth organizations to increase community awareness and demand.

Based on your experience in different states, what state-specific activities would you suggest that the 'state' task group should focus on?

In Iowa, we were glad to learn that a previously problematic inability of electronic health record (EHR) systems to communicate and populate the state immunization registry was recently resolved. This remedy meant clinicians no longer have to enter information on every patient twice, and ensured that the pharmacists, who only have access to the immunization registry, are guaranteed to view up-to-date information. An area that remains for improvement is the lack of agreement between insurance companies about the responsibility of payment for vaccines administered in alternative settings. The implementation of a statewide policy improving ease of pharmacy payment would greatly enhance the ability of our teams to deliver the vaccine, and the ability of investigators to recruit additional teams for the coordinated model of vaccine delivery.

In Kentucky, we found that pharmacy enrollment in VFC was a difficult process. Pharmacists perceived that time and effort required was excessive, and decided to forgo enrollment, thus impeding their ability to offer the vaccine to a critical segment of the population. It should be noted that even if the pharmacy had participated in the VFC program, additional Medicaid policy changes are needed to waive the vaccine administration fee.

In Oregon, the implementation of the project was dependent on additional factors not encountered in the other states. The NPAIHB is made up of 45 tribal representatives from Northwest tribes across three states, and their decisions are driven by their perception of whether any project presents specific benefit to tribal communities. Although the leadership of the board provides important general guidance, the clinics we visited were often facing unique problems, and it would be helpful to find ways of improving the program's ability to focus more on the issues faced by individual clinics.

If the target audience is >15 years old, how would you structure the program?

If the target population was over 15 years of age, we would conduct the program in the same way with any necessary adjustments to promotional messaging based on vaccine requirements for the differing age groups. The program could focus its community awareness efforts more on events such as back-to-school activities and physicals.

Are there other partners you wish you'd had helping with the project?

The foundation of our partnerships with pharmacies, clinics, local health departments, and public school systems was promising, and all would benefit from additional pilot project length. We would have liked to focus more on public school system involvement and building sufficient community healthcare provider buy-in. Conversations with payers about reimbursing pharmacies for delivering HPV vaccines also would be useful.

Conclusion

The coordinated delivery of the HPV vaccine using clinic-pharmacy partnerships is a promising model for the improvement of immunization rates through the use of alternative settings. Preliminary public reactions were positive, praising the convenience presented by longer business hours and the walk-in availability of HPV vaccinations in pharmacies.

Pharmacists were eager and competent vaccine providers, with the largest barrier encountered during the payment process. The Kentucky pharmacy declined to enroll in VFC due to lack of time, and all participating pharmacists encountered refusal from insurance policies to cover immunization in the alternative setting of pharmacies. Future initiatives similar to the pilot project would benefit greatly from improved ease of pharmacist payment, with supported and simplified VFC enrollment, and expansion of locations covered by insurance payment policies.

Investigators encountered various reasons from those who declined participation, finding lack of time and interest to be the most common. Future initiatives would benefit from consideration of possible strategies to improve provider interest and buy-in. Such strategies would also facilitate the sustainability of the coordinated HPV vaccination model.

The investigators are grateful to have been given the opportunity to participate in the ACS National HPV Vaccination Roundtable pilot project, and will apply lessons learned to future collaborative opportunities to increase HPV vaccination rates.

References

1. Centers for Disease Control and Prevention. Genital HPV Infection – Fact Sheet [Cited Sept 2016] http://www.cdc.gov/std/HPV/STDFact-HPV.htm#a7
2. Centers for Disease Control and Prevention. HPV and Cancer [Cited Oct 2016] http://www.cdc.gov/cancer/hpv/statistics/cases.htm
3. Centers for Disease Control and Prevention. (2016). *CDC recommends only two HPV shots for younger adolescents* [Press release]. Retrieved from http://www.cdc.gov/media/releases/2016/p1020-hpv-shots.html
4. Reagan-Steiner S, Yankey D, Jeyarajah J, Elam-Evans LD, Curtis R, MacNeil J, Markowitz LE, Singleton JA. National, regional, state, and selected local area vaccination coverage among adolescents aged 13-17 years – United States, 2015. Morbidity and Mortality Weekly Report 2016;65(33):850-858
5. Cancer Prevention and Control Research Network. [Cited Oct 2016] http://www.cpcrn.org

Appendix A – Recruitment and Training

PHARMACIST - PRESCRIBER TEAM MANAGED CARE INITIATIVE

THE UNIVERSITY OF IOWA

Dear Pharmacy Colleague,

We are writing because you have expressed interest in a recently funded collaboration of care initiative coordinated by the University of Iowa College of Pharmacy and the University of Iowa College of Public Health. We are recruiting four pharmacist-prescriber teams across the state of Iowa that will collaborate to improve HPV vaccination rates within their community. A 6 month period of team care will be evaluated.

Your pharmacy will partner with a local clinic to create a pharmacy-clinic pair. At least one pharmacist and one prescriber is needed for a viable team. Upon creation of your pharmacy-clinic pair, we will host an in-person start-up session, where team members will outline the processes and procedures they wish to use to communicate and manage patient healthcare. As discussed, the objective of the pilot project is to effectively establish a team management approach to initiate and complete HPV vaccination in eligible adolescents. The patient will receive the first dose in a clinical setting, and be given a prescription to receive the second and third doses at a pharmacy.

Specifics:

- Multiple practitioners may participate in the team care initiative.
- A 1-hour, face-to-face team building session will be held for each team.
- During the team building session, the practitioners will discuss their approach to HPV vaccination, identify specific roles for the practitioners, and determine procedures to exchange patient information necessary for team managed care.
- Educational and promotional materials on HPV vaccination can be provided for pharmacists, clinicians and parents.
- Pharmacists will be expected to administer the vaccine, record vaccinations in a patient log and the state Immunization Registry Information System (IRIS), and work with patients and prescribers to coordinate the completion of the vaccine series.

Compensation: $1,000 is budgeted per pharmacy for this project, which includes an initial payment and subsequent payments pending continued collaboration and receipt of redacted patient logs.

Participation: Please suggest at least one prescriber from an area clinic who would work with a pharmacist in a collaborative team effort. Please include the clinic name, the prescriber's name and phone # to help us contact them. Please fax your preferences to Bill Doucette at 319-353-5646. Thank you.

William R. Doucette, PhD
University of Iowa College of Pharmacy
319-335-8786

William R Doucette

Pharmacy: _____

Pharmacist Name: _____

Telephone: (____) _____ -- _____

Clinic information is provided below:

City: _____

Clinic:	**Physician/Prescriber's Name(s):**
Phone #:	

THE UNIVERSITY OF IOWA
COLLEGE OF PHARMACY

COLLEGE OF PHARMACY
Division of Health Services Research
Pharmacy Practice and Science
115 S. Grand Avenue, S511 Phar
Iowa City, Iowa 52242-1112
319-335-8838 Fax 319-353-5646
http://www.pharmacy.uiowa.edu/pps

&Date

Provider Name
Clinic Name
Street Address
City, IA, Zip Code

Dear *Name*:

We are inviting providers to participate in a nationally-funded collaboration of care initiative coordinated by the University of Iowa College of Pharmacy and the University of Iowa College of Public Health. Our purpose is to implement and evaluate a program to foster provider-pharmacist collaboration within the community to help patients receive the HPV vaccine series.

Pharmacy Name has already agreed to participate in this initiative, and has suggested you as a potential clinical partner in the team approach. The objective is to effectively establish a team management approach of working with patients in need of the HPV vaccine, by providing the first dose in a clinical setting and prescribing the administration of the second and third doses in a pharmacy.

Specifics:

- Each pharmacy and clinic can have multiple practitioners participating on the team.
- A 1-hour, face-to-face team building session will be held for each team of pharmacists & prescribers.
- During the team building session, the practitioners will discuss their approach to HPV vaccination, identify specific roles for the practitioners, and determine procedures to exchange patient information necessary for team managed care.
- Educational and promotional HPV vaccination materials will be provided for pharmacists, clinicians, patients, and parents.
- Pharmacists will be expected to administer the vaccine, record vaccinations in a patient log and in the state Immunization Registry Information System (IRIS), and work with patients and prescribers to deliver the HPV vaccine series.

Compensation: $1,000 is budgeted per clinic for this project, which includes an initial payment and subsequent payments pending continued collaboration and receipt of redacted patient logs.

Participation: We hope you are interested in joining a care team with the pharmacy. Please fax us your reply form included in this letter to Bill Doucette at 319-353-5646. If interested, we will contact you about arrangements to begin the team work. Thank you.

Sincerely,

William R Doucette

Professor and Head
Division of Health Services Research
University of Iowa College of Pharmacy
Phone: 319-335-8786

Provider Name
Clinic Name
Street Address
City, IA, Zip Code

☐ I am not interested at this time.

☐ I may be interested. Please contact me with more details using my contact information given below.

☐ I am interested in participating in this project. My contact information is below.

Phone number (best number to reach me): (____) _____- _____

Email Address: _____

Name: _____

Please fax your reply to 319-353-5646. No cover sheet is needed. Thank you very much.

ATTN: Bill Doucette

HPV Vaccination Team
Building Worksheet

Prescriber's Roles	• Administer first dose of HPV vaccine series to eligible patients • Refer patients to local pharmacy with prescription for 2nd and 3rd doses (e-Rx?)
Pharmacist's Roles	• Administer 2nd dose 2 months after first dose, and the 3rd dose 6 months after first dose. • Patient reminders for completion of HPV vaccine series • Upon vaccination, record to IRIS and communicate with referring clinic • Maintain pharmacy logs
Patient Identification	• Clinic identifies eligible patients in need of the HPV vaccine series • First dose can be delivered at any appointment

HPV Vaccination Team
Building Worksheet

Communication and Follow-up	• Faxes - Email – Face to Face – Phone – EMR's • Pharmacist-Provider communication forms (e.g. immunization administration notice)
First Steps	• Firm up any workflow adjustments with coordinated care staff • Start identifying potential patients for team care
Team Follow-up Conference Call	• **Recommended in 4-5 weeks** • Discuss team care activities done to date AND what yet needs to be done • Identify modifications
Project Timeline	• **Overall project timeline: February-September 2016** • April: coordinated care teams begin administration of HPV vaccine • August/September: provide redacted log information to research team for analysis

Human Papillomavirus (HPV) Vaccination:

Role of the Pharmacist in Increasing Vaccine Series Completion



Trish Freeman, RPh, PhD
Clinical Associate Professor

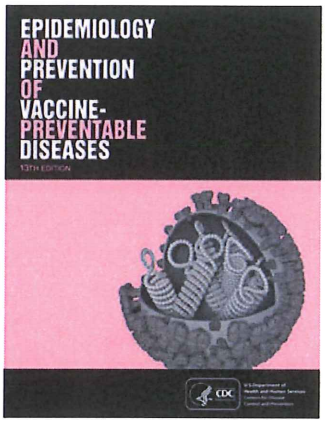
Robin Vanderpool, DrPh
Associate Professor

Learning Objectives

- Describe the incidence and clinical course of HPV disease
- Identify the potential complications of HPV
- Discuss the efficacy and safety of vaccination with HPV vaccine
- Identify opportunities and strategies for pharmacists to facilitate series completion

Required Reading

- CDC Pink Book Chapter 11: HPV



Human Papillomavirus (HPV)

- Small DNA virus
- More than 120 types identified based on the genetic sequence of the outer capsid protein L1
- About 40 types infect the mucosal epithelium

HPV Types Differ in their Disease Associations

~40 Types

Mucosal sites of infection

Cutaneous sites of infection

~ 80 Types

High risk (oncogenic)
HPV 16, 18

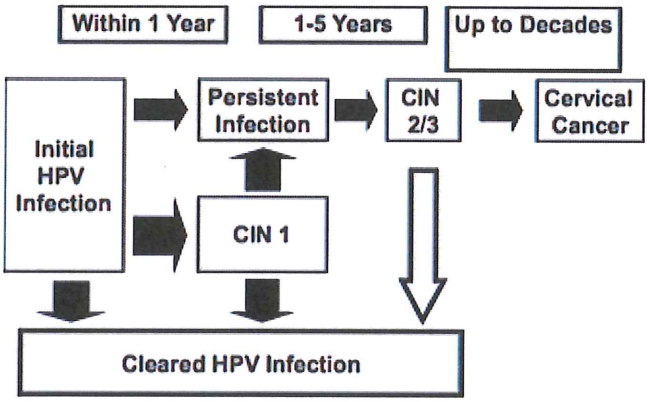
Cervical Cancer
Anogenital Cancers
Oropharyngeal Cancer Cancer Precursors
Low Grade Cervical Disease

Low risk (non-oncogenic)
HPV 6, 11

Genital Warts
Laryngeal Papillomas
Low Grade Cervical Disease

"Common" Hand and Foot Warts

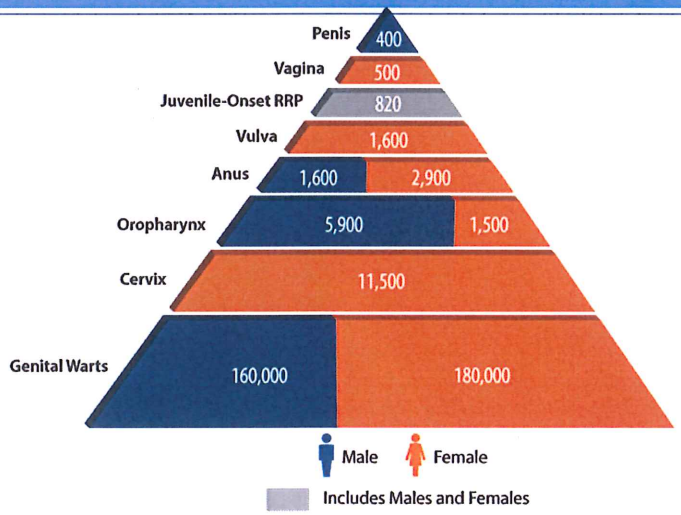
Natural History of HPV Infection



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 head and neck cancer)

Warts Attributed to HPV Infections, U.S.



CDC. Human papillomavirus (HPV)-associated cancers. Atlanta, GA: US Department of Health and Human Services, CDC; 2013. Available at http://www.cdc.gov/cancer/hpv/statistics/cases.htm

Cancers Attributed to HPV, U.S.

Cancer site	Average number of cancers per year in sites where HPV is often found			Percentage of cancers per year probably caused by HPV	Average number of cancers per year probably caused by HPV†		
	Male	Female	Both Sexes		Male	Female	Both Sexes
Anus	1,549	2,821	4,370	**91%**	1,400	2,600	4,000
Cervix	0	11,422	11,422	**91%**	0	10,400	10,400
Oropharynx	9,974	2,443	12,417	**72%**	7,200	1,800	9,000
Penis	1,048	0	1,048	**63%**	700	0	700
Vagina	0	735	735	**75%**	0	600	600
Vulva	0	3,168	3,168	**69%**	0	2,200	2,200
TOTAL	**12,571**	**20,589**	**33,160**		**9,300**	**17,600**	**26,900**

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

HPV Epidemiology

- Reservoir ⟶ Human
- Transmission ⟶ Direct contact, usually sexual
- Temporal pattern ⟶ None
- Communicability ⟶ Presumed to be high

HPV Disease Burden in the U.S.

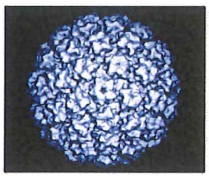
- Anogenital HPV is the most common sexually transmitted infection in the U.S.
  - Estimated 79 million currently infected
  - 14 million new infections/year
- Common among adolescents and young adults
  - Prospective study in college women showed a 40% cumulative incidence of infection by 24 months after 1st intercourse
- Estimated 80% of sexually active women will have been infected by age 50

Cervical Cancer Screening

- Cervical cancer screening – no change
  - 30% of cervical cancers caused by HPV types not prevented by the quadrivalent HPV vaccine
  - Vaccinated females could subsequently be infected with non-vaccine HPV types
  - Sexually active females could have been infected prior to vaccination
- Providers should educate women about the importance of cervical cancer screening

HPV Vaccine

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



HPV Virus-Like Particle

3 FDA-licensed HPV Vaccines

	Bivalent (Cervarix®)	Quadrivalent (Gardasil®)	9-Valent (Gardasil 9®)
Manufacturer	GlaxoSmithKline	Merck	Merck
VLP Types	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Licensed in U.S.	Females, 9-25 years – 2009	Females – 2006 Males – 2009	Females and Males, 9-26 years – 2014
Protection	Cervical cancer, pre-cancers	Cervical, vulvar, and vaginal cancers; pre-cancers; genital warts	Cervical, vulvar, vaginal, and anal cancers; pre-cancers; genital warts
Dosing/Schedule	3-dose schedule 2nd dose: at least 1-2 mos. after 1st dose 3rd dose: at least 6 mos. after 1st dose		
Retail Price	$128/dose	$147/dose	$163/dose

HPV Vaccine Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types
- No evidence of efficacy against disease caused by vaccine types of which participants were infected at the time of vaccination
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

Routine HPV Vaccination Recommendations

- ACIP recommends routine vaccination of females and males 11 or 12 years of age
  - HPV2 not approved for use in males
  - Can be started as young as 9 years of age
- "Catch-up" vaccination recommended for females 13-26 years of age and for males age 13–21 years of age although may consider vaccination in males up to 26
  - Immunocompromised and MSM **should** be vaccinated through 26 years of age

HPV Vaccination Schedule

- Routine schedule is 0, 2, 6 months
- Third dose should follow the first dose by at least 24 weeks
- An accelerated schedule using minimum intervals is not recommended
- Series does not need to be restarted if the schedule is interrupted

HPV Vaccine: Important Considerations

- Does not remove the need for cervical cancer screening
- Does not protect the person from a disease that is caused by other types of HPV, other viruses or bacteria
- Does not treat HPV infection
- Does not protect the person from HPV types that he/she may already have

HPV Vaccine Special Situations*

- Equivocal or abnormal Pap test
- Positive HPV DNA test
- Genital warts
- Immunosuppression
- Breastfeeding

***Vaccine can be administered**

HPV 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)

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 manufacturer

HPV Vaccine Adverse Reactions

- Local reactions (pain, swelling) 20-90%
- Fever 10-13%*
- No serious adverse reactions reported

***similar to reports in placebo recipients**

Syncope Following Vaccination

- An increase in the number of reports of syncope has been detected by the Vaccine Adverse Event Reporting System (VAERS)
- 11-18 year old females have contributed most of the increase
- Serious injuries have resulted
- Patient should be seated during administration
- Providers should strongly consider observing patients for 15 minutes after they are vaccinated

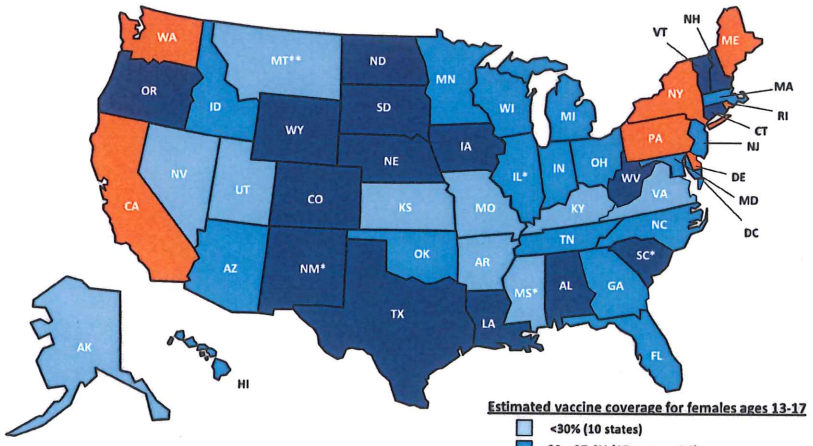
HPV Vaccine Storage and Handling

- Store at 36° F-46° F (2° C - 8° C)
- Protect from light
- Do not expose to freezing temperature
- Remove from refrigeration immediately before administration

Figure 3

HPV Vaccination Rates of Adolescent Girls ages 13-17, by State

Completion of 3 dose HPV vaccine series among females ages 13-17, 2013



2013 U.S. average= 37.6%

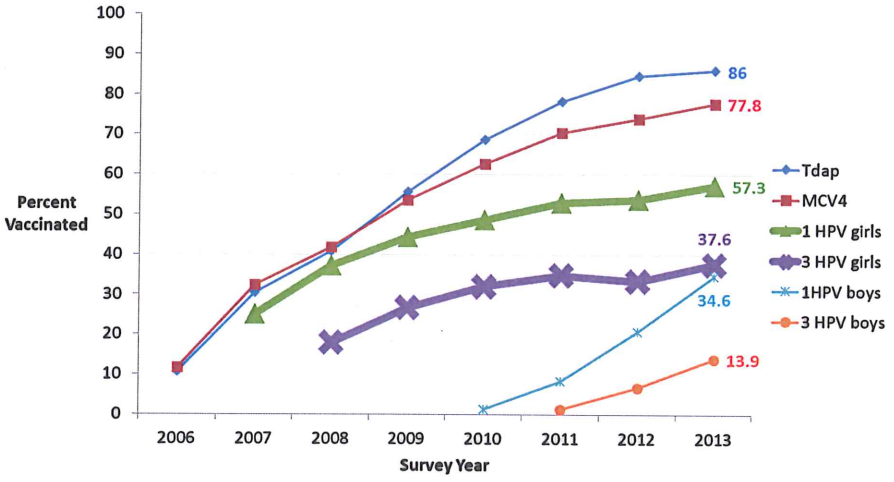
Estimated vaccine coverage for females ages 13-17

- <30% (10 states)
- 30 – 37.6% (17 states + DC)
- 37.7 – 44.9% (16 states)
- ≥45 (7 states)

NOTES: Share of females ages 13-17 who have received all 3 doses of the HPV vaccine series. *Statistically significant (p<.05) increase from 2012.
**Statistically significant (p<.05) decrease from 2012.
SOURCE: CDC. (2014). National, state, and local area vaccination coverage among adolescents aged 13-17 years--U.S.2013.

THE HENRY J. KAISER FAMILY FOUNDATION

Adolescent Vaccination Coverage United States, 2006-2013



MMWR 2014; 63(29);625-633.

President's Cancer Panel Annual Report 2012-2013

ACCELERATING HPV VACCINE UPTAKE: URGENCY FOR ACTION TO PREVENT CANCER

- Call for HPV vaccination to become a national and global health priority
- Develop a strategy to increase HPV vaccine uptake
- 4 goals

***Ultimate goal:* Completion of the HPV vaccine series by all age-eligible adolescents for whom the vaccine is not contraindicated.**

Goal 3: Maximize Access

PCP Recommendations

- Promote and facilitate HPV vaccination in venues outside of the medical home.
- Enact and implement laws to allow pharmacists to administer vaccines.
- Overcome remaining barriers to paying for HPV vaccines.

Opportunities for Pharmacists

- Rates of HPV vaccine series completion are low
- Pharmacists can play key role in series completion
  - Identification of possible vaccine candidates presenting at pharmacy
  - Partnership with physicians and other healthcare providers in community

Screening

Screening Checklist for Contraindications to HPV Vaccine for Adolescents / Teens

Patient Name: _____

Date of Birth: ____/____/____ (Month / Day / Year)

For parents / guardians: The following questions will help us determine if human papillomavirus (HPV) vaccine may be given to your adolescent / teen today. If you answer "yes" to any question, it does not necessarily mean your teen should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your pharmacist to explain it.

	Yes	No	Don't Know
1. Is your adolescent / teen sick today?	☐	☐	☐
2. Does your adolescent / teen have allergies to a vaccine component or to latex?	☐	☐	☐
3. Has your adolescent / teen had a serious reaction to a vaccine in the past?	☐	☐	☐
4. For females: Is your adolescent / teen pregnant?	☐	☐	☐

Form completed by: _____ Date: _____

Form reviewed by: _____ Date: _____

Did you bring your adolescent's / teen's immunization record card with you? Yes ☐ No ☐

HPV VIS

VACCINE INFORMATION STATEMENT

HPV Vaccine Gardasil® (Human Papillomavirus)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 What is HPV?

Genital **human papillomavirus (HPV)** is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 12,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women, and anal and oropharyngeal (back of the throat, including base of tongue and tonsils) cancers in both men and women. HPV can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the

3 Who should get this HPV vaccine and when?

HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

Routine vaccination

- This HPV vaccine is recommended for girls and boys **11 or 12 years of age.** It *may* be given starting at age 9.

Why is HPV vaccine recommended at 11 or 12 years of age?
HPV infection is easily acquired, even with only one sex partner. That is why it is important to get HPV vaccine before any sexual contact takes place. Also, response to the vaccine is better at this age than at older ages.

Catch-up vaccination
This vaccine is recommended for the following people who have not completed the 3-dose series:

- Females 13 through 26 years of age.

Consent

Informed Consent Statement

I have been given a copy and have read or have had explained to me the U.S. Public Health Service important information statement about _____, dated _____.
I have had a chance to ask questions, which were answered to my satisfaction. I believe I understand the risks and benefits of the vaccine and request that it be given to the person named below and for whom I am authorized to make this request.

Information About Person to Receive Vaccine (Please Print)				For Pharmacy Use Only
Last Name	First Name	MI	Birthdate	Pharmacy Name
Address				Date Vaccinated
City	ST	Zip		Manufacturer and Lot #
x				Site of Injection

Signature of Person Authorized to Make the Request

Notification of Vaccination

Notification of Vaccination Letter Template

Dear doctor or nurse at: _____:
Patient's primary care clinic

We recently provided HPV vaccination services to one of your patients.

We want to make certain that you have information about the vaccine we administered so you can update your patient's medical record.

Please contact us if you have any questions about this information.

- [x] We provided the patient (or parent) with a written record of the vaccination given.
- [x] We entered information about the vaccine we administered in the regional immunization information system.

Patient's Name:	**Patient's birthdate:**
For a child, parent' name:	**Parent's birthdate:**

The vaccine was administered on _____
Date

Questions?



Appendix B – Educational Materials for Providers

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

Emiko Petrosky, MD[1,2], Joseph A. Bocchini Jr, MD[3], Susan Hariri, PhD[2], Harrell Chesson, PhD[2], C. Robinette Curtis, MD[4], Mona Saraiya, MD[5], Elizabeth R. Unger, PhD, MD[6], Lauri E. Markowitz, MD[2] (Author affiliations at end of text)

During its February 2015 meeting, the Advisory Committee on Immunization Practices (ACIP) recommended 9-valent human papillomavirus (HPV) vaccine (9vHPV) (Gardasil 9, Merck and Co., Inc.) as one of three HPV vaccines that can be used for routine vaccination (Table 1). HPV vaccine is recommended for routine vaccination at age 11 or 12 years (*1*). ACIP also recommends vaccination for females aged 13 through 26 years and males aged 13 through 21 years not vaccinated previously. Vaccination is also recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) if not vaccinated previously (*1*). 9vHPV is a noninfectious, virus-like particle (VLP) vaccine. Similar to quadrivalent HPV vaccine (4vHPV), 9vHPV contains HPV 6, 11, 16, and 18 VLPs. In addition, 9vHPV contains HPV 31, 33, 45, 52, and 58 VLPs (*2*). 9vHPV was approved by the Food and Drug Administration (FDA) on December 10, 2014, for use in females aged 9 through 26 years and males aged 9 through 15 years (*3*). For these recommendations, ACIP reviewed additional data on 9vHPV in males aged 16 through 26 years (*4*). 9vHPV and 4vHPV are licensed for use in females and males. Bivalent HPV vaccine (2vHPV), which contains HPV 16, 18 VLPs, is licensed for use in females (*1*). This report summarizes evidence considered by ACIP in recommending 9vHPV as one of three HPV vaccines that can be used for vaccination and provides recommendations for vaccine use.

Recommendations for routine use of vaccines in children, adolescents and adults are developed by the Advisory Committee on Immunization Practices (ACIP). ACIP is chartered as a federal advisory committee to provide expert external advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC) on use of vaccines and related agents for the control of vaccine-preventable diseases in the civilian population of the United States. Recommendations for routine use of vaccines in children and adolescents are harmonized to the greatest extent possible with recommendations made by the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and the American College of Obstetricians and Gynecologists (ACOG). Recommendations for routine use of vaccines in adults are harmonized with recommendations of AAFP, ACOG, and the American College of Physicians (ACP). ACIP recommendations approved by the CDC Director become agency guidelines on the date published in the Morbidity and Mortality Weekly Report *(*MMWR*). Additional information about ACIP is available at http://www.cdc.gov/vaccines/acip/.*

Methods

From October 2013 to February 2015, the ACIP HPV Vaccine Work Group reviewed clinical trial data assessing the efficacy, immunogenicity, and safety of 9vHPV, modeling data on cost-effectiveness of 9vHPV, and data on burden of type-specific HPV-associated disease in the United States. Summaries of reviewed evidence and Work Group discussions were presented to ACIP before recommendations were proposed. Recommendations were approved by ACIP in February 2015. Evidence supporting 9vHPV use was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework (*5*) and determined to be type 2 (moderate level of evidence) among females and 3 (low level of evidence) among males; the recommendation was categorized as a Category A recommendation (for all persons in an age- or risk-factor–based group) (*6*).

HPV-Associated Disease

HPV is associated with cervical, vulvar, and vaginal cancer in females, penile cancer in males, and anal cancer and oropharyngeal cancer in both females and males (*7–10*). The burden of HPV infection also includes cervical precancers, including cervical intraepithelial neoplasia grade 2 or 3 and adenocarcinoma in situ (≥CIN2). The majority of all HPV-associated cancers are caused by HPV 16 or 18, types targeted by 2vHPV, 4vHPV and 9vHPV (*2*,*11*,*12*). In the United States, approximately 64% of invasive HPV-associated cancers are attributable to HPV 16 or 18 (65% for females; 63% for males; approximately 21,300 cases annually) and 10% are attributable to the five additional types in 9vHPV: HPV 31, 33, 45, 52, and 58 (14% for females; 4% for males; approximately 3,400 cases annually) (*1*,*12*,*13*). HPV 16 or 18 account for 66% and the five additional types for about 15% of cervical cancers (*12*). Approximately 50% of ≥CIN2 are caused by HPV 16 or 18

TABLE 1. Characteristics of the three human papillomavirus (HPV) vaccines licensed for use in the United States

Characteristic	Bivalent (2vHPV)*	Quadrivalent (4vHPV)†	9-valent (9vHPV)§
Brand name	Cervarix	Gardasil	Gardasil 9
VLPs	16, 18	6, 11, 16, 18	6, 11, 16, 18, 31, 33, 45, 52, 58
Manufacturer	GlaxoSmithKline	Merck and Co., Inc.	Merck and Co., Inc.
Manufacturing	*Trichoplusia ni* insect cell line infected with L1 encoding recombinant baculovirus	*Saccharomyces cerevisiae* (Baker's yeast), expressing L1	*Saccharomyces cerevisiae* (Baker's yeast), expressing L1
Adjuvant	500 μg aluminum hydroxide, 50 μg 3-O-desacyl-4′ monophosphoryl lipid A	225 μg amorphous aluminum hydroxyphosphate sulfate	500 μg amorphous aluminum hydroxyphosphate sulfate
Volume per dose	0.5 ml	0.5 ml	0.5 ml
Administration	Intramuscular	Intramuscular	Intramuscular

Abbreviation: L1 = the HPV major capsid protein; VLPs = virus-like particles.
* Only licensed for use in females in the United States. Package insert available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM186981.pdf.
† Package insert available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM111263.pdf.
§ Package insert available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf.

and 25% by HPV 31, 33, 45, 52, or 58 (*14*). HPV 6 or 11 cause 90% of anogenital warts (condylomata) and most cases of recurrent respiratory papillomatosis (*15*).

9vHPV Efficacy, Immunogenicity, and Safety

In a phase III efficacy trial comparing 9vHPV with 4vHPV among approximately 14,000 females aged 16 through 26 years, 9vHPV efficacy for prevention of ≥CIN2, vulvar intraepithelial neoplasia grade 2 or 3, and vaginal intraepithelial neoplasia grade 2 or 3 caused by HPV 31, 33, 45, 52, or 58 was 96.7% in the per protocol population* (Table 2) (*2*,*16*). Efficacy for prevention of ≥CIN2 caused by HPV 31, 33, 45, 52, or 58 was 96.3% and for 6-month persistent infection was 96.0% (*16*). Few cases were caused by HPV 6, 11, 16, or 18 in either vaccine group. Noninferior immunogenicity of 9vHPV compared with 4vHPV was used to infer efficacy for HPV 6, 11, 16, and 18. Geometric mean antibody titers (GMTs) 1 month after the third dose were noninferior for HPV 6, 11, 16, and 18; in the 9vHPV group, >99% seroconverted to all nine HPV vaccine types (Table 3).

Two immunobridging trials were conducted. One compared 9vHPV in approximately 2,400 females and males aged 9 through 15 years with approximately 400 females aged 16 through 26 years. Over 99% seroconverted to all nine HPV vaccine types; GMTs were significantly higher in adolescents aged 9 through 15 years compared with females aged 16 through 26 years. In a comparison of 4vHPV with 9vHPV in approximately 600 adolescent females aged 9 through 15 years, 100% seroconverted to HPV 6, 11, 16, and 18 in both groups, and GMTs were noninferior in the 9vHPV group compared with the 4vHPV group.

Immunogenicity in males aged 16 through 26 years was compared with females of the same age group in a separate study. In both females and males, >99% seroconverted to all nine HPV vaccine types, and GMTs in males were noninferior to those in females (*4*).

The immunogenicity of concomitant and nonconcomitant administration of 9vHPV with quadrivalent meningococcal conjugate vaccine (Menactra, MenACWY-D) and tetanus, diphtheria, acellular pertussis vaccine (Adacel, Tdap) was evaluated. The GMTs were noninferior for all nine HPV vaccine types in the co-administered group (all $p<0.001$). For Menactra, the noninferiority criterion was met for all four serogroups, and for Adacel, for diphtheria, tetanus, and all four pertussis antigens.

Safety has been evaluated in approximately 15,000 subjects in the 9vHPV clinical development program; approximately 13,000 subjects in six studies were included in the initial application submitted to FDA (*2*). The vaccine was well-tolerated, and most adverse events were injection site-related pain, swelling, and erythema that were mild to moderate in intensity. The safety profiles were similar in 4vHPV and 9vHPV vaccinees. Among females aged 9 through 26 years, 9vHPV recipients had more injection-site adverse events, including swelling (40.3% in the 9vHPV group compared with 29.1% in the 4vHPV group) and erythema (34.0% in the 9vHPV group compared with 25.8% in the 4vHPV group). Males had fewer injection site adverse events. In males aged 9 through 15 years, injection site swelling and erythema in 9vHPV recipients occurred in 26.9% and 24.9%, respectively. Rates of injection-site swelling and erythema both increased following each successive dose of 9vHPV.

* Females who received all 3 vaccinations within 1 year of enrollment, did not have major deviations from the study protocol, were naïve (polymerase chain reaction [PCR] negative and seronegative) to the relevant HPV type(s) before dose 1, and who remained PCR negative to the relevant HPV type(s) through 1 month after dose 3 (month 7).

TABLE 2. Results of a Phase III efficacy trial comparing 9-valent human papillomavirus (HPV) vaccine (9vHPV) with quadrivalent HPV vaccine (4vHPV), per protocol population* in females aged 16 through 26 years†

		9vHPV		4vHPV		Vaccine efficacy	
Endpoint-related types	Endpoint	No. participants	Cases	No. participants	Cases	%	(95% CI)
HPV 31, 33, 45, 52, 58	≥CIN2, VIN2/3, VaIN2/3	6,016	1	6,017	30	96.7	(80.9–99.8)
	≥CIN2	5,948	1	5,943	27	96.3	(79.5–99.8)
	6-month persistent infection	5,939	35	5,953	810	96.0	(94.4–97.2)
HPV 6, 11, 16, 18	≥CIN2§	5,823	1	5,832	1	—	—
	Anogenital warts	5,876	5	5,893	1	—	—

Abbreviations: CI = confidence interval; ≥CIN2 = cervical intraepithelial neoplasia grade 2 or 3 or adenocarcinoma in situ; VaIN2/3 = vaginal intraepithelial neoplasia grade 2 or 3; VIN2/3 = vulvar intraepithelial neoplasia grade 2 or 3.
Sources: Package insert available at http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM426457.pdf.
Joura EA, Giuliano AR, Iversen OE, et al. A 9-valent HPV vaccine against infection and intraepithelial neoplasia in women. N Engl J Med 2015;372:711–23.
* Females who received all 3 vaccinations within 1 year of enrollment, did not have major deviations from the study protocol, were naïve (polymerase chain reaction [PCR] negative and seronegative) to the relevant HPV type(s) before dose 1, and who remained PCR negative to the relevant HPV type(s) through 1 month after dose 3 (month 7).
† Participants were enrolled from sites in 18 countries; median duration of follow-up was 40 months.

TABLE 3. Human papillomavirus (HPV) 6, 11, 16, and 18 seroconversion and geometric mean titers (GMTs*) after 3 doses of 9-valent HPV vaccine (9vHPV) compared with quadrivalent HPV vaccine (4vHPV), per protocol population† in females aged 16 through 26 years§

	9vHPV			4vHPV		
Assay (cLIA)	No. participants	Seropositivity (%)	GMT (mMU/mL)	No. participants	Seropositivity (%)	GMT (mMU/mL)
Anti-HPV 6	3,993	(99.8)	893	3,975	(99.8)	875
Anti-HPV 11	3,995	(100)	666	3,982	(99.9)	830
Anti-HPV 16	4,032	(100)	3,131	4,062	(100)	3,157
Anti-HPV 18	4,539	(99.8)	805	4,541	(99.7)	679

Abbreviations: cLIA = competitive Luminex immunoassay; mMU = milli-Merck units.
Source: Joura EA, Giuliano AR, Iversen OE, et al. A 9-valent HPV vaccine against infection and intraepithelial neoplasia in women, and supplementary appendix. N Engl J Med 2015;372:711–23.
* The noninferiority criterion for GMTs was met for all four HPV types (p<0.001).
† Females who received all 3 vaccinations within 1 year of enrollment, did not have major deviations from the study protocol, were naïve (polymerase chain reaction [PCR] negative and seronegative) to the relevant HPV type(s) before dose 1, and who remained PCR–negative to the relevant HPV type(s) through 1 month after dose 3 (month 7).
§ Participants were enrolled from sites in 18 countries; median duration of follow-up was 40 months.

Health Impact and Cost Effectiveness

Introduction of 9vHPV in both males and females was cost-saving when compared with 4vHPV for both sexes in a cost-effectiveness model that assumed 9vHPV cost $13 more per dose than 4vHPV. Cost-effectiveness ratios for 9vHPV remained favorable compared with 4vHPV (9vHPV was cost-saving in most scenarios, and the cost per quality-adjusted life year gained did not exceed $25,000 in any scenario) when varying assumptions about HPV natural history, cervical cancer screening, vaccine coverage, vaccine duration of protection, and health care costs, but were sensitive to 9vHPV cost assumptions (*17*). Because the additional five types in 9vHPV account for a higher proportion of HPV-associated cancers in females compared with males and cause cervical precancers, the additional protection from 9vHPV will mostly benefit females.

Recommendations for Use of HPV Vaccines

ACIP recommends that routine HPV vaccination be initiated at age 11 or 12 years. The vaccination series can be started beginning at age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series (*1*). Males aged 22 through 26 years may be vaccinated.† Vaccination of females is recommended with 2vHPV, 4vHPV (as long as this formulation is available), or 9vHPV. Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV.

2vHPV, 4vHPV, and 9vHPV all protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States (*1,12*). 9vHPV targets five additional cancer causing types, which account for about 15% of cervical cancers (*12*). 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause anogenital warts.

† Vaccination is also recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) if not vaccinated previously.

What is currently recommended?

The Advisory Committee on Immunization Practices (ACIP) recommends routine HPV vaccination at age 11 or 12 years. The vaccination series can be started beginning at age 9 years. Vaccination is also recommended for females aged 13 through 26 years and for males aged 13 through 21 years who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years may be vaccinated. ACIP recommends vaccination of men who have sex with men and immunocompromised persons through age 26 years if not vaccinated previously.

Why are the recommendations being updated now?

9-valent HPV vaccine (9vHPV) was approved by the Food and Drug Administration on December 10, 2014. This vaccine targets HPV types 6, 11, 16, and 18, the types targeted by the quadrivalent HPV vaccine (4vHPV), as well as five additional types, HPV types 31, 33, 45, 52, and 58. ACIP reviewed results of a randomized trial among approximately 14,000 females aged 16 through 26 years that showed noninferior immunogenicity for the types shared by 4vHPV and 9vHPV and high efficacy for the five additional types. Other trials in the 9vHPV clinical development program included studies that compared antibody responses across age groups and females and males and concomitant vaccination studies. The evidence supporting 9vHPV vaccination was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined to be type 2 (moderate level of evidence) among females and 3 (low level of evidence) among males; the recommendation was designated as a Category A recommendation (recommendation for all persons in an age- or risk-factor–based group).

What are the new recommendations?

9vHPV, 4vHPV or 2vHPV can be used for routine vaccination of females aged 11 or 12 years and females through age 26 years who have not been vaccinated previously or who have not completed the 3-dose series. 9vHPV or 4vHPV can be used for routine vaccination of males aged 11 or 12 years and males through age 21 years who have not been vaccinated previously or who have not completed the 3-dose series. ACIP recommends either 9vHPV or 4vHPV vaccination for men who have sex with men and immunocompromised persons (including those with HIV infection) through age 26 years if not vaccinated previously.

Administration. 2vHPV, 4vHPV, and 9vHPV are each administered in a 3-dose schedule. The second dose is administered at least 1 to 2 months after the first dose, and the third dose at least 6 months after the first dose[§] (*1*). If the vaccine schedule is interrupted, the vaccination series does not need to be restarted.

If vaccination providers do not know or do not have available the HPV vaccine product previously administered, or are in settings transitioning to 9vHPV, any available HPV vaccine product may be used to continue or complete the series for females for protection against HPV 16 and 18; 9vHPV or 4vHPV may be used to continue or complete the series for males. There are no data on efficacy of fewer than 3 doses of 9vHPV.

Special Populations. HPV vaccination is recommended through age 26 years for men who have sex with men and for immunocompromised persons (including those with HIV infection) who have not been vaccinated previously or have not completed the 3-dose series.

Precautions and Contraindications. HPV vaccines are contraindicated for persons with a history of immediate hypersensitivity to any vaccine component. 4vHPV and 9vHPV are contraindicated for persons with a history of immediate hypersensitivity to yeast. 2vHPV should not be used in persons with anaphylactic latex allergy.

HPV vaccines are not recommended for use in pregnant women (*1*). If a woman is found to be pregnant after initiating the vaccination series, the remainder of the 3-dose series should be delayed until completion of pregnancy. Pregnancy testing is not needed before vaccination. If a vaccine dose has been administered during pregnancy, no intervention is needed. A new pregnancy registry has been established for 9vHPV (*2*). Pregnancy registries for 4vHPV and 2vHPV have been closed with concurrence from FDA (*1*,*18*). Exposure during pregnancy can be reported to the respective manufacturer.[¶] Patients and health care providers can report an exposure to HPV vaccine during pregnancy to the Vaccine Adverse Event Reporting System (VAERS).

Adverse events occurring after administration of any vaccine should be reported to VAERS. Additional information about VAERS is available by telephone (1–800–822–7967) or online at http://vaers.hhs.gov.

Cervical Cancer Screening. Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women (*19*,*20*). Recommendations will continue to be evaluated as further postlicensure monitoring data become available.

Future Policy Issues

A clinical trial is ongoing to assess alternative dosing schedules of 9vHPV. ACIP will formally review the results as data become available. HPV vaccination should not be delayed pending availability of 9vHPV or of future clinical trial data.

[§] Minimum intervals are 1 month between the first and second dose, 3 months between the second and third dose, and 6 months between the first and third dose.

[¶] 9vHPV exposure during pregnancy should be reported to the Merck Pregnancy Registry at telephone 1-800-986-8999; 4vHPV exposure during pregnancy can be reported to Merck at telephone 1-877-888-4231. 2vHPV exposure during pregnancy can be reported to GlaxoSmithKline at telephone 1-888-825-5249.

Acknowledgments

ACIP members (membership roster for July 2014–June 2015 available at http://www.cdc.gov/vaccines/acip/committee/members-archive.html). ACIP HPV Work Group.

[1]Epidemic Intelligence Service, CDC; [2]National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention, CDC; [3]Louisiana State University Health Sciences Center, Shreveport, Louisiana; [4]National Center for Immunization and Respiratory Diseases, CDC; [5]National Center for Chronic Disease Prevention and Health Promotion, CDC; [6]National Center for Emerging and Zoonotic Infectious Diseases, CDC (Corresponding author: Emiko Petrosky, xfq7@cdc.gov, 404-639-1817)

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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.

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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 dose (6 months after the first dose). ACIP does not state maximum intervals between HPV doses.
- Antibody titers have not been found to be diminished after longer than standard intervals between doses. Data from a few studies of bivalent and quadrivalent HPV vaccines showed similar or higher antibody titers when 2 doses were administered at an interval of 6 months compared with 2 months. An ongoing immunogenicity study is evaluating 2 doses of 9-valent HPV vaccine in 9-14 year olds separated by an interval of 6 or 12 months.

If a person desires protection against the 5 additional types prevented by the 9-valent HPV vaccine and has started a series with another HPV vaccine product, what issues should be considered?

- The majority of all HPV-associated cancers that can be prevented by vaccination are due to HPV 16 and 18. These are the HPV types prevented by all three vaccines: bivalent vaccine, quadrivalent vaccine and 9-valent vaccine.
- 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. This is because only a small percentage of HPV-associated cancers in males is due to the 5 additional types in 9-valent HPV vaccine.
- 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 at least 12 months earlier.
- Cervical cancer screening is recommended beginning at age 21 years and continuing through age 65 years for both vaccinated and unvaccinated women.

What data are available on the number of doses of 9-valent vaccine needed for protection against the 5 additional types for a series started with quadrivalent HPV vaccine and completed with 9-valent HPV vaccine?

- There are no data on efficacy or immunogenicity of 1, 2 or 3 doses of 9-valent HPV vaccine among persons who have received 1 or 2 doses of quadrivalent HPV vaccine.
- In an immunogenicity and safety clinical trial, 3 doses of 9-valent HPV vaccine (on a 0,2,6 month schedule) were given to females who had completed a 3-dose quadrivalent HPV vaccine series; the first dose of 9-valent HPV vaccine was administered 12 to 36 months after completing a quadrivalent vaccine series.
  - After 3 doses, over 98% of vaccinees developed antibodies to all 5 additional types. Antibody was also measured after the first dose of 9-valent HPV vaccine; most but not all of the vaccinees in this trial developed antibody against all 5 additional types. Antibody titers were higher after the third dose than after the first dose. Antibody was not measured after the second dose.
  - In a cross study comparison, geometric antibody titers for the 5 additional types among persons who received 3 doses of 9-valent HPV vaccine after 3 doses of quadrivalent HPV vaccine were lower than those of persons who received 3 doses of 9-valent HPV vaccine without prior HPV vaccination. The significance of the lower antibody titers is not known because there is no immune correlate of protection.
- An immunogenicity trial of 2 doses of 9-valent HPV vaccine in HPV vaccine naïve adolescents 9-14 years is ongoing; results are expected to be available within a year. In this trial, the 2 doses are separated by an interval of 6 or 12 months.
  - Results from this trial will not directly address additional 9-valent vaccination in persons who already received quadrivalent HPV vaccine.

What data are available on the safety of 9-valent HPV vaccination after a series started with another HPV vaccine product?

- In a randomized trial, 9-valent HPV vaccine was compared with placebo in females aged 12-26 years who had previously received 3 doses of quadrivalent HPV vaccine. Among the 608 females who received 9-valent HPV vaccine, there was an acceptable safety profile.
- Compared to persons in other studies who were vaccinated with 9-valent HPV vaccine and had never received any HPV vaccination, those who received 9-valent HPV vaccine after a 3-dose quadrivalent vaccine series had higher rates of injection site swelling and redness.

- 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 completed a 3-dose HPV vaccination series

Is additional vaccination with 9-valent HPV vaccine recommended for persons who have completed a 3-dose series of either quadrivalent or bivalent HPV vaccine?

- There is no ACIP recommendation for routine additional 9-valent HPV vaccination of persons who previously completed a quadrivalent or bivalent vaccination series.

If a person desires protection against the 5 additional types prevented by the 9-valent HPV vaccine and has completed a 3-dose series of quadrivalent HPV vaccine, what issues should be considered?

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

What data are available on efficacy and immunogenicity of 9-valent HPV vaccination when administered after a complete 3-dose series of another HPV vaccine product?

- In an immunogenicity and safety clinical trial, 3 doses of 9-valent HPV vaccine (on a 0,2,6 month schedule) were given to females who had completed a 3-dose quadrivalent HPV vaccine series; the first dose of 9-valent HPV vaccine was administered 12 to 36 months after completing a quadrivalent vaccine series.
  - After 3 doses, over 98% of vaccinees developed antibodies to all 5 additional types. Antibody was also measured after the first dose of 9-valent HPV vaccine; most but not all of the vaccinees in this trial developed antibody against all 5 additional types. Antibody titers were higher after the third dose than after the first dose. Antibody was not measured after the second dose.
  - In a cross study comparison, geometric antibody titers for the 5 additional types among persons who received 3 doses of 9-valent HPV vaccine after 3 doses of quadrivalent HPV vaccine were lower than those of persons who received 3 doses of 9-valent HPV vaccine without prior HPV vaccination. The significance of the lower antibody titers is not known because there is no immune correlate of protection.
- An immunogenicity trial of 2 doses of 9-valent HPV vaccine in HPV vaccine naïve persons is ongoing; results will be available within a year. In this trial, the 2 doses are separated by an interval of 6 or 12 months.
  - Results from this trial will not directly address additional 9-valent vaccination in persons who already received quadrivalent HPV vaccine.

What data are available on the safety of 9-valent HPV vaccination when administered after a complete 3-dose series of another HPV vaccine product?

- In a randomized trial, 9-valent HPV vaccine was compared with placebo in females aged 12-26 years who had previously received 3 doses of quadrivalent HPV vaccine. Among the 608 who received 9-valent HPV vaccine, there was an acceptable safety profile.
- Compared to persons in other studies who were vaccinated with 9-valent HPV vaccine and had never received any HPV vaccination, those who received 9-valent HPV vaccine after a 3-dose quadrivalent vaccine series had higher rates of injection site swelling and redness.
- 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.

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-adjusted life year (QALY) gained for giving 3 doses of 9-valent HPV vaccine to females aged 13-18 years who have received 3 doses of quadrivalent vaccine is over $100,000.
- The potential benefit would be lower and the cost per QALY gained higher in females older than 18 years and in males of any age.
- In contrast, models have estimated that routine 9-valent HPV vaccination in the United States would be cost-saving, compared with routine quadrivalent HPV vaccination.

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HPV Vaccine Information for Clinicians

CDC recommends HPV vaccination for girls and boys at ages 11 or 12 years to protect against cancers caused by HPV infections. CDC encourages clinicians to recommend HPV vaccination the same way and same day they recommend other routinely recommended vaccines for adolescents.

Background

Human papillomavirus (HPV) is a very common virus that infects epithelial tissue. More than 120 HPV types have been identified. Most HPV types infect cutaneous epithelial cells and cause common warts, such as those that occur on the hands and feet. Approximately 40 HPV types infect mucosal epithelial cells on the genitals, and the mouth and throat. Although most HPV infections are asymptomatic and resolve spontaneously or become undetectable, some HPV infections can persist and lead to cancer.

Persistent infections with high-risk (oncogenic) HPV types can cause cancers of the anus, cervix, penis, vulva, and vagina, as well as the oropharynx (defined as the back of the throat, including the base of the tongue and tonsils). The most common high-risk types are 16 and 18.

Infection with low-risk (non-oncogenic) HPV types can cause genital warts and rarely laryngeal papillomas. These types can also cause benign or low-grade cervical cell abnormalities. The most common low-risk HPV types are 6 and 11.

About 79 million Americans are infected with HPV, and roughly 14 million people become infected each year, mostly occurring among teens and young adults. Almost every person who is sexually active will acquire HPV at some time in their life.

Every year in the United States, an estimated 17,600 women and 9,300 men are diagnosed with a cancer caused by HPV.

Of the women diagnosed with an HPV cancer, cervical cancer is the most common with about 11,000 women diagnosed annually in the United States; subsequently about 4,400 women die every year from cervical cancer in our country.

Of the men in the United States diagnosed with an HPV cancer, oropharyngeal cancer is the most common. Around 7,200 U.S. men each year are diagnosed with oropharyngeal cancer caused by HPV infection. HPV infection and precancerous/dysplastic lesions of the oropharynx cannot be screened for, making prevention of infection a priority.

HPV Vaccines

Three HPV vaccines have been licensed by the U.S. Food and Drug Administration (FDA) since 2006. CDC recommends these HPV vaccines for routine use among girls and boys at ages 11 or 12. HPV vaccines are administered as a 3-dose series with doses given at 0, 1-2, and 6 months.

	Bivalent/2vHPV (Cervarix)	Quadrivalent/4vHPV (Gardasil)	9-valent/9vHPV (Gardasil 9)
Manufacturer	GlaxoSmithKline	Merck	Merck
Year Licensed	October 2009 - females	June 2006 - females; October 2009 - males	December 2014 - males and females
HPV types in vaccine	16 and 18	6, 11, 16, and 18	6, 11, 16, 18, 31, 33, 45, 52, and 58
Adjuvant in vaccine	AS04: 500 µg aluminum hydroxide 50 µg 3-*O*-desacyl-4′-monophosphoryl lipid A	AAHS: 225 µg amorphous aluminum hydroxyphosphate sulfate	AAHS: 500 µg amorphous aluminum hydroxyphosphate sulfate
Recommended for…	• Females ages 11-12 • Females ages 13 through 26 who have not been previously vaccinated	• Females and males ages 11-12 • Females ages 13 through 26 and males ages 13 through 21 who have not been previously vaccinated • Unvaccinated males ages 22 through 26 who have sex with men or who are immunocompromised	• Females and males ages 11-12 • Females ages 13 through 26 and males ages 13 through 21 who have not been previously vaccinated • Unvaccinated males ages 22 through 26 who have sex with men or who are immunocompromised
Contraindicated for…	• People with hypersensitivity to latex	• People with hypersensitivity to yeast	• People with hypersensitivity to yeast

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Bivalent, quadrivalent, and 9-valent HPV vaccine all protect against HPV 16 and 18, the HPV types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States. 9-valent HPV vaccine targets five additional cancer-causing types, which account for about 15% of cervical cancers (12). Quadrivalent and 9-valent HPV vaccine also protect against HPV 6 and 11, the HPV types that cause anogenital warts.

The additional five types in 9-valent HPV vaccine account for a higher proportion of HPV-associated cancers in women compared with men, and also cause cervical precancers in women. Therefore, the additional protection from 9-valent HPV vaccine will mostly benefit women.

HPV Vaccine Recommendations

HPV vaccine is routinely recommended for 11- or 12-year-old girls and boys. Any HPV vaccine can be given to girls. Either the quadrivalent or 9-valent HPV vaccine can be given to boys. Vaccination is also recommended for females ages 13 through 26 years and males ages 13 through 21 years who were not vaccinated when they were younger. Vaccination is also recommended for both men who have sex with men and men who are immunocompromised (including men with HIV infection) aged 22 through 26 years who were not vaccinated when they were younger.

Ideally, patients should be vaccinated before they are exposed to HPV. However, patients who have already been infected with one or more HPV types can still get protection from other HPV types in the vaccine that have not been acquired.

HPV vaccines can safely be given to…

- Patients with minor acute illnesses, such as diarrhea or mild upper respiratory tract infections, with or without fever.
- Women who have had an unclear or abnormal Pap test, a positive HPV test, or genital warts. However, these patients should be advised that the vaccine may not have any therapeutic effect on existing Pap test abnormalities, HPV infection, or genital warts.
- Patients who are immunocompromised, either from disease or medication. However, the immune response to vaccination and effectiveness of the vaccine might be less than in people with a normally functioning immune system.
- Women who are breastfeeding.

HPV vaccines <u>should not</u> be given to…

- Patients with a history of allergies to any vaccine component. Quadrivalent vaccine (4vHPV) is not recommended for people with a history of allergies to yeast. Bivalent vaccine (2vHPV) is not recommended for people with a life-threatening latex allergy.
- Patients with moderate or severe acute illnesses. In these cases, patients should wait until the illness improves before getting vaccinated.
- Pregnant women. However, the vaccine has not been linked to causing adverse pregnancy outcomes or possible side effects (adverse events) to the developing fetus.
  - If a woman is found to be pregnant after starting the HPV vaccine series, second and/or third doses should not be given until after delivery.
  - If a woman receives HPV vaccine and later learns that she is pregnant, there is no reason to be alarmed.
  - 9vHPV exposure during pregnancy <u>should</u> be reported to the Merck Pregnancy Registry at 1-800-986-8999.
  - 4vHPV exposure during pregnancy can be reported to Merck at 1-877-888-4231.
  - 2vHPV exposure during pregnancy <u>can</u> be reported to GlaxoSmithKline at telephone 1-888-825-5249.
  - 2vHPV exposure during pregnancy <u>can</u> be reported to GlaxoSmithKline at telephone 1-888-825-5249.

HPV Vaccine Safety

HPV vaccines are very safe. Scientific research shows the benefits of HPV vaccination far outweigh the potential risks. Like all medical interventions, vaccines can have some side effects. More than 80 million doses of HPV vaccine have been distributed since the vaccine was introduced in 2006. The most common side effects associated with HPV vaccines are mild, and include pain, redness, or swelling in the arm where the shot was given.

All vaccines used in the United States, including HPV vaccines, are required to go through years of extensive safety testing before they are licensed by the U.S. Food and Drug Administration (FDA). During clinical trials conducted before they were licensed:

- 9-valent HPV vaccine was studied in more than 15,000 males and females
- Quadrivalent HPV vaccine was studied in more than 29,000 males and females
- Bivalent HPV vaccine was studied in more than 30,000 females

Each HPV vaccine was found to be safe and effective.

Fainting (syncope) can occur after any medical procedure, including vaccination. Recent data suggest that syncope after any vaccination is more common in adolescents. Adolescents and adults should be seated or lying down during vaccination. Providers are encouraged to observe patients in seated or lying positions for 15 minutes after vaccination. This is to prevent any injuries that could occur from a fall during a syncopal event.

HPV Vaccine Effectiveness

The HPV vaccine works extremely well. In the four years after the vaccine was recommended in 2006 in the United States, quadrivalent type HPV infections in teen girls decreased by 56% and decreases in prevalence have also been observed in women in their early 20s. Research has also shown that fewer teens are getting genital warts since HPV vaccines have been in use in the United States. Decreases in vaccine-type prevalence, genital warts, and cervical dysplasia have also been observed in other countries with HPV vaccination programs.

There are no data to suggest HPV vaccines will treat existing diseases or conditions caused by HPV. However, people can still get protection from HPV types in the vaccine that have not been acquired.

Cervical cancer screening is recommended for women beginning at age 21 years and continuing through age 65 years. Women who have received the HPV vaccine series should still be screened for cervical cancer beginning at age 21 years, in accordance with currently published cervical cancer screening guidelines.

Duration of Vaccine Protection

Studies suggest that HPV vaccines offer long-lasting protection against HPV infection and therefore disease caused by HPV infection. Studies of the bivalent and quadrivalent vaccines have followed vaccinated individuals for eight to ten years and have found no evidence of protection decreasing over time. Duration of protection provided by HPV vaccination will continue to be studied.

HPV Vaccine Administration

HPV vaccines should be administered as a 3-dose series intramuscular injections given at 0, 1-2, and 6 months. The third dose should follow the first dose by at least 24 weeks.

While there is a minimum interval in the dosing schedule, there is no maximum interval. There is no reason to restart the vaccine series if the HPV vaccine schedule is interrupted; patients who have exceeded the minimum interval for the next dose by months or even years, may be given the next dose needed.

Vaccination of females is recommended with bivalent, quadrivalent (as long as this formulation is available), or 9-valent HPV vaccine. Vaccination of males is recommended with quadrivalent (as long as this formulation is available) or 9-valent HPV vaccine.

If vaccination providers do not know or do not have available the HPV vaccine product previously administered, or are in settings transitioning to 9-valent HPV vaccine, any available HPV vaccine product may be used to continue or complete the series for females for protection against HPV 16 and 18; 9vHPV or 4vHPV may be used to continue or complete the series for males. There are no data on efficacy or immunogenicity of fewer than 3 doses of 9vHPV.

HPV vaccine can safely be administered at the same visit as other vaccines recommended at ages 11 or 12 years, such as Tdap vaccine, quadrivalent meningococcal conjugate vaccine, and influenza vaccine. Administering all indicated vaccines at a single visit at ages 11 or 12 years increases the likelihood that patients receive their vaccinations on schedule.

As mentioned previously, patients should be observed for 15 minutes after receiving any shot, including HPV vaccine.

Paying for HPV Vaccine

As with all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), HPV vaccines are covered by insurance. For patients that need assistance paying for HPV vaccine, the Vaccines for Children (VFC) program may be able to help. VFC provides vaccines for children ages 18 years and younger who are uninsured, Medicaid-eligible, or American Indian/Alaska Native. Learn more about the VFC program at www.cdc.gov/Features/VFCprogram/.

Related Resources

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) 2015.

Markowitz L, Dunne EF, Saraiya M, Curtis RC, Gee J, Bocchini JA, et al. Human papillomavirus vaccination: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR. 2014 Aug 29; 63(rr05):1-30.

Provider Information: Gardasil® 9 VIS

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis.

Gardasil 9 is a 9-valent vaccine for prevention of disease caused by 9 types of human papillomavirus: HPV types 6, 11, 16, 18, 31, 33, 45, 52, & 58.

Gardasil (quadrivalent) contains types 6, 11, 16, & 18. At this time, both Gardasil and Gardasil 9 are available, and either may be used.

Gardasil 9 is recommended for **females** for the prevention of cervical, vulvar, vaginal and anal cancers and genital warts caused by these human papillomavirus types, and for **males** for the prevention of anal cancer and genital warts caused by these human papillomavirus types.

Burden of Disease Associated with HPV Vaccine Types

	HPV Type	Cervical Cancer	All HPV-Associated Cancers	Anogenital Warts	
Gardasil	6			90%	Gardasil 9
	11				
	16	66%	64%		
	18				
	31	15%	10%		
	33				
	45				
	52				
	58				

Gardasil 9 is approved by FDA for males and females 9 through 26 years of age. Note: Gardasil 9 was originally approved for males through age 15 only, and CDC's recommendations for vaccinating older males were off-label. But on December 14, 2015, FDA approved the vaccine for males through age 26.

Age Recommendations:

- **Age 11 or 12:** Recommended ages for routine vaccination.
- **Age 9 and 10:** May be given at the discretion of the provider.
- **Age 13 through 26 (females):** Recommended, if not given at the routine age.
- **Age 13 through 26 (males):**
  - Recommended for all males through age 21, if not given at routine age.
  - Recommended for MSM, males with immune deficiencies, and HIV-infected males (regardless of their immune status) through age 26.
  - *May* be given to all males through age 26.

Schedule:

The recommended schedule is **3 doses**

- **First Dose**: Any time during recommended age range.
  - Routinely recommended at 11-12 years of age.
- **Second Dose**: 1-2 months after the first.*
  - *Minimum interval* after first dose = 4 weeks.
- **Third Dose**: 6 months after the first.
  - *Minimum interval* after second dose = 12 weeks
  - *Minimum interval* after first dose = 6 months

  NOTE: The FDA-approved interval between the first and second doses of Gardasil 9 is **2 months. However, ACIP has harmonized the schedules for Gardasil, Gardasil 9 and Cervarix (for which the approved interval is 1 month), recommending that the 2nd dose may be given at either **1 or 2 months** after the 1st for any HPV vaccine.*
- Gardasil 9 may be given concurrently with other vaccines indicated during the same time frame.

Special Circumstances:

- People who started or completed a series with quadrivalent or bivalent HPV vaccine (Gardasil or Cervarix)
  - A person who has received one or two doses of another HPV vaccine may complete the series with Gardasil 9.
  - There is no recommendation at this time for administering Gardasil 9 to a person who has completed a 3-dose series with another HPV vaccine.
- Pregnant Women
  - Gardasil 9 is not recommended for use in pregnant women.
  - Pregnancy testing is not necessary before vaccination, but if a woman is found to be pregnant after the vaccine series has been initiated, the remaining doses should be delayed until after delivery. It is not necessary to restart the series.
  - If the vaccine is administered during pregnancy, no intervention is needed.
  - Women who receive Gardasil 9 around the time of conception or during pregnancy are encouraged to contact the manufacturer's Pregnancy Registry at 1-800-986-8999, to allow monitoring of outcomes of pregnant women exposed to the vaccine.
  - Published data have not found any safety concerns among pregnant women who have been inadvertently vaccinated.

Contraindications and Precautions

Contraindications:

- "The only contraindication applicable to all vaccines is a history of a severe allergic reaction (i.e., anaphylaxis) after a previous dose of [the] vaccine or to a vaccine component" (ACIP *General Recommendations on Immunization*). *Anaphylaxis following a dose of quadrivalent Gardasil is also a contraindication to Gardasil 9.*

  Components of the Gardasil 9, from the December 2014 package insert, are:
  - yeast protein
  - vitamins
  - amino acids
  - mineral salts
  - carbohydrates
  - amorphous aluminum hydroxyphosphate sulfate
  - L-histidine
  - polysorbate 80
  - sodium borate

  Gardasil 9 vials and syringes do not contain latex.

Precautions:

- "The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines." (ACIP *General Recommendations on Immunization*) The definition of "moderate or severe acute illness" is left to the clinical judgment of the provider. A vaccination deferred because of an acute illness should be rescheduled after the illness has resolved.

Safety

The vaccine was well-tolerated in clinical trials. The most common local and systemic adverse events after any dose of Gardasil 9 were injection-site related pain, swelling, erythema, headache, and pyrexia that were mild to moderate in intensity:

Adverse Event	Females 9-15 Years of Age	Females 16-26 Years of Age	Males 9-15 Years of Age
Pain	89%	90%	72%
Swelling	48%	40%	27%
Erythema	34%	34%	25%
Headache	11%	15%	9%
Temperature ≥100°F	7%	6%	10%
Temperature ≥102°F	1%	1%	-

Rates of adverse events can vary depending on which dose of the series is given. For a more detailed analysis of adverse events, see the manufacturer's package insert.

85 million doses of HPV vaccine were distributed in the US from June 2006 through September 2015. No new safety concerns were identified during post-licensure vaccine safety monitoring.

HPV vaccine safety findings are similar to those identified in safety reviews of meningococcal and Tdap vaccines.

Most commonly reported non-serious possible side effects are:

- Pain, redness, or swelling in the arm where the shot was given
- Fever
- Headache or feeling tired
- Nausea
- Fatigue
- Dizziness

A study was conducted through CDC's Vaccine Safety Datalink, looking at 9 conditions (Guillain-Barré syndrome, seizures, syncope, appendicitis, stroke, venous thromboembolism, anaphylaxis, and other allergic reactions). After 600,558 doses of (quadrivalent) Gardasil had been administered to females, no statistically significant associations were found among those who received HPV vaccination compared with those who were unvaccinated or who received other vaccines. Other large epidemiologic studies have been reassuring on the safety of HPV vaccines.

Some deaths among persons who received HPV vaccine have been reported to the Vaccine Adverse Event Reporting System (VAERS). All reports of death are reviewed by medical doctors at CDC or FDA. While not all death reports can be verified because not enough information was reported, detailed review of every report of death following of Gardasil vaccine has shown:

1. There is no pattern of death occurring with respect to time after vaccination.
2. There is no consistent vaccine dose number or combination of vaccines given.
3. There is no diagnosis at death that would suggest that the Gardasil vaccine caused the death.

Problems that could happen after any vaccine:

A 2012 Institute of Medicine report titled *Adverse Effects of Vaccines: Evidence and Causality* concluded that evidence supports a causal relation between injection of vaccines and both **syncope** and **deltoid bursitis**. In both cases, IOM determined that the injection itself, and not the contents of the vaccine, contributes to the development of these adverse events.

For more information, see the following ACIP recommendation:

"Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices" (March 27, 2015)
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6411a3.htm

"Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP)" (August 29, 2014)
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6305a1.htm

December, 2015

Human papillomavirus (HPV) is the most common sexually transmitted infection in the United States. The relationship of cervical cancer and sexual behavior was suspected for more than 100 years and was established by epidemiologic studies in the 1960s. In the early 1980s, cervical cancer cells were demonstrated to contain HPV DNA. Epidemiologic studies showing a consistent association between HPV and cervical cancer were published in the 1990s. The first vaccine to prevent infection with four types of HPV was licensed in 2006.

Human Papillomaviruses

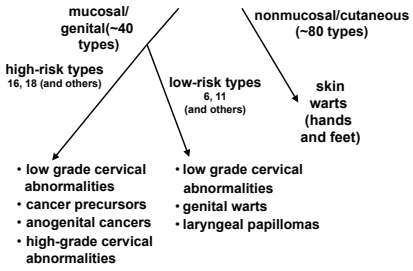
Human papillomaviruses are small, double-stranded DNA viruses that infect the epithelium. More than 120 HPV types have been identified; they are differentiated by the genetic sequence of the outer capsid protein L1. Most HPV types infect the cutaneous epithelium and can cause common skin warts. About 40 types infect the mucosal epithelium; these are categorized according to their epidemiologic association with cervical cancer. Infection with low-risk, or nononcogenic types, such as types 6 and 11, can cause benign or low-grade cervical cell abnormalities, genital warts and laryngeal papillomas. High-risk, or oncogenic, HPV types act as carcinogens in the development of cervical cancer and other anogenital cancers. High-risk types (currently including types 16 and 18, among others) can cause low-grade cervical cell abnormalities, high-grade cervical cell abnormalities that are precursors to cancer, and anogenital cancers. High-risk HPV types are detected in 99% of cervical cancers. Type 16 is the cause of approximately 50% of cervical cancers worldwide, and types 16 and 18 together account for about 70% of cervical cancers. Infection with a high-risk HPV type is considered necessary for the development of cervical cancer, but by itself it is not sufficient to cause cancer because the vast majority of women with HPV infection do not develop cancer.

In addition to cervical cancer, HPV infection is also associated with anogenital cancers less common than cervical cancer, such as cancer of the vulva, vagina, penis and anus. The association of genital types of HPV with non-genital cancers is less well established, but studies support a role for these HPV types in some oropharyngeal cancers.

Human Papillomaviruses (HPV)

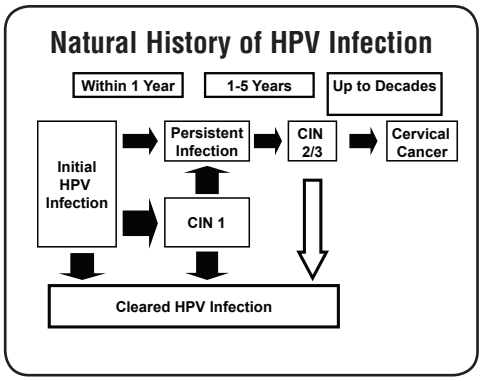
- Small DNA virus
- More than 120 types identified based on the genetic sequence of the outer capsid protein L1
- About 40 types infect the mucosal epithelium

Human Papillomavirus Types and Disease Association



Pathogenesis

HPV infection occurs at the basal epithelium. Although the incidence of infection is high, most infections resolve spontaneously. A small proportion of infected persons become persistently infected; persistent infection is the most important risk factor for the development of cervical cancer.



The most common clinically significant manifestation of persistent genital HPV infection is cervical intraepithelial neoplasia, or CIN. Within a few years of infection, low-grade CIN—called CIN 1—may develop, which may spontaneously resolve and the infection clear.

Persistent HPV infection, however, may progress directly to higher-grade CIN, called CIN2 or CIN3. High-grade abnormalities are at risk of progression to cancer and so are considered cancer precursors. Some high-grade abnormalities spontaneously regress. If left undetected and untreated, years or decades later CIN2 or 3 can progress to cervical cancer.

Infection with one type of HPV does not prevent infection with another type. Of persons infected with mucosal HPV, 5% to 30% are infected with multiple types of the virus.

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 oropharyngeal cancer)

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), and cancers, including cervical, anal, vaginal, vulvar, penile, and oropharyngeal cancer.

Laboratory Diagnosis

HPV has not been cultured by conventional methods. Infection is identified by detection of HPV DNA from clinical samples. Assays for HPV detection differ considerably in their sensitivity and type specificity, and detection is also affected by the anatomic region sampled as well as the method of specimen collection.

Several HPV tests have been approved by the Food and Drug Administration (FDA) and detect 13-14 high-risk types (HPV 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68). Test results are reported as positive or negative for any of the types; some tests specifically identify HPV 16 and 18. These tests are approved for triage of Papanicolaou (Pap) test results (ASC-US, atypical cells of undetermined significance) and in combination with the Pap test for cervical cancer screening in women 30 years of age and older. The tests are not clinically indicated nor approved for use in men.

Epidemiologic and basic research studies of HPV generally use nucleic acid amplification methods that generate type-specific results. The polymerase chain reaction (PCR) assays used most commonly in epidemiologic studies target genetically conserved regions in the L1 gene.

The most frequently used HPV serologic assays are virus-like particle (VLP)-based enzyme immunoassays. However, laboratory reagents used for these assays are not standardized and there are no standards for setting a threshold for a positive result.

Medical Management

There is no specific treatment for HPV infection. Medical management depends on treatment of the specific clinical manifestation of the infection (such as genital warts or abnormal cervical cell cytology).

Epidemiology

Occurrence

HPV infection occurs throughout the world.

HPV Epidemiology

- Reservoir
  - Human
- Transmission
  - Direct contact, usually sexual
- Temporal pattern
  - None
- Communicability
  - Presumed to be high

Reservoir

Viruses in the papillomavirus family affect other species. Humans are the only natural reservoir of HPV.

Transmission

HPV is transmitted by direct contact, usually sexual, with an infected person. Transmission occurs most frequently with sexual intercourse but can occur following nonpenetrative sexual activity.

Studies of newly acquired HPV infection demonstrate that infection occurs soon after onset of sexual activity. In a prospective study of college women, the cumulative incidence of infection was 40% by 24 months after first sexual intercourse. HPV 16 accounted for 10.4% of infections.

Genital HPV infection also may be transmitted by nonsexual routes, but this appears to be uncommon. Nonsexual routes of genital HPV transmission include transmission from a woman to a newborn infant at the time of birth.

Temporal Pattern

There is no known seasonal variation in HPV infection.

Communicability

HPV is presumably communicable during the acute infection and during persistent infection. This issue is difficult to study because of the inability to culture the virus. Communicability can be presumed to be high because of the large number of new infections estimated to occur each year.

Risk Factors

Risk factors for HPV infection are primarily related to sexual behavior, including lifetime and recent sex partners. Results of epidemiologic studies are less consistent for other risk factors, including young age at sexual initiation, number of pregnancies, genetic factors, smoking, and lack of circumcision of male partner.

Disease Burden in the United States

HPV Disease Burden in the United States

- Anogenital HPV is the most common sexually transmitted infection in the US
  - estimated 79 million infected
  - 14 million new infections/ year
- Common among adolescents and young adults

Anogenital HPV infection is believed to be the most common sexually transmitted infection in the United States. An estimated 79 million persons are infected, and an estimated 14 million new HPV infections occur annually with half of these in persons 15-24 years.

The two most common types of cervical cancer worldwide, squamous cell carcinoma followed by adenocarcinoma, are both caused by HPV. The CDC and National Cancer Institute's United States Cancer Statistics Working Group reports that from 2005 through 2009 there were annual averages of 12,595 cases and 3,968 deaths due to cervical cancer. HPV is believed to be responsible for nearly all of these cases of cervical cancer. HPV types 16 and 18 are associated with 70% of these cancers.

In addition to cervical cancer, HPV is believed to be responsible for 90% of anal cancers, 71% of vulvar, vaginal, or penile cancers, and 72% of oropharyngeal cancers.

Population-based estimates, primarily from clinics treating persons with sexually transmitted infections, indicate that about 1% of the sexually active adolescent and adult population in the United States have clinically apparent genital warts. More than 90% of cases of anogenital warts are associated with the low-risk HPV types 6 and 11.

About 8 billion dollars are spent annually on management of sequelae of HPV infections, primarily for the management of abnormal cervical cytology and treatment of cervical neoplasia. This exceeds the economic burden of any other sexually transmitted infection except human immunodeficiency virus.

Prevention

HPV Infection

HPV transmission can be reduced but not eliminated with the use of physical barriers such as condoms. Recent studies demonstrated a significant reduction in HPV infection among young women after initiation of sexual activity when their partners used condoms consistently and correctly.

Abstaining from sexual activity (i.e., refraining from any genital contact with another individual) is the surest way to prevent genital HPV infection. For those who choose to be sexually active, a monogamous relationship with an uninfected partner is the strategy most likely to prevent future genital HPV infections.

Cervical Cancer Screening

Most cases and deaths from cervical cancer can be prevented through detection of precancerous changes within the cervix by cervical cytology using the Pap test. Currently available Pap test screening can be done by a conventional Pap or a liquid-based cytology. CDC does not issue recommendations for cervical cancer screening, but various professional groups have published recommendations. Cervical cancer screening recommendations were revised in 2012 after the U.S. Preventive Services Task Force (USPSTF) and a multidisciplinary group, including the American Cancer Society (ASC), American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) reviewed new evidence. Previously, recommendations varied by organization. Since 2012, all organizations have recommended that screening should begin at age 21 years. While there are slight differences in other aspects of the recommendations, all groups recommend screening in women aged 21 to 65 years with cytology (Pap test) every 3 years. For women aged 30 to 65 years who want to lengthen the screening interval, screening can be done with a combination of cytology and HPV testing ("co-testing") every 5 years.

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

The use of HPV vaccine does not eliminate the need for continued Pap test screening, since 30% of cervical cancers are caused by HPV types not included in the vaccine.

Human Papillomavirus Vaccine

Characteristics

Three HPV vaccines are licensed in the United States. The vaccines are non-infectious subunit vaccines. The antigen for the vaccines is the L1 major capsid protein of HPV, produced by using recombinant DNA technology. L1 proteins self-assemble into noninfectious, nononcogenic units called virus-like particles (VLP).

Quadrivalent HPV (HPV4) vaccine (Gardasil, Merck) was approved by the FDA in June 2006. The vaccine is approved for females and males 9 through 26 years of age. Each 0.5-mL dose of HPV4 contains 20 micrograms HPV 6 L1 protein, 40 micrograms HPV 11 L1 protein, 40 micrograms HPV 16 L1 protein, and 20 micrograms HPV 18 L1 protein. The vaccine antigen is adsorbed on alum adjuvant.

Human Papillomavirus Vaccine

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

HPV Vaccines

- HPV4 (Gardasil, Merck)
  - approved for females and males 9 through 26 years of age
  - contains types 16 and 18 (high risk) and types 6 and 11 (low risk)
- a 9-valent vaccine licensed in December 2014
- HPV2 (Cervarix, GlaxoSmithKline)
  - approved for females 9 through 25 years of age
  - contains types 16 and 18 (high risk)

The vaccine also includes sodium chloride, L-histidine, polysorbate 80, and sodium borate. HPV4 does not contain a preservative or antibiotic. The vaccine is supplied in single-dose vials and syringes. A 9-valent vaccine (Merck) was approved by the FDA in December 2014.

Bivalent HPV (HPV2) vaccine (Cervarix, GlaxoSmithKline) was approved by the FDA in October 2009. The vaccine is approved for females 9 through 25 years of age. HPV2 is not approved for males. The L1 antigen is adsorbed onto aluminum hydroxide. The unique adjuvant system, AS04, is composed of 3-O-desacyl-4'-monophosphoryl lipid A (MPL) adsorbed onto aluminum hydroxide. Each 0.5-mL dose contains 20 micrograms of HPV type 16 L1 protein and 20 micrograms of HPV type 18 L1 protein. HPV2 does not contain a preservative or antibiotic. It is available in 2 types of prefilled syringes.

Immunogenicity and Vaccine Efficacy

HPV vaccines are highly immunogenic. More than 99% of recipients develop an antibody response to HPV types included in the respective vaccines 1 month after completing the three-dose series. However, there is no known serologic correlate of immunity and no known minimal titer determined to be protective. The high efficacy found in the clinical trials to date has precluded identification of a minimum protective antibody titer. Further follow-up of vaccinated cohorts may allow determination of serologic correlates of immunity in the future.

Both HPV vaccines have been found to have high efficacy for prevention of HPV vaccine type–related persistent infection, CIN 2/3 and adenocarcinoma in-situ (AIS). Clinical efficacy for HPV4 against cervical disease was determined in two double-blind, placebo-controlled trials. In women 16 through 26 years of age vaccine efficacy for HPV 16 or 18–related CIN 2/3 or AIS was 97%. HPV4 efficacy against HPV 6, 11, 16 or 18–related genital warts was 99%.

HPV2 efficacy was evaluated in two randomized, double-blind, controlled clinical trials in females aged 15 through 25 years. In the phase III trial, efficacy against HPV 16 or 18-related CIN 2/3 or AIS was 93%.

HPV4 was evaluated in men 16 through 26 years and found to have 88% efficacy against vaccine type genital warts. Among men who have sex with men (MSM), efficacy against anal intraepithelial neoplasia grade 2 or 3 (AIN2/3) was 75%.

Although high efficacy among persons without evidence of infection with vaccine HPV types was demonstrated in clinical trials of both HPV vaccines, there is no evidence of

efficacy against disease caused by vaccine types with which participants were infected at the time of vaccination (i.e., the vaccines had no therapeutic effect on existing infection or disease). Participants infected with one or more vaccine HPV types prior to vaccination were protected against disease caused by the other vaccine types. Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types.

The duration of protection following HPV vaccine is not known. For both vaccines a subset of participants have been followed for more than 60 months with no evidence of waning protection. Study populations will continue to be followed for any evidence of waning immunity.

HPV Vaccine Efficacy

- High efficacy among females without evidence of infection with vaccine HPV types
- No evidence of efficacy against disease caused by vaccine types with which participants were infected at the time of vaccination
- Prior infection with one HPV type did not diminish efficacy of the vaccine against other vaccine HPV types

Vaccination Schedule and Use

ACIP recommends vaccination of females with HPV2 or HPV4 for prevention of cervical cancers and precancers. HPV4 is recommended also for prevention of genital warts. ACIP recommends routine vaccination at age 11 or 12 years with HPV4 or HPV2 for females and with HPV4 for males. The vaccination series can be started beginning at age 9 years.

HPV4 and HPV2 are each administered in a 3-dose series. The second dose should be administered 1 to 2 months after the first dose and the third dose 6 months after the first dose. Vaccination also is recommended for females aged 13 through 26 years and for males aged 13 through 21 years, who have not been previously vaccinated or who have not completed the 3-dose series. For immunocompromised males (including HIV infection) and men who have sex with men, ACIP recommends routine vaccination with HPV4, as for all males, through 26 years of age for those who have not been vaccinated previously or who have not completed the 3-dose series. Males aged 22 through 26 years without these risk factors may be vaccinated as well. HPV2 is neither licensed nor recommended for males.

If females or males reach age 27 years before the vaccination series is complete, the second and/or third doses of vaccine can be administered after age 26 to complete the vaccination series.

Prevaccination assessments (e.g., Pap testing or screening for high-risk HPV DNA, type-specific HPV tests, or HPV antibody) to establish the appropriateness of HPV vaccination are not recommended.

Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, persons who may have already been exposed to HPV should be

HPV Vaccination Recommendations

- ACIP recommends routine vaccination at age 11 or 12 years with HPV4 or HPV2 for females and HPV 4 for males
- The vaccination series can be started as young as 9 years of age
- Vaccination also recommended for females 13 through 26 years of age
- Vaccination also recommended for males 13 through 21 years of age
- All immunocompromised males (including HIV infection) and MSM through 26 years of age should be vaccinated
- Males aged 22 through 26 years may be vaccinated

vaccinated. Sexually active persons who have not been infected with any of the HPV vaccine types will receive full benefit from vaccination. Vaccination will provide less benefit to persons if they have already been infected with one or more of the HPV vaccine types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk of HPV infection may continue as long as persons are sexually active. Pap testing or screening for HPV DNA or HPV antibody is not recommended prior to vaccination at any age.

Both HPV vaccines are administered in a three-dose series of intramuscular injections. The second and third doses should be administered 1 to 2 and 6 months after the first dose. The third dose should follow the first dose by at least 24 weeks. The third dose need not be repeated as long as it was administered at least 16 weeks after the first dose and at least 12 weeks after the second dose. An accelerated schedule for HPV vaccine is not recommended.

HPV Vaccination Schedule

- Routine schedule is 0, 1 to 2, 6 months
- An accelerated schedule using minimum intervals is not recommended
- Series does not need to be restarted if the schedule is interrupted
- Prevaccination assessments not recommended
- No therapeutic effect on HPV infection, genital warts, cervical lesions

There is no maximum interval between doses. If the HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If only the third dose is delayed, it should be administered as soon as possible.

Whenever feasible, the same HPV vaccine should be used for the entire vaccination series. No studies address interchangeability of HPV vaccines. However, if the vaccine provider does not know or have available the HPV vaccine product previously administered, either HPV vaccine can be used to complete the series to provide protection against HPV 16 and 18. For protection against HPV 6 or 11-related genital warts, a vaccination series with fewer than 3 doses of HPV4 might provide less protection than a complete 3-dose HPV4 series.

HPV vaccine should be administered at the same visit as other age-appropriate vaccines, such as Tdap and quadrivalent meningococcal conjugate (MCV4) vaccines. Administering all indicated vaccines at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine should be administered using a separate syringe at a different anatomic site.

As mentioned, prevaccination assessments (e.g. Pap testing or screening for high-risk HPV DNA, type-specific HPV tests, or HPV antibody) to establish the appropriateness

of HPV vaccination are not recommended at any age. HPV vaccination can provide protection against infection with HPV vaccine types not already acquired. Therefore, vaccination is recommended through the recommended age for females regardless of whether they have an abnormal pap test result, and for females or males regardless of known HPV infection.

Women should be advised that the vaccine will not have a therapeutic effect on existing HPV infection, genital warts or cervical lesions.

A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, these persons may be infected with HPV types other than the HPV4 vaccine types, and therefore they may receive HPV4 vaccine if they are in the recommended age group. Persons with a history of genital warts should be advised that data do not indicate HPV4 vaccine will have any therapeutic effect on existing HPV infection or genital warts.

Because HPV vaccines are subunit vaccines, they can be administered to persons who are immunosuppressed because of disease or medications. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent. Women who are breastfeeding may receive HPV vaccine.

Contraindications and Precautions to Vaccination

A severe allergic reaction (e.g., anaphylaxis) to a vaccine component or following a prior dose of HPV vaccine is a contraindication to receipt of HPV vaccine. Anaphylactic allergy to latex is a contraindication to bivalent HPV vaccine in a prefilled syringe since the tip cap contains natural rubber latex. A moderate or severe acute illness is a precaution to vaccination, and vaccination should be deferred until symptoms of the acute illness improve. A minor acute illness (e.g., diarrhea or mild upper respiratory tract infection, with or without fever) is not a reason to defer vaccination.

HPV vaccine is not recommended for use during pregnancy. The vaccine has not been causally associated with adverse pregnancy outcomes or with adverse effects on the developing fetus, but data on vaccination during pregnancy are limited. Pregnancy testing before vaccination is not needed. However, if a woman is found to be pregnant after initiation of the vaccination series, the remainder of the series should be delayed until after completion of the

HPV 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)

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 may be reported to the respective manufacturer

HPV Vaccine Adverse Reactions

- Local reactions (pain, redness, swelling)
  - 20%-90%
- Fever (100°F)
  - 10%-13%*
- No serious adverse reactions associated with either vaccine

*similar to reports in placebo recipients

pregnancy. No intervention is indicated. Women known to be pregnant should delay initiation of the vaccine series until after delivery.

Pregnancy registries for both HPV2 and HPV4 have been terminated. However, vaccination with either vaccine during pregnancy may still be reported to VAERS or to the manufacturer: GlaxoSmithKline at 1-888-825-5249 (for HPV2), or Merck at 1-877-888-4231 (for HPV4).

Adverse Reactions Following Vaccination

The most common adverse reactions reported during clinical trials of HPV vaccines were local reactions at the site of injection. In prelicensure clinical trials, local reactions, such as pain, redness or swelling were reported by 20% to 90% of recipients. A temperature of 100°F during the 15 days after vaccination was reported in 10% to 13% of recipients of either vaccine. A similar proportion of placebo recipients reported an elevated temperature. Local reactions generally increased in frequency with increasing doses. However, reports of fever did not increase significantly with increasing doses. No serious adverse events have been associated with either HPV vaccine based on monitoring by CDC and the Food and Drug Administration.

A variety of systemic adverse reactions were reported by vaccine recipients, including nausea, dizziness, myalgia and malaise. However, these symptoms occurred with equal frequency among both vaccine and placebo recipients.

Syncope has been reported among adolescents who received HPV and other vaccines recommended for this age group (Tdap, MCV4). Recipients should always be seated during vaccine administration. Clinicians should consider observing recipient for 15 minutes after vaccination.

Vaccine Storage and Handling

HPV vaccines should be maintained at refrigerator temperature between 35°F and 46°F (2°C and 8°C). Manufacturer package inserts contain additional information and can be found at http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093830.htm. For complete information on best practices and recommendations please refer to CDC's Vaccine Storage and Handling Toolkit, http://www.cdc.gov/vaccines/recs/storage/toolkit/storage-handling-toolkit.pdf.

Acknowledgment

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Addressing Parents' Top Questions about HPV VACCINE

Parents may be interested in vaccinating, yet still have questions. Some parents might just need additional information from you, the clinician they trust. Taking the time to answer their questions and address their concerns can help parents to accept a recommendation for HPV vaccination.

WHEN PARENTS SAY:	TRY SAYING:
Why does my child need the HPV vaccine?	HPV vaccine is important because it prevents certain cancers. Cervical, vaginal and vulvar cancers in females and anal cancer in both males and females. That is why I recommend that he/she be vaccinated today.
What diseases are caused by HPV?	Certain types of HPV can cause cervical, vaginal, and vulvar cancers in females and anal cancer in both males and females. We can help prevent this, and I recommend we start the HPV vaccine series for your child today.
Is my child really at risk for HPV?	HPV is a widespread virus that infects males and females. We can help protect your child from HPV-related cancers and diseases by starting HPV vaccine today.
Why do they need HPV vaccine at such a young age?	With every vaccine, it is important to vaccinate before exposure and we can't predict when exposure might occur. Like other vaccines, the HPV vaccine works to help prevent disease when given before there is any contact with the virus. This is why we need to start protecting with HPV vaccine today.
I have some concerns about the safety of the vaccine—I keep reading things online that says HPV vaccination isn't safe. Do you really know if it's safe?	I know there are stories in the media and online about vaccines, and I can see how that could concern you. However, I want you to know that HPV vaccine has been carefully studied for many years by medical and scientific experts. HPV vaccine is very safe, and it is effective at protecting against some HPV types that cause cancer.Vaccines, like any medication, can cause side effects. With HPV vaccination this can include pain, swelling and redness where you got the shot as well as headache.
Could HPV vaccine cause my child to have problems with infertility?	There is no data available to suggest that getting HPV vaccine will have an effect on future fertility.
I'm just worried that my child will perceive this as a green light to have sex.	Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.
How do you know if the vaccine works?	In clinical trials, the vaccine was shown to be very effective at helping to prevent certain HPV-related cancers and diseases.
Why do boys need HPV vaccine?	HPV infection can cause cancers of the anus in men and it can also cause genital warts in men. HPV vaccine can help prevent these diseases in men.
Would you get HPV vaccine for your kids?	Yes, I have given HPV vaccine to my child (or grandchild, etc) because I believe in the importance of this vaccine for preventing against certain cancers. The American Academy of Pediatrics, cancer doctors, and the CDC, also agree that getting the HPV vaccine is very important for your child.

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Jan 2016

Screening Checklist for Contraindications to HPV, MenACWY, MenB, and Tdap Vaccines for Teens

YOUR NAME _____

DATE OF BIRTH ____ / ____ / ____
month day year

For parents/guardians: The following questions will help us determine if human papillomavirus (HPV), meningococcal conjugate (MenACWY), meningococcal serogroup B (MenB), and tetanus, diphtheria, and acellular pertussis (Tdap) vaccines may be given to your teen today. If you answer "yes" to any question, it does not necessarily mean your teen should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

	yes	no	don't know
1. Is your teen sick today?	☐	☐	☐
2. Does your teen have allergies to a vaccine component or to latex?	☐	☐	☐
3. Has your teen had a serious reaction to a vaccine in the past?	☐	☐	☐
4. Has your teen had brain or other nervous system problems?	☐	☐	☐
5. For females: Is your teen pregnant?	☐	☐	☐

FORM COMPLETED BY _____ DATE _____

FORM REVIEWED BY _____ DATE _____

Did you bring your teen's immunization record card with you? **yes** ☐ **no** ☐

It is important to have a personal record of your teen's vaccinations. If you don't have one, ask your healthcare provider to give you one with all of your teen's vaccinations on it. Keep it in a safe place and be sure your teen carries it every time he/she seeks medical care. Your teen will likely need this document to enter school or college, for employment, or for international travel.

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Information for Healthcare Professionals about the Screening Checklist for Contraindications to HPV, MenACWY, MenB, and Tdap Vaccines for Teens

Are you interested in knowing why we included a certain question on the screening checklist? If so, read the information below. If you want to find out even more, consult the references listed at the end.

1. Is your teen sick today?
(This question applies to HPV, MenACWY, MenB, Tdap.)

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events.[1,2] However, all vaccines should be delayed until a moderate or severe acute illness has improved. Mild illnesses (such as otitis media, upper respiratory infections, and diarrhea) are NOT contraindications or precautions to vaccination. Do not withhold vaccination if a teen is taking antibiotics unless he/she is moderately or severely ill.

2. Does your teen have allergies to a vaccine component or to latex?
(This question applies to HPV, MenACWY, MenB, Tdap.)

A delayed-type local reaction following a prior vaccine dose is not a contraindication to a subsequent dose. History of severe allergy to a vaccine component occurs in minutes to hours, requires medical attention, and is a contraindication. For a table of vaccine components, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf. For a table of vaccines supplied in vials or syringes that contain latex, go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latex-table.pdf.

3. Has your teen had a serious reaction to a vaccine in the past?
(This question applies to HPV, MenACWY, MenB, Tdap.)

A local reaction following a prior vaccine dose is not a contraindication to a subsequent dose. However, history of an anaphylactic reaction (hives, swelling of the lips or tongue, acute respiratory distress, or collapse) following a previous dose of vaccine or vaccine component is a contraindication for subsequent doses.[1]

4. Has the teen had brain or other nervous system problems?
(This question applies to Tdap.)

Tdap is contraindicated in teens who have a history of encephalopathy within 7 days following DTP/DTaP. An unstable progressive neurologic problem is a precaution to the use of Tdap. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit of vaccinating outweighs the risk (e.g., during a community pertussis outbreak). For teens with stable neurologic disorders (including seizures) unrelated to vaccination, or for those with a family history of seizures, vaccinate as usual. A history of Guillain-Barré syndrome (GBS) is a consideration with Td or Tdap: if GBS occurred within 6 weeks of receipt of a tetanus-containing vaccine and a decision is made to continue vaccination, give age-appropriate Tdap instead of Td if there is no history of a prior Tdap dose, to improve pertussis protection.

5. For females; Is your teen pregnant?
(This question applies to HPV.)

Teens who are pregnant should not be given HPV vaccine. However, pregnancy is not a contraindication or precaution for administering Tdap, MenACWY, or MenB vaccine.

REFERENCES

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2. AAP. *Red Book: Report of the Committee on Infectious Diseases* at www.aapredbook.org.

Medical Management of Vaccine Reactions in Children and Teens

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered. Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). If reactions occur, staff should be prepared with procedures for their management. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Children and Teens" on the next page for detailed steps to follow in treating anaphylaxis.

CONTINUED ON NEXT PAGE ▶

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Needed medications for a community immunization clinic

FIRST-LINE medication

☐ **Epinephrine**, aqueous 1:1000 dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine auto-injectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available (both pediatric and adult formulations).

Optional medication: H_1 antihistamines

☐ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).

☐ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 10 mg or 25 mg tablets, or 25 mg capsules).

Needed supplies for a community immunization clinic

☐ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.

☐ Alcohol wipes

☐ Tourniquet

☐ Pediatric and adult airways (small, medium, and large)

☐ Pediatric and adult size pocket masks with one-way valve

☐ Oxygen (if available)

☐ Stethoscope

☐ Sphygmomanometer (blood pressure measuring device) with child, adult, and extra-large cuffs

☐ Tongue depressors

☐ Flashlight with extra batteries (for examination of the mouth and throat)

☐ Wristwatch with a second hand or other timing device

☐ Cell phone or access to onsite phone

Emergency medical protocol for management of anaphylactic reactions in children and teens

1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient.

3 **DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**

a **First-line treatment:** Administer aqueous **epinephrine** 1:1000 dilution (i.e., 1 mg/mL) intramuscularly; the standard dose is 0.01 mg/kg body weight, up to 0.5 mg maximum single dose in children and adolescents. See dosing chart on page 3.

b **Optional treatment: H_1 antihistamines** for hives or itching, you may also administer **diphenhydramine** (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg body weight, up to 50 mg maximum dose in children and adolescents*) or **hydroxyzine** (orally; the standard dose is 0.5–1 mg/kg/dose up to 50–100 mg maximum per day in children and adolescents). See dosing charts on page 3.

* According to AAP's *Red Book*, for children age ≥12 years, the diphenhydramine maximum single dose is 100 mg.

4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.

6 Record all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information.

7 Notify the patient's primary care physician.

CONTINUED ON NEXT PAGE ▶

These standing orders for the medical management of vaccine reactions in child and teenage patients shall remain in effect for patients of the _____ until rescinded or until _____
NAME OF CLINIC DATE

_____ _____
MEDICAL DIRECTOR'S SIGNATURE DATE OF SIGNING

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For your convenience, approximate dosages based on weight and age are provided in the following charts. Please confirm that you are administering the correct dose for your patient.

First-Line Treatment: Epinephrine

Recommended dose is 0.01 mg/kg body weight up to 0.5 mg maximum dose. May be repeated every 5–15 minutes for a total of 3 doses.

	Age group	Range of weight (lb)	Range of weight (kg)*	Epinephrine Dose: 1 mg/mL injectable (1:1000 dilution); intramuscular Minimum dose: 0.05 mL	Epinephrine Dose: Epinephrine auto-injector, 0.15 mg or 0.3 mg
Infants and children	1–6 months	9–19 lb	4–8.5 kg	0.05 mL (or mg)	off label
	7–36 months	20–32 lb	9–14.5 kg	0.1 mL (or mg)	off label
	37–59 months	33–39 lb	15–17.5 kg	0.15 mL (or mg)	0.15 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	0.2–0.25 mL (or mg)	0.15 mg/dose
	8–10 years	57–76 lb	26–34.5 kg	0.25–0.3 mL (or mg)	0.15 mg or 0.3 mg/dose
Teens	11–12 years	77–99 lb	35–45 kg	0.35–0.4 mL (or mg)	0.3 mg/dose
	13 years & older	100+ lb	46+ kg	0.5 mL (or mg) – max. dose	0.3 mg/dose

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* *Rounded weight at the 50th percentile for each age range*

Optional Treatment: Diphenhydramine

▶ **commonly known as Benadryl**

Recommended dose is 1–2 mg/kg body weight every 4–6 hrs

	Age group	Range of weight (lb)	Range of weight (kg)*	Diphenhydramine Dose: Liquid: 12.5 mg/5 mL Tablets: 25 mg or 50 mg Injectable: 50 mg/mL (IV or IM)
Infants and children	7–36 months	20–32 lb	9–14.5 kg	10–15 mg/dose
	37–59 months	33–39 lb	15–17.5 kg	15–20 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	20–25 mg/dose
	8–12 years	57–99 lb	26–45 kg	25–50 mg/dose†
Teens	13 years & older	100+ lb	46+ kg	50 mg/dose (up to 50 mg or 100 mg† single dose)

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* *Rounded weight at the 50th percentile for each age range*

† According to AAP's *Red Book*, for children age ≥12 years, the diphenhydramine maximum single dose is 100 mg.

Optional Treatment: Hydroxyzine

▶ **commonly known as Atarax, Vistaril**

Recommended oral dose is 0.5–1 mg/kg body weight every 4–6 hrs

	Age group	Range of weight (lb)	Range of weight (kg)*	Hydroxyzine Dose: Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg
Infants and children	7–36 months	20–32 lb	9–14.5 kg	5–7.5 mg/dose
	37–59 months	33–39 lb	15–17.5 kg	7.5–10 mg/dose
	5–7 years	40–56 lb	18–25.5 kg	10–12.5 mg/dose
	8–10 years	57–76 lb	26–34.5 kg	12.5–15 mg/dose
Teens	11–12 years	77–99 lb	35–45 kg	15–25 mg/dose
	13 years & older	100+ lb	46+ kg	25 mg/dose (50–100 mg, maximum per day)

NOTE: If body weight is known, then dosing by weight is preferred. If weight is not known or not readily available, dosing by age is appropriate.

* *Rounded weight at the 50th percentile for each age range*

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Administering Vaccines:
Dose, Route, Site, and Needle Size

Vaccine	Dose	Route
Diphtheria, Tetanus, Pertussis (DTaP, DT, Tdap, Td)	0.5 mL	IM
***Haemophilus influenzae* type b** (Hib)	0.5 mL	IM
Hepatitis A (HepA)	≤18 yrs: 0.5 mL	IM
	≥19 yrs: 1.0 mL	
Hepatitis B (HepB) *Persons 11–15 yrs may be given Recombivax HB (Merck) 1.0 mL adult formulation on a 2-dose schedule.*	≤19 yrs: 0.5 mL	IM
	≥20 yrs: 1.0 mL	
Human papillomavirus (HPV)	0.5 mL	IM
Influenza, live attenuated (LAIV)	0.2 mL (0.1 mL in each nostril)	Intranasal spray
Influenza, inactivated (IIV); **recombinant** (RIV), for ages 18 years and older	6–35 mos: 0.25 mL	IM
	≥3 yrs: 0.5 mL	
Influenza (IIV) **Fluzone Intradermal,** for ages 18 through 64 years	0.1 mL	ID
Measles, Mumps, Rubella (MMR)	0.5 mL	Subcut
Meningococcal conjugate (MCV4 [MenACWY])	0.5 mL	IM
Meningococcal serogroup B (MenB)	0.5 mL	IM
Meningococcal polysaccharide (MPSV)	0.5 mL	Subcut
Pneumococcal conjugate (PCV)	0.5 mL	IM
Pneumococcal polysaccharide (PPSV)	0.5 mL	IM or Subcut
Polio, inactivated (IPV)	0.5 mL	IM or Subcut
Rotavirus (RV)	Rotarix: 1.0 mL	Oral
	Rotateq: 2.0 mL	
Varicella (Var)	0.5 mL	Subcut
Zoster (Zos)	0.65 mL	Subcut
Combination Vaccines		
DTaP-HepB-IPV (Pediarix) DTaP-IPV/Hib (Pentacel) DTaP-IPV (Kinrix; Quadracel) Hib-HepB (Comvax) Hib-MenCY (MenHibrix)	0.5 mL	IM
MMRV (ProQuad)	≤12 yrs: 0.5 mL	Subcut
HepA-HepB (Twinrix)	≥18 yrs: 1.0 mL	IM

Injection Site and Needle Size

Subcutaneous (Subcut) injection

Use a 23–25 gauge needle. Choose the injection site that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Infants (1–12 mos)	5/8"	Fatty tissue over anterolateral thigh muscle
Children 12 mos or older, adolescents, and adults	5/8"	Fatty tissue over anterolateral thigh muscle or fatty tissue over triceps

Intramuscular (IM) injection

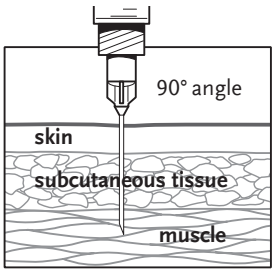
Use a 22–25 gauge needle. Choose the injection site and needle length that is appropriate to the person's age and body mass.

AGE	NEEDLE LENGTH	INJECTION SITE
Newborns (1st 28 days)	5/8"	Anterolateral thigh muscle
Infants (1–12 mos)	1"	Anterolateral thigh muscle
Toddlers (1–2 years)	1–1¼" 5/8–1"	Anterolateral thigh muscle or deltoid muscle of arm
Children and teens (3–18 years)	5/8–1"* 1–1¼"	Deltoid mucle of arm or anterolateral thigh muscle
Adults 19 years or older		
Female or male <130 lbs	5/8–1"*	Deltoid muscle of arm
Female or male 130–152 lbs	1"	Deltoid muscle of arm
Female 153–200 lbs Male 130–260 lbs	1–1½"	Deltoid muscle of arm
Female 200+ lbs Male 260+ lbs	1½"	Deltoid muscle of arm

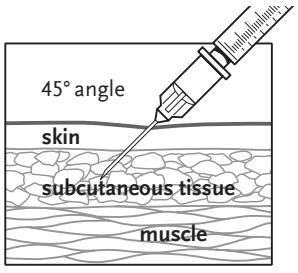
* A 5/8" needle may be used for patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle **only** if the skin stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle.

NOTE: Always refer to the package insert included with each biologic for complete vaccine administration information. CDC's Advisory Committee on Immunization Practices (ACIP) recommendations for the particular vaccine should be reviewed as well. Access the ACIP recommendations at www.immunize.org/acip.

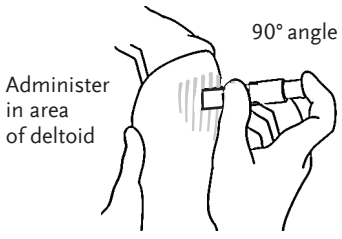
Intramuscular (IM) injection



Subcutaneous (Subcut) injection



Intradermal (ID) administration of Fluzone ID vaccine



Intranasal (NAS) administration of Flumist (LAIV) vaccine



Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p3085.pdf • Item #P3085 (11/15)

VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine — Gardasil®-9: *What You Need to Know*

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Gardasil-9 prevents human papillomavirus (HPV) types that cause many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, Gardasil-9 prevents HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cases of cervical cancer.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

2 HPV vaccine

Gardasil-9 is an FDA-approved HPV vaccine. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second dose given 1–2 months after the first dose and the third dose given 6 months after the first dose.

3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

  Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.
- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got Gardasil-9 vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get HPV vaccine do not have any serious problems with it.

Mild or moderate problems following Gardasil-9:

- Reactions in the arm where the shot was given:
  - Soreness (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- Fever:
  - Mild (100°F) (about 1 person in 10)
  - Moderate (102°F) (about 1 person in 65)
- Other problems:
  - Headache (about 1 person in 3)

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety**/.

5 What if there is a serious reaction?

What should I look for?

Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/hpv**

Vaccine Information Statement

HPV Vaccine (Gardasil-9)

03/31/2016

42 U.S.C. § 300aa-26

Office Use Only

Standing Orders for Administering Human Papillomavirus Vaccine to Children and Teens

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all children and teens who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate children and teens who meet the criteria below.

Procedure

1. Identify all children and teens ages 11 years and older who have not completed the HPV vaccination series.
2. Screen all patients for contraindications and precautions to HPV vaccine:
   a. **Contraindication:** a history of a serious allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent or 9-valent HPV vaccine [4vHPV or 9vHPV: Gardasil, Merck] or latex for bivalent HPV vaccine [2vHPV: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   b. **Precautions:**
      - Moderate or severe acute illness with or without fever
      - Pregnancy; delay vaccination until after completion of the pregnancy
3. Provide all patients (or, if minors, their parent or legal representative) with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Provide 1) either 2vHPV, 4vHPV, or 9vHPV to girls or 2) 4vHPV4 or 9vHPV to boys. Provide either vaccine in a 3-dose schedule at 0, 1–2, and 6 calendar months. Provide routine vaccination with HPV vaccine to girls and boys at age 11 or 12 years; vaccine may be administered to girls or boys as young as age 9 years. Administer 0.5 mL HPV vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ⅝" needle may be used for children and teens weighing less than 130 lbs [60 kg] for injection in the deltoid muscle *only* if the subcutaneous tissue is not bunched and the injection is made at a 90˚ angle.)
5. For children and teens who have not received HPV vaccine at the ages and/or intervals specified in #4, administer one dose at the earliest opportunity and then schedule subsequent doses to complete the 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third doses, and at least 24 weeks between the first and third doses.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Children and Teens," go to www.immunize.org/catg.d/p3082a.pdf. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ (name of practice or clinic) until rescinded or until _____ (date).

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

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www.immunize.org/catg.d/p3090.pdf • Item #P3090 (5/15)

Standing Orders for Administering Human Papillomavirus Vaccine to Adults

Purpose: To reduce morbidity and mortality from human papillomavirus (HPV) infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy: Under these standing orders, eligible nurses and other healthcare professionals (e.g., pharmacists), where allowed by state law, may vaccinate adults who meet the criteria below.

Procedure

1. Identify adults in need of vaccination against human papillomavirus (HPV) based on the following criteria:
   a. Female, age 26 years or younger
   b. Male, age 21 years or younger
   c. Male, age 22 through 26 years meeting any of the following conditions:
      i. Immunocompromised as a result of infection (including HIV), disease, or medications
      ii. Has sex with other males
      iii. Wants to be vaccinated and lacks any of the above criteria
2. Screen all patients for contraindications and precautions to HPV vaccine:
   a. **Contraindication:** a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose of HPV vaccine or to a HPV vaccine component (e.g., yeast for quadrivalent or 9-valent HPV vaccine [4vHPV or 9vHPV: Gardasil, Merck] or latex for bivalent HPV vaccine [2vHPV: Cervarix, GSK]). For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
   b. **Precautions:**
      - Moderate or severe acute illness with or without fever
      - Pregnancy; delay vaccination until after completion of the pregnancy
3. Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). You must document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at www.immunize.org/vis.
4. Provide 1) either 2vHPV, 4vHPV, or 9vHPV to women or 2) 4vHPV or 9vHPV to men. Provide either vaccine in a 3-dose schedule at 0, 1–2, and 6 calendar months. Administer 0.5 mL HPV vaccine intramuscularly (22–25g, 1–1½" needle) in the deltoid muscle; the anterolateral thigh muscle may be used if deltoid is inadequate. (Note: a ⅝" needle may be used for adults weighing less than 130 lbs [60 kg] for injection in the deltoid muscle *only* if the subcutaneous tissue is not bunched and the injection is made at a 90˚ angle.)
5. For adults who have not received HPV vaccine at the intervals specified in #4, administer subsequent doses of HPV vaccine to complete each patient's 3-dose schedule by observing a minimum interval of 4 weeks between the first and second doses, 12 weeks between the second and third dose, and at least 24 weeks between the first and third doses. Men age 27 years and older who meet the criteria of 1.c.i. or 1.c.ii. above and women age 27 years and older who have received at least 1 dose before their 27th birthday should complete the 3-dose series as soon as feasible. Men age 22 years and older who have received at least 1 dose before their 22nd birthday should also complete the 3-dose series as soon as feasible.
6. Document each patient's vaccine administration information and follow up in the following places:
   a. **Medical chart:** Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).
   b. **Personal immunization record card:** Record the date of vaccination and the name/location of the administering clinic.
7. Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adult Patients, go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.
8. Report all adverse reactions following the administration of HPV vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or by calling (800) 822-7967. VAERS report forms are available at www.vaers.hhs.gov.

This policy and procedure shall remain in effect for all patients of the _____ until rescinded or until _____ (date).
(name of practice or clinic)

Medical Director's signature: _____ Effective date: _____

For standing orders for other vaccines, go to www.immunize.org/standing-orders

Technical content reviewed by the Centers for Disease Control and Prevention

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www.immunize.org/catg.d/p3091.pdf • Item #P3091 (5/15)

Appendix C – Educational Materials for Patients and Parents

HPV

also known as *Human Papillomavirus*

As parents, you do everything you can to protect your children's health for now and for the future. Today, there is a strong weapon to prevent several types of cancer in our kids: the HPV vaccine.

HPV and Cancer

HPV is short for Human Papillomavirus, a common virus. In the United States each year, there are about 17,500 women and 9,300 men affected by HPV-related cancers. Many of these cancers **could be prevented with vaccination.** In both women and men, HPV can cause anal cancer and mouth/throat (oropharyngeal) cancer. It can also cause cancers of the cervix, vulva and vagina in women; and cancer of the penis in men.

For women, screening is available to detect most cases of cervical cancer with a Pap smear. Unfortunately, there is no routine screening for other HPV-related cancers for women or men, and these cancers can cause pain, suffering, or even death. **That is why a vaccine that prevents most of these types of cancers is so important.**

More about HPV

HPV is a virus passed from one person to another during skin-to-skin sexual contact, including vaginal, oral, and anal sex. HPV is most common in people in their late teens and early 20s. Almost all sexually active people will get HPV at some time in their lives, though most will never even know it.

Most of the time, the body naturally fights off HPV, before HPV causes any health problems. But in some cases, the body does not fight off HPV, and HPV can cause health problems, like cancer and genital warts. Genital warts are not a life-threatening disease, but they can cause emotional stress, and their treatment can be very uncomfortable. About 1 in 100 sexually active adults in the United States have genital warts at any given time.

HPV vaccination is recommended for preteen girls and boys at age 11 or 12 years

All preteens need HPV vaccination so they can be protected from HPV infections that cause cancer. Teens and young adults who didn't start or finish the HPV vaccine series also need HPV vaccination. Young women can get HPV vaccine until they are 27 years old and young men can get HPV vaccine until they are 22 years old. Young men who have sex with other men or who have weakened immune systems can also get HPV vaccine until they are 27.

HPV vaccination is a series of shots given over several months. The best way to remember to get your child all of the shots they need is to make an appointment for the remaining shots before you leave the doctor's office or clinic.

Is the HPV vaccine safe?

Yes. HPV vaccination has been studied very carefully and continues to be monitored by CDC and the Food and Drug Administration (FDA). No serious safety concerns have been linked to HPV vaccination. **These studies continue to show that HPV vaccines are safe.**

The most common side effects reported after HPV vaccination are mild. They include pain and redness in the area of the arm where the shot was given, fever, dizziness, and nausea. Some preteens and teens may faint after getting a shot or any other medical procedure. Sitting or lying down for about 15 minutes after getting shots can help prevent injuries that could happen if your child were to fall while fainting. ▶



Why does my child need this now?

HPV vaccines offer the best protection to girls and boys who receive all three vaccine doses and have time to develop an immune response **before** they begin sexual activity with another person. This is not to say that your preteen is ready to have sex. In fact, it's just the opposite—it's important to get your child protected before you or your child have to think about this issue. The immune response to this vaccine is better in preteens, and this could mean better protection for your child. ❖

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Serious side effects from HPV vaccination are rare. Children with severe allergies to yeast or latex shouldn't get certain HPV vaccines. Be sure to tell the doctor or nurse if your child has any severe allergies.

Help paying for vaccines

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger who are uninsured, Medicaid-eligible, or American Indian/Alaska Native. Learn more about the VFC program at **www.cdc.gov/Features/VFCprogram/**

Whether you have insurance, or your child is VFC-eligible, some doctors' offices may also charge a fee to give the vaccines.

Jacquelyn's story: "I was healthy—and got cervical cancer."

When I was in my late 20's and early 30's, in the years before my daughter was born, I had some abnormal Pap smears and had to have further testing. I was told I had the kind of HPV that can cause cancer and mild dysplasia.

For three more years, I had normal tests. But when I got my first Pap test after my son was born, they told me I needed a biopsy. The results came back as cancer, and my doctor sent me to an oncologist. Fortunately, the cancer was at an early stage. My lymph nodes were clear, and I didn't need radiation. But I did need to have a total hysterectomy.

My husband and I have been together for 15 years, and we were planning to have more children. We are so grateful for our two wonderful children, but we were hoping for more—which is not going to happen now.

The bottom line is they caught the cancer early, but the complications continue to impact my life and my family. For the next few years, I have to get pelvic exams and Pap smears every few months, the doctors measure tumor markers, and I have to have regular x-rays and ultrasounds, just in case. I have so many medical appointments that are taking time away from my family, my friends, and my job.

Worse, every time the phone rings, and I know it's my oncologist calling, I hold my breath until I get the results. I'm hopeful I can live a full and healthy life, but cancer is always in the back of my mind.

In a short period of time, I went from being healthy and planning more children to all of a sudden having a radical hysterectomy and trying to make sure I don't have cancer again. It's kind of overwhelming. And I am one of the lucky ones!

Ultimately I need to make sure I'm healthy and there for my children. I want to be around to see their children grow up.

I will do everything to keep my son and daughter from going through this. I will get them both the HPV vaccine as soon as they turn 11. I tell everyone—my friends, my family—to get their children the HPV vaccine series to protect them from this kind of cancer.



What about boys?

HPV vaccine is for boys too! This vaccine can help prevent boys from getting infected with the types of HPV that can cause cancers of the mouth/throat, penis and anus. The vaccine can also help prevent genital warts. HPV vaccination of males is also likely to benefit females by reducing the spread of HPV viruses.

Learn more about HPV and HPV vaccine at **www.cdc.gov/hpv**

For more information about the vaccines recommended for preteens and teens:
800-CDC-INFO *(800-232-4636)*
http://www.cdc.gov/vaccines/teens

VPH

también conocido como virus del papiloma humano

Como padres, ustedes hacen todo lo posible para proteger la salud de sus hijos en el presente y el futuro. En la actualidad, existe un arma poderosa para prevenir diferentes tipos de cáncer en nuestros hijos: la vacuna contra el VPH.

VPH y cáncer

VPH son las iniciales de virus del papiloma humano, un virus común. En los Estados Unidos, distintos tipos de cáncer relacionados con el VPH afectan aproximadamente a 17,500 mujeres y 9,300 hombres cada año. Estos tipos de cáncer se podrían prevenir con vacunas. En hombres y mujeres, el VPH puede causar cáncer de ano y cáncer de boca y garganta (de orofaringe). También puede causar cáncer de cuello de útero, vulva y vagina en mujeres y cáncer de pene en hombres.

En el caso de las mujeres, hay disponible pruebas para detectar la mayoría de los cánceres de cuello de útero con un examen de Papanicolaou. Lamentablemente, no existe una prueba de detección de rutina para otros cánceres relacionados con el VPH que afectan a mujeres y hombres. Estos cánceres pueden causar dolor, sufrimiento e incluso la muerte. Por eso es tan importante una vacuna que prevenga la mayoría de estos tipos de cáncer.

Más información acerca del VPH

El VPH es un virus que se transmite de una persona a otra durante el contacto sexual de piel con piel, incluidas las relaciones sexuales vaginales, orales y anales. El VPH es muy común en personas que se encuentran en los últimos años de la adolescencia y a principios de los 20. Casi todas las personas sexualmente activas tendrán el VPH en algún momento de sus vidas aunque la mayoría nunca lo sabrá.

La mayoría de las veces, el cuerpo combate naturalmente el VPH antes de que cause problemas de salud. Pero en algunos casos, el cuerpo no lo combate y el VPH puede causar problemas de salud, como cáncer y verrugas genitales. Las verrugas genitales no son una enfermedad que ponga en riesgo la vida, pero pueden causar estrés emocional y el tratamiento puede ser muy incómodo. En los Estados Unidos, aproximadamente 1 de 100 adultos sexualmente activos tienen verrugas genitales en algún momento.

Se recomienda la vacuna contra el VPH en preadolescentes de entre 11 y 12 años de edad

También se recomienda para niñas de 13 a 26 años de edad y para niños de 13 a 21 años de edad, que no hayan recibido la vacuna. Por lo tanto, si su hijo o hija no ha comenzado o finalizado la serie de vacunas contra el VPH, no es demasiado tarde. Consulte a su médico sobre cómo obtenerlas ahora.

Hay disponibles dos vacunas, Cervarix y Gardasil, para prevenir los tipos de VPH que causan la mayoría de los cánceres de cuello de útero y de ano. Una de las vacunas contra el VPH, Gardasil, también previene el cáncer de vulva y vagina en mujeres y las verrugas genitales en hombres y mujeres. Solo Gardasil ha sido probado y autorizado para usarse en varones. Ambas vacunas se administran en una serie de tres dosis durante seis meses. La mejor manera de recordar que su hijo debe recibir las tres vacunas es realizar una cita para la segunda y la tercera vacuna antes de salir del consultorio del médico después de la primera vacuna.

¿Es segura la vacuna contra el VPH?

Sí. Las dos vacunas contra el VPH han sido estudiadas en decenas de miles de personas alrededor del mundo. Se han distribuido más de 57 millones de dosis hasta la fecha y no ha habido problemas de seguridad graves. Los Centros para el Control y la Prevención de Enfermedades (CDC, por sus siglas en inglés) y la Administración de Alimentos y Fármacos (FDA, por sus siglas en inglés) continúan controlando la seguridad de las vacunas. Estos estudios siguen demostrando que las vacunas contra el VPH son seguras. Los efectos adversos más comunes que se informan son leves. Entre ellos se



¿Por qué mi hijo necesita esa vacuna ahora?

Las vacunas contra el VPH ofrecen la mejor protección para los niños y las niñas que reciben las tres dosis de la vacuna y tienen tiempo para desarrollar una respuesta inmunológica antes de comenzar la actividad sexual con otra persona. Esto no significa que su hijo preadolescente esté listo para tener relaciones sexuales. De hecho, es justamente lo opuesto. Es importante proteger a su hijo antes de que usted o su hijo tengan que pensar en el tema. La respuesta inmunológica a esta vacuna es mejor en los preadolescentes y esto podría significar una mejor protección para su hijo.

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incluyen dolor donde se administró la vacuna (por lo general, el brazo), fiebre, mareos y náuseas. Es posible que haya escuchado que algunos niños se desmayan cuando reciben la vacuna. El desmayo es común entre preadolescentes y adolescentes en diferentes procedimientos médicos, no solo en la vacunación contra el VPH. Asegúrese de que su hijo coma algo antes de ir a recibir la vacuna. Es una buena idea que su hijo se siente o se recueste cuando le den la vacuna y por 15 minutos después de recibir la vacuna para evitar que se desmaye y sufra lesiones que podrían producirse al desmayarse. La vacuna contra el VPH se puede administrar de manera segura al mismo tiempo que las otras vacunas recomendadas, incluidas las vacunas Tdap, antimeningocócica y antigripal.

Ayuda para pagar las vacunas

El Programa Vacunas para Niños (VFC, por sus siglas en inglés) proporciona vacunas para niños menores de 19 años de edad que no reciben suficiente seguro, no tienen seguro médico, son elegibles para Medicaid o son indígenas americanos o nativos de Alaska. Para obtener más información sobre el programa VFC, visite **http://www.cdc.gov/spanish/especialesCDC/ProgramaVacunas/**

Aunque usted tenga seguro o su hijo sea elegible para el VFC, algunos consultorios pueden cobrarle también un cargo por administrar las vacunas.

La historia de Jacquelyn "Yo estaba sana y tuve cáncer de cuello de útero".

Al final de mis 20 años y principios de mis 30, antes de que naciera mi hija, tuve algunos exámenes de Papanicolaou anormales y me hicieron pruebas adicionales. Me dijeron que tenía el tipo de VPH que puede causar cáncer y displasia leve.

Durante tres años más, mis pruebas fueron normales. Pero cuando me realizaron el primer examen de Papanicolaou después de que naciera mi hijo, me dijeron que necesitaban realizar una biopsia. Los resultados dieron que era cáncer y mi médico me envió a un oncólogo. Afortunadamente, el cáncer estaba en un estadio temprano. Los ganglios linfáticos estaban limpios y no necesitaba radiación. Pero debían realizarme una histerectomía total.

Mi marido y yo hemos estado juntos por 15 años y planeábamos tener más hijos. Estamos tan agradecidos por nuestros dos hermosos hijos, pero esperábamos tener más, lo que no sucederá ahora.

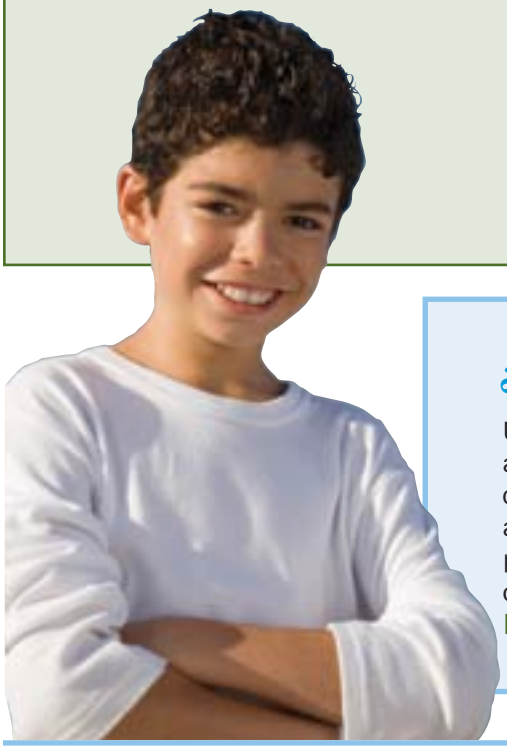
Lo bueno fue que detectaron el cáncer a tiempo, pero las complicaciones siguen teniendo un impacto en mi vida y en mi familia. En los próximos años, me tengo que realizar exámenes pélvicos y de Papanicolaou cada algunos meses, los médicos miden los marcadores de tumores y me deben realizar radiografías y ecografías con regularidad, por si acaso. Tengo tantas citas médicas que me alejan de mi familia, mis amigos y mi trabajo.

Lo peor es que cada vez que el teléfono suena y sé que es mi oncólogo, contengo la respiración hasta que me da los resultados. Tengo esperanzas de poder llevar una vida completa y sana, pero siempre pienso en el cáncer.

En tan poco tiempo, pasé de tener una vida sana y planificar más hijos a tener una histerectomía total e intentar asegurarme de no tener cáncer de nuevo. Es abrumador. Y soy una de las personas con suerte.

En última instancia, debo asegurarme de estar sana y estar presente para mis hijos. Quiero ver a mis nietos crecer.

Haré todo lo posible para que mi hijo y mi hija no deban pasar por esto. Cuando cumplan los 11 años, los vacunaré contra el VPH. Le digo a todo el mundo, a mis amigos y familiares, que sus hijos necesitan la serie de vacunas contra el VPH para protegerlos de este tipo de cáncer.



¿Qué sucede con los varones?

Una de las vacunas, Gardasil, es para varones también. Esta vacuna puede ayudarles a los varones a evitar infecciones con los tipos de VPH que pueden causar cánceres de la boca/garganta, el pene, y el ano. Esta vacuna también ayuda a prevenir las verrugas genitales. La vacunación contra el VPH en hombres también puede beneficiar a las mujeres al reducir el contagio de los virus de VPH. Para obtener más información sobre el VPH y la vacuna contra el VPH, visite **http://www.cdc.gov/spanish/especialesCDC/VacunaVPH/**

Para obtener más información sobre las vacunas recomendadas para preadolescentes y adolescentes, llame al:

800-CDC-INFO *(800-232-4636)*

http://www.cdc.gov/spanish/especialesCDC/VacunasPreadolescentes/

o **http://www.cdc.gov/vaccines/teens** *(para más información en inglés)*

AUG 2014

What Parents Should Know About HPV Vaccine Safety and Effectiveness

Last updated JUNE 2014

HPV vaccines prevent cancer

About 14 million people, including teens, become infected with human papillomavirus (HPV) each year. When HPV infections persist, people are at risk for cancer. Every year, approximately 17,600 women and 9,300 men are affected by cancers caused by HPV. HPV vaccination could prevent many of these cancers.

HPV vaccines are safe

There are two vaccines licensed by the Food and Drug Administration (FDA) and recommended by CDC to protect against HPV-related illness. All vaccines used in the United States are required to go through extensive safety testing before they are licensed by FDA. Once in use, they are continually monitored for safety and effectiveness.

Numerous research studies have been conducted to make sure HPV vaccines were safe both before and after the vaccines were licensed. No serious safety concerns have been confirmed in the large safety studies that have been done since HPV vaccine became available in 2006. CDC and FDA have reviewed the safety information available to them for both HPV vaccines and have determined that they are both safe.

The HPV vaccine is made from one protein from the HPV virus that is not infectious (cannot cause HPV infection) and non-oncogenic (does not cause cancer).

HPV vaccines work

The HPV vaccine works extremely well. In the four years after the vaccine was recommended in 2006, the amount of HPV infections in teen girls decreased by 56%. Research has also shown that fewer teens are getting genital warts since HPV vaccines have been in use. In other countries such as Australia, research shows that HPV vaccine has already decreased the amount of pre-cancer of the cervix in women, and genital warts have decreased dramatically in both young women and men.

HPV vaccines provide long-lasting protection

Data from clinical trials and ongoing research tell us that the protection provided by HPV vaccine is long-lasting. Currently, it is known that HPV vaccine works in the body for at least 10 years without becoming less effective. Data suggest that the protection provided by the vaccine will continue beyond 10 years.

HPV vaccine is recommended and safe for boys

One HPV vaccine (Gardasil) is recommended for boys. This vaccine can help prevent boys from getting infected with the HPV-types that can cause cancers of the mouth/throat, penis and anus as well as genital warts.

Like any vaccine or medicine, HPV vaccines might cause side effects

HPV vaccines occasionally cause adverse reactions. The most commonly reported symptoms among females and males are similar, including injection-site reactions (such as pain, redness, or swelling in the area of the upper arm where the vaccine is given), dizziness, fainting, nausea, and headache.

Brief fainting spells and related symptoms can happen after many medical procedures, including vaccination. Fainting after getting a shot is more common among adolescents. Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries that can be caused by falls.

When fainting was found to happen after vaccination, FDA changed prescribing information to include information about preventing falls and possible injuries from fainting after vaccination. CDC consistently reminds doctors and nurses to share this information with all their patients. Tell the doctor or nurse if your child feels dizzy, faint, or light-headed.

HPV vaccines don't negatively affect fertility

There is no evidence to suggest that HPV vaccine causes fertility problems. However, not getting HPV vaccine leaves people vulnerable to HPV cancers. If persistent high-risk HPV infection in a woman leads to cervical cancer, the treatment of cervical cancer (hysterectomy, chemotherapy, or radiation, for example) could leave a woman unable to have children. Treatment for cervical pre-cancer could put a woman at risk for problems with her cervix, which could cause preterm delivery or other problems.

How can I get help paying for these vaccines?

The Vaccines for Children (VFC) program provides vaccines for children ages 18 years and younger, who are not insured, Medicaid-eligible, American Indian or Alaska Native. You can find out more about the VFC program by going online to www.cdc.gov and typing VFC in the search box.

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

CS 249472_F

Lo que los padres deben saber acerca de la seguridad y eficacia de las vacunas contra el VPH

Actualizado en junio de 2014

Las vacunas contra el VPH previenen el cáncer

Alrededor de 14 millones de personas, incluidos los adolescentes, se infectan con el virus del papiloma humano (VPH) cada año. Cuando una infección por el VPH persiste, las personas corren riesgo de presentar cáncer. Cada año, aproximadamente 17 600 mujeres y 9300 hombres se ven afectados por los cánceres que causa el VPH. Las vacunas contra el VPH pueden prevenir muchos de estos cánceres.

Las vacunas contra el VPH son seguras

Existen dos vacunas aprobadas por la Administración de Alimentos y Medicamentos (FDA), y recomendadas por los CDC, para proteger contra las enfermedades relacionadas con el VPH. Todas las vacunas que se usan en los Estados Unidos deben pasar por pruebas exhaustivas de seguridad antes de que la FDA les dé su aprobación. Una vez en uso, se las somete a continuos controles para evaluar su seguridad y eficacia.

Tanto antes como después de que fueran aprobadas, se han hecho numerosos estudios de investigación para asegurarse de que las vacunas contra el VPH sean seguras. No se han detectado problemas de seguridad graves en la gran cantidad de estudios de seguridad que se han realizado desde que la vacuna contra el VPH comenzó a usarse en el 2006. Los CDC y la FDA han revisado la información sobre seguridad que tienen disponible acerca de ambas vacunas contra el VPH y han determinado que las dos son seguras.

La vacuna contra el VPH está hecha con una proteína del virus del VPH que no es infecciosa (no puede causar la infección por este virus) y que tampoco es oncógena (no causa cáncer).

Las vacunas contra el VPH funcionan

Las vacunas contra el VPH funcionan muy bien. En los cuatro años transcurridos desde que se empezó a recomendar la vacunación en el 2006, la cantidad de infecciones por el VPH en las niñas adolescentes disminuyó en un 56 %. Las investigaciones también han demostrado que hay menos adolescentes afectados por verrugas genitales desde que se comenzaron a usar las vacunas contra el VPH. En otros países como Australia, las investigaciones demuestran que la vacuna contra el VPH ya ha disminuido la cantidad de casos de precáncer de cuello uterino en las mujeres, y las verrugas genitales han disminuido de manera considerable en los hombres y las mujeres jóvenes.

Las vacunas contra el VPH proporcionan protección a largo plazo

De acuerdo con los datos provenientes de ensayos clínicos e investigaciones en curso, la protección que da la vacuna contra el VPH es a largo plazo. En la actualidad, se sabe que la vacuna contra el VPH sigue funcionando en el cuerpo por al menos 10 años, sin que se reduzca la eficacia. La información disponible parece indicar que la protección de la vacuna continúa más allá de los 10 años.

La vacuna contra el VPH se recomienda para los niños varones y es segura

Una de las vacunas contra el VPH (Gardasil) es segura y es la que se recomienda para los niños varones Esta vacuna puede ayudar a prevenir que los niños varones contraigan la infección por los tipos de VPH que pueden causar cánceres de boca, garganta, pene y ano, así como las verrugas genitales.

Como cualquier otra vacuna o medicamento, las vacunas contra el VPH pueden causar efectos secundarios

A veces, las vacunas contra el VPH causan reacciones adversas. Los síntomas más frecuentemente reportados en hombres y mujeres son similares, incluidas las reacciones en el lugar donde se coloca la inyección (como dolor, enrojecimiento o hinchazón en el área superior del brazo donde se recibió la vacuna), mareos, desmayos, náuseas y dolor de cabeza.

Después de muchos procedimientos médicos, incluso con las vacunas, pueden suceder breves episodios de desmayo y presentarse síntomas relacionados. Los desmayos después de recibir una vacuna ocurren con más frecuencia en los adolescentes. Sentarse o acostarse por unos 15 minutos después de recibir una vacuna puede ayudar a prevenir los desmayos y las lesiones que pueden causar las caídas.

Cuando se determinó que los desmayos sucedían después de la vacunación, la FDA cambió la información de la receta para incluir información sobre la prevención de caídas y posibles lesiones por desmayos después de recibir una vacuna. Los CDC les recuerdan constantemente a los médicos y al personal de enfermería que den a conocer esta información a todos los pacientes. Dígale al médico o al personal de enfermería si su hijo se siente mareado, aturdido o se desmaya.

Las vacunas contra el VPH no afectan negativamente la fertilidad

No hay evidencia que indique que las vacunas contra el VPH causen problemas de fertilidad. Sin embargo, no recibir la vacuna contra el VPH deja a la persona vulnerable a los cánceres causados por el virus del papiloma humano. Si las infecciones por el VPH persistentes y de alto riesgo en una mujer conducen al cáncer de cuello uterino, el tratamiento para este tipo de cáncer (por ejemplo, histerectomía, quimioterapia o radioterapia) puede dejarla sin la posibilidad de tener hijos. El tratamiento de las lesiones precancerosas en el cuello uterino puede poner a la mujer en riesgo de presentar problemas en el cuello del útero, lo cual podría causar partos prematuros u otros problemas.

¿Cómo puedo obtener ayuda para pagar por estas vacunas?

El programa de Vacunas para Niños (VFC, por sus siglas en inglés) proporciona vacunas para niños de hasta 18 años que no tengan seguro médico, que cumplan con los requisitos para recibir Medicaid o que sean indoamericanos o nativos de Alaska. Hable con el médico o el personal de enfermería que atiende a su hijo para obtener más información sobre este programa. Puede obtener más información sobre el Programa VFC entrando en línea a la siguiente dirección: http://www.cdc.gov/spanish/especialesCDC/ProgramaVacunas.

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Centers for Disease Control and Prevention

CS 249472_F_SP

Human Papillomavirus

A Parent's Guide to Preteen and Teen HPV Vaccination



HPV

Why vaccinate against HPV at 11 or 12 years of age?

- The vaccine produces better immunity to fight infection when given at younger ages compared with older ages.
- Vaccination for HPV is much more effective at preventing disease and cancer if all three doses are administered before someone's first sexual contact.
- Most American men and women who become sexually active will contract at least one type of HPV virus in their lifetime. Vaccination can reduce their risk of HPV infection.
- Most people who become infected with HPV do not even know it.
- HPV is easily spread by skin-to-skin contact during sexual activity. Even if someone does not have sexual intercourse, they can still get HPV.
- People who choose to have only one lifetime sex partner can still get HPV if their partner has had previous partners who were infected.
- Both vaccines have been tested in thousands of people around the world and have been proven to have no serious side effects.
- Both vaccines are highly effective against HPV types that cause most cervical cancers; one of the vaccines, Gardasil, also protects against 90 percent of HPV-associated genital warts.

What is HPV?

Human papillomavirus (HPV) is a common family of viruses that causes infection of the skin or mucous membranes of various areas of the body. There are over 100 different types of HPV viruses. Different types of HPV infection affect different areas of the body. For instance, some types of HPV cause warts in the genital area and other types can lead to abnormal cells on the cervix, vulva, anus, penis, mouth, and throat, sometimes leading to cancer.

How common is HPV?

HPV is very common. According to the Centers for Disease Control and Prevention (CDC), most sexually active American men and women will contract at least one type of HPV virus during their lifetime. HPV is considered the most common sexually transmitted disease in the United States. It is the cause of almost all cervical cancers in women and has been linked to the rise of oral cancers in young people in the United States.

How serious is HPV?

HPV is extremely serious. Approximately 79 million Americans are currently infected with HPV, and about 14 million more become infected each year. In the United States, there are around 12,000 new cervical cancer cases diagnosed annually, and 4,000 women die from cervical cancer every year. Men are affected too. Around 9,000 HPV-associated cancer cases occur in American men each year.

How is HPV spread?

The most common ways to get an HPV infection is from vaginal or anal sex with an infected person; however, this is NOT the only way to get HPV. Infection can also be acquired from oral sex and any skin-to-skin contact with areas infected by HPV. It is possible to have HPV and not know it, so a person can unknowingly spread HPV to another person.

continued on page 2 ▶

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota ▪ 651-647-9009 ▪ www.vaccineinformation.org ▪ www.immunize.org

www.immunize.org/catg.d/p4250.pdf ▪ Item #P4250 (3/16)

Resources for more information

- Your healthcare provider or local health department
- CDC's information on vaccines and immunization: www.cdc.gov/vaccines
- Immunization Action Coalition's vaccine information website: www.vaccineinformation.org
- Vaccine Education Center at the Children's Hospital of Philadelphia: www.chop.edu/vaccine
- CDC's Vaccines For Children (VFC) program: www.cdc.gov/vaccines/programs/vfc/index.html

SOURCES

American College of Obstetricians and Gynecologists (ACOG) Committee on Adolescent Health Care. Fact Sheet: Human Papillomavirus. ■ www.acog.org

Centers for Disease Control and Prevention (CDC). National Center for Chronic Disease Prevention and Health Promotion. HPV and Cancer. ■ www.cdc.gov/hpv/parents/cancer.html

CDC. National Center for Emerging and Zoonotic Infectious Diseases. Vaccine Safety: Human Papillomavirus Vaccine. ■ www.cdc.gov/vaccinesafety/Vaccines/HPV-vaccine.html

CDC. National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. Genital HPV Infection Fact Sheet. ■ www.cdc.gov/std/HPV/STDFact-HPV.htm

CDC. National Center for Immunization and Respiratory Diseases. HPV Vaccine-Questions and Answers. ■ www.cdc.gov/vaccines/vpd-vac/hpv/parents/questions-answers.html

CDC. National Center for Immunization and Respiratory Diseases. Preteens and Teens Need Vaccines Too! ■ www.cdc.gov/Features/PreteenVaccines/index.html

Reduction in human papillomavirus (HPV) prevalence among young women following HPV vaccine introduction in the United States, National Health and Nutrition Examination Surveys, 2003-2010. *J Infect Dis.* 2013 Aug 1; 208(3):385-93.

Related press release: ■ www.cdc.gov/media/releases/2013/p0619-hpv-vaccinations.html

Talk to your healthcare provider today about protecting your son or daughter from HPV infection!

Can HPV infection be treated?

There is no treatment for HPV infection; there are only treatments available for the health problems that HPV can cause, such as genital warts, cervical changes, and cancer. In some cases, the body fights off the virus naturally. In cases where the virus cannot be fought off naturally, the person is at risk for serious complications, including cancer.

What is HPV vaccine?

There are two HPV vaccines licensed by the Food and Drug Administration (FDA) and recommended by CDC: Cervarix and Gardasil. Both vaccines protect against cervical cancers in women. One vaccine, Gardasil, also protects against genital warts and cancers of the anus, vagina, and vulva. Both vaccines are available for females. Only Gardasil is available for males. HPV vaccines are given in three shots over six months; it is important to get all three doses to get the best protection.

At what age should my son or daughter get HPV vaccine?

Routine vaccination with three doses of HPV vaccine is recommended for all 11- and 12-year-old boys and girls. The vaccines can be given as early as 9 years of age. If your son or daughter did not receive the three doses of vaccine at the recommended age, they should still start or complete their HPV vaccine series. Your son can be given the vaccine through the age of 21 (and also certain males through age 26 years), and your daughter can be given the vaccine through the age of 26. Check with your healthcare provider to make sure your child is up to date with HPV vaccination.

For HPV vaccine to work best, it is very important for preteens to get all three doses before any sexual activity begins. It is possible to get infected with HPV the very first time they have sexual contact with another person, even if they do not have intercourse. Also, the vaccine produces better immunity to fight infection when given at the younger ages compared to the older ages.

Are HPV vaccines safe?

HPV vaccines have been shown to be very safe. Every vaccine used in the United States is required to go through rigorous safety testing before licensure by the FDA. Both HPV vaccines have been extensively tested in clinical trials with more than 28,000 male and female participants. Since the first HPV vaccine was licensed for use in 2006, more than 50 million doses of HPV vaccine have been distributed in the United States. Now in routine use, these vaccines are continually monitored for safety.

In the years of HPV vaccine safety monitoring, no serious safety concerns have been identified. Like other vaccinations, most side effects from HPV vaccination are mild, including fever, headache, and pain and redness in the arm where the shot was given.

Are HPV vaccines effective?

The vaccines have been shown to be highly effective in protecting against the HPV types targeted by the vaccines. A study looking at HPV infections in girls and women before and after the introduction of HPV vaccines shows a significant reduction in vaccine-type HPV in U.S. teens since the vaccine was introduced.

Adapted from a publication developed by the Michigan Department of Community Health, Division of Immunization

HPV is a serious disease…
Make sure your child is protected!

What is HPV?

Human papillomavirus (HPV) is the most common sexually transmitted infection in the U.S. HPV can lead to cervical cancer in women, as well as other oral and genital (sex organ) cancers in men and women. HPV also causes genital warts.

How do you catch HPV?

A person can get the HPV virus during sexual contact without knowing it.



Is HPV serious?

Yes. HPV is the main cause of cervical cancer. In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 die from it. It can also lead to cancers of the vagina, vulva, penis, anus, throat, and mouth.

Is my child at risk?

If and when your child ever begins sexual activity, then they are at risk. At least half of sexually active people get infected with HPV at some point in their lives.

How can I protect my child from HPV?

Vaccination is the best way to protect your child from HPV infection. The vaccine is most effective if given before a person becomes sexually active. However, even if sexual activity has begun, a person can still be protected by the vaccine and should be vaccinated.

Ask your child's healthcare provider if your child is up to date for all vaccines!



Both girls and boys should get 3 doses of HPV vaccine, starting at around 11–12 years of age. Older teens and young adults should also start or complete their HPV vaccine series.

▶ For more information, visit www.vaccineinformation.org

For other vaccine handouts in this series,
visit www.immunize.org/vaccine-summaries

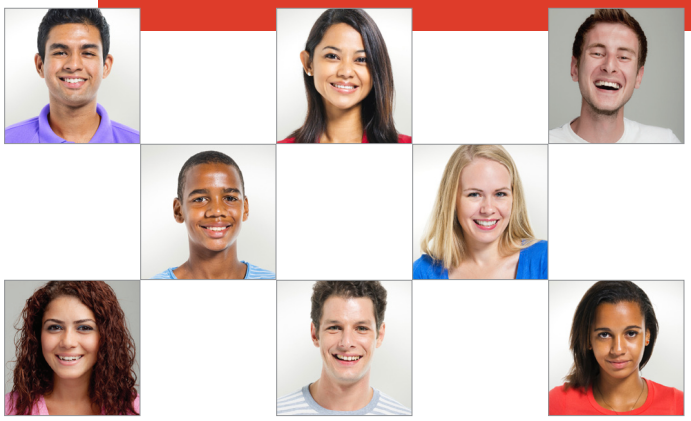
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Technical content reviewed by the Centers for Disease Control and Prevention
1573 Selby Avenue ▪ Saint Paul, Minnesota ▪ www.immunize.org
www.immunize.org/catg.d/p4310.pdf ▪ Item #P4310 (6/13)

HPV* Vaccine

A Guide for Young Adults

* human papillomavirus



HPV is a very common virus that can lead to:

- ▶ Cancers of the mouth and throat
- ▶ Cancer of the cervix
- ▶ Cancer of the penis, vagina, vulva, or anus
- ▶ Genital warts

HPV vaccine can prevent these!

Do I really need HPV vaccine? Yes!

You should get HPV vaccine because it can prevent some types of cancer and genital warts.

Do I need it if I haven't had sex yet? Yes!

- You don't have to have sex to catch HPV, but sex increases your risk.
- You can get HPV by skin-to-skin intimate contact.
- People can get and spread HPV without knowing it.
- It's best to get vaccinated before you ever have sex.

Should I get HPV vaccine if I've already had sex? Yes!

You still need to get vaccinated even if you have had sex. The vaccine provides a lot of protection.

Why do I need 3 shots?

You need 3 HPV shots to be fully protected.

I didn't get the vaccine at age 11 or 12. Should I get it now? Yes!

HPV vaccination is recommended for people ages 9 through 26. Even though it is ideal to get HPV vaccine as a preteen, it is still highly effective in teens and young adults.

Is HPV vaccine safe? Yes!

- Millions of doses of HPV vaccine have been given without any problem.
- You may get a sore arm.
- Occasionally, a few people faint, so sit for 15 minutes after getting the vaccine.

Make sure you get all 3 HPV shots. Complete your series!

For more information on vaccines for teens and young adults, visit www.vaccineinformation.org/teens or www.vaccineinformation.org/adults

Adapted with permission from the Academic Pediatric Association

When Should I Get HPV Vaccine?

Have your healthcare provider fill in this chart about when you should be vaccinated.

VACCINE DOSE	RECOMMENDED	DATE DOSE GIVEN OR DUE
#1	For people ages 9–26 years	
#2	1–2 months after vaccine dose #1	
#3	At least 6 months after vaccine dose #1	

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immunize.org

Technical content reviewed by the Centers for Disease Control and Prevention

Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p4251.pdf • Item #4251 (2/15)

Dear Total Care Pharmacy Customer,

As a young adult, now is the time in your life when you are able to experience more freedom and make your own choices. You can drive a car, vote in the upcoming presidential election, and pursue new academic and career options. You are also able to make important health decisions for yourself. So ask yourself this question—If I could prevent myself from getting certain types of cancer by choosing to get an immunization, why wouldn't I?

Human papillomavirus (HPV) is a very common cancer-causing virus, but the good news is we have a vaccine that helps protect you. The CDC recommends routine vaccination with three doses of HPV vaccine for all males and females ages 11-26. As a young adult, you fall into the age group of individuals who may not have received the HPV vaccine as an adolescent. We're excited to announce that you can now receive the HPV vaccine at **Total Care Pharmacy** without a prescription.

Please call or stop by Total Care Pharmacy at our 206 West Main Street location and talk with our staff about receiving the HPV vaccine: (606) 784-4491. No appointment needed!



total care pharmacy
diabetes & wellness center

Dear Parent/Guardian,

As a parent, you know that nothing is more important than the safety of your child and protecting him or her from illness or injury. You make sure your child has a healthy diet. You get the right gear to protect him or her from sports injuries. You take your child to the doctor for regular checkups. If you could prevent them from getting cancer, wouldn't you?

Human papillomavirus (HPV) is a very common cancer-causing virus, but the good news is we have a vaccine that helps protect youth. The American Academy of Pediatrics (AAP) and the CDC recommend routine vaccination with three doses of HPV vaccine for all boys and girls ages 11-26. With your permission, your child can receive the vaccine at **Total Care Pharmacy** with a prescription from their health care provider (if they are younger than age 14) or without a prescription (if they are age 14 or older).

Please call Total Care Pharmacy at our 206 West Main Street location if you have questions or to schedule an immunization appointment: (606) 784-4491.

Total Care Pharmacy
University of Kentucky Colleges of Public Health and Pharmacy



Appendix D – Promotional Materials

HPV CANCER PREVENTION

1 HPV VACCINE IS CANCER PREVENTION

HPV vaccine protects against HPV types that most commonly cause anal, cervical, oropharyngeal, penile, vaginal, and vulvar cancers.

Every year in the U.S., 27,000 people get cancer caused by HPV.

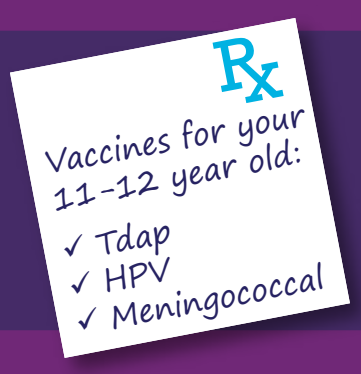


That's 1 person every 20 minutes of every day, all year long.

Most of these cancers can be prevented by HPV vaccine.

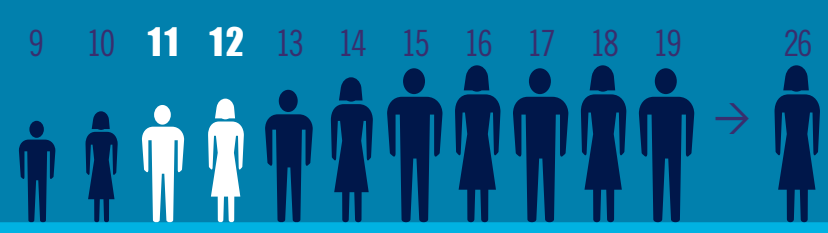
2 HPV VACCINE IS RECOMMENDED AT THE SAME TIME AS OTHER TEEN VACCINES

Preteens need three vaccines at 11 or 12. They protect against whooping cough, cancers caused by HPV, and meningitis.



3 HPV VACCINE IS BEST AT 11-12 YEARS

Preteens have a higher immune response to HPV vaccine than older teens.



While there is very little risk of exposure to HPV before age 13, the risk of exposure increases thereafter.

Parents and healthcare professionals are the key to protecting adolescents from HPV cancers.

VACCINATE YOUR 11-12 YEAR OLDS.

www.cdc.gov/vaccines/teens

Distributed by:

YOU ARE THE KEY TO HPV CANCER PREVENTION

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

NCIRDig406 | 07.23.2014

You're not opening the door to sex.

You're closing the door to cancer.

HPV vaccine is cancer prevention.

Talk to your child's doctor about vaccinating your 11–12 year old against HPV.

www.cdc.gov/vaccines/teens

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

YOU ARE THE KEY TO HPV CANCER PREVENTION

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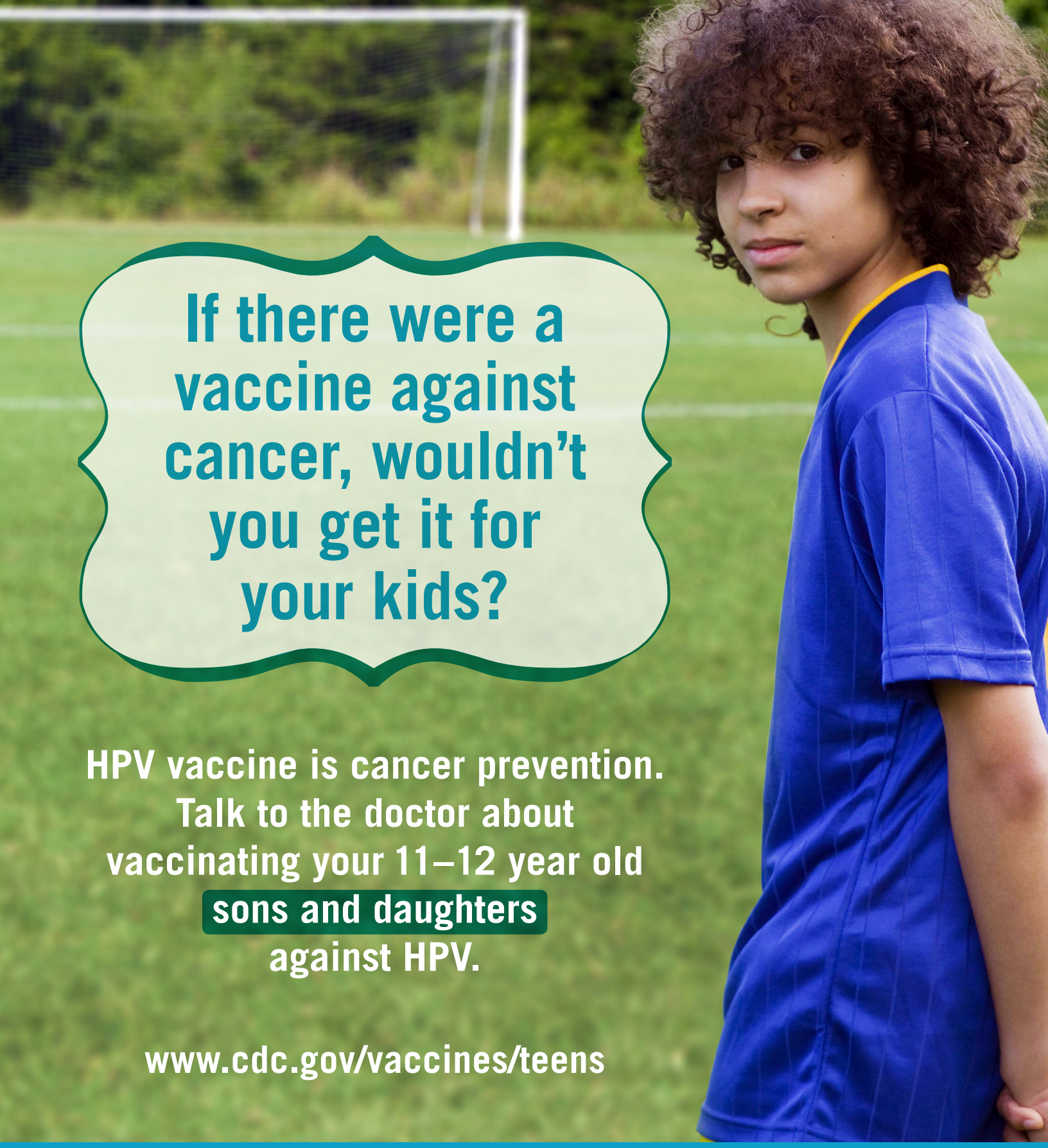


U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

YOU ARE THE KEY TO HPV CANCER PREVENTION

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If there were a vaccine against cancer, wouldn't you get it for your kids?

HPV vaccine is cancer prevention. Talk to the doctor about vaccinating your 11–12 year old sons and daughters against HPV.

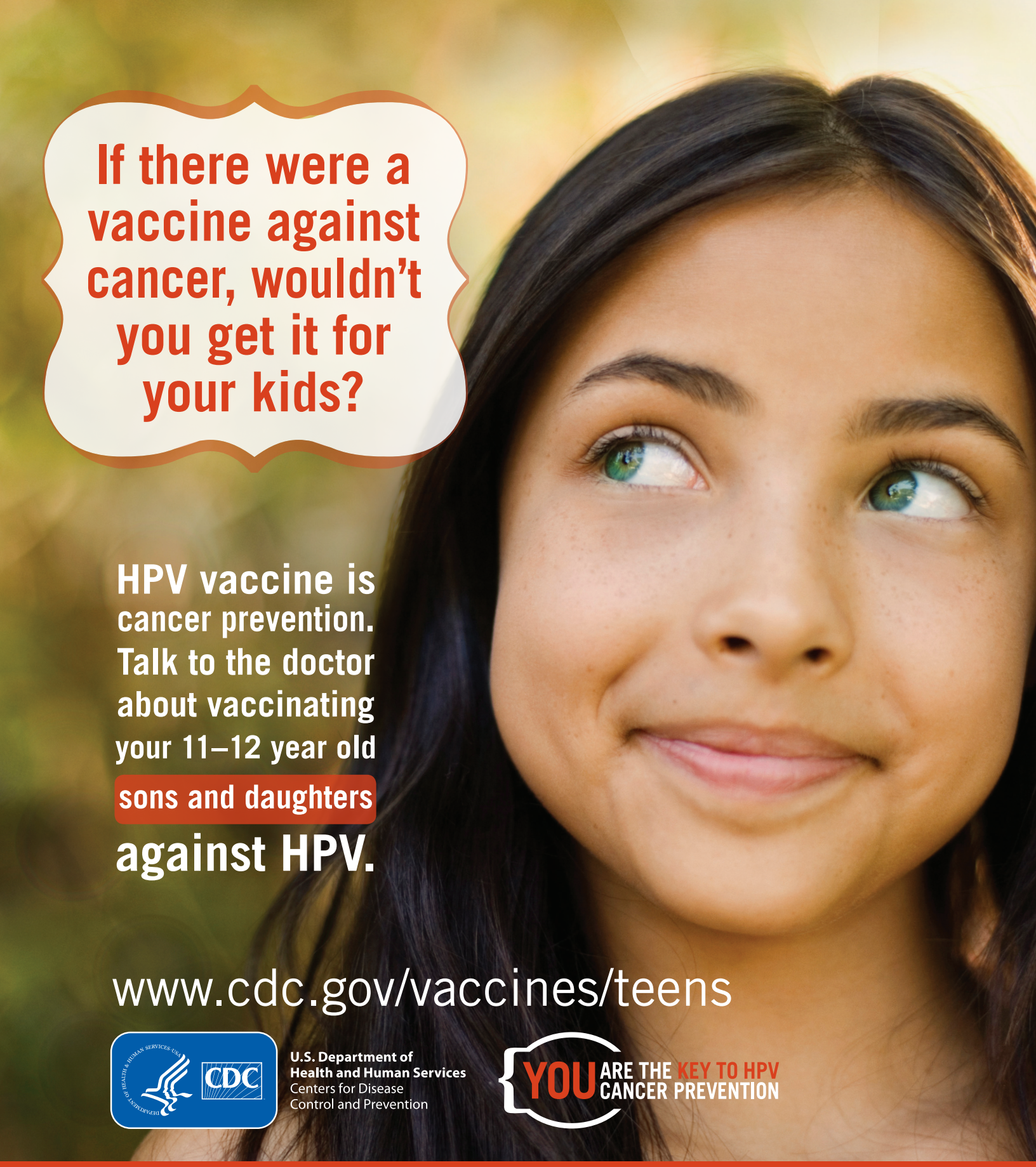
www.cdc.gov/vaccines/teens

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

YOU ARE THE KEY TO HPV CANCER PREVENTION

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Si hubiese una vacuna contra el cáncer, ¿se la pondría a sus hijos?

La vacuna contra el VPH previene el cáncer.

Consulte a su médico sobre cómo vacunar a sus **hijos e hijas** de entre 11 y 12 años contra el VPH.

www.cdc.gov/vaccines/teens

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

YOU ARE THE KEY TO HPV CANCER PREVENTION

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HUMAN PAPILLOMAVIRUS (HPV)



ABOUT

79 MILLION

AMERICANS

ARE CURRENTLY INFECTED WITH HPV
AND ANOTHER

14 MILLION

PEOPLE BECOME NEWLY INFECTED

EACH YEAR.

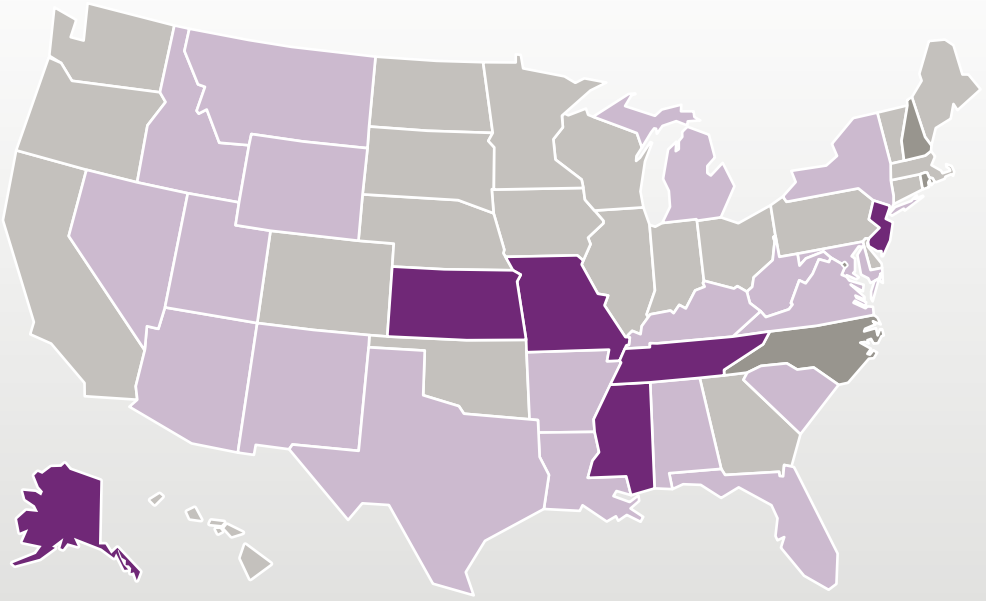
Learn more about the diseases that can be prevented by vaccines at VaccinateYourFamily.org

HPV Vaccine Now Available At Total Care Pharmacy—206 West Main St.

HPV VACCINATION IS THE BEST WAY TO PREVENT MANY TYPES OF CANCER
MANY ADOLESCENTS HAVEN'T STARTED THE HPV VACCINE SERIES

NATIONWIDE 4 OUT OF 10 GIRLS ARE UNVACCINATED

Percentage of adolescent girls who have received one or more doses of HPV vaccine*

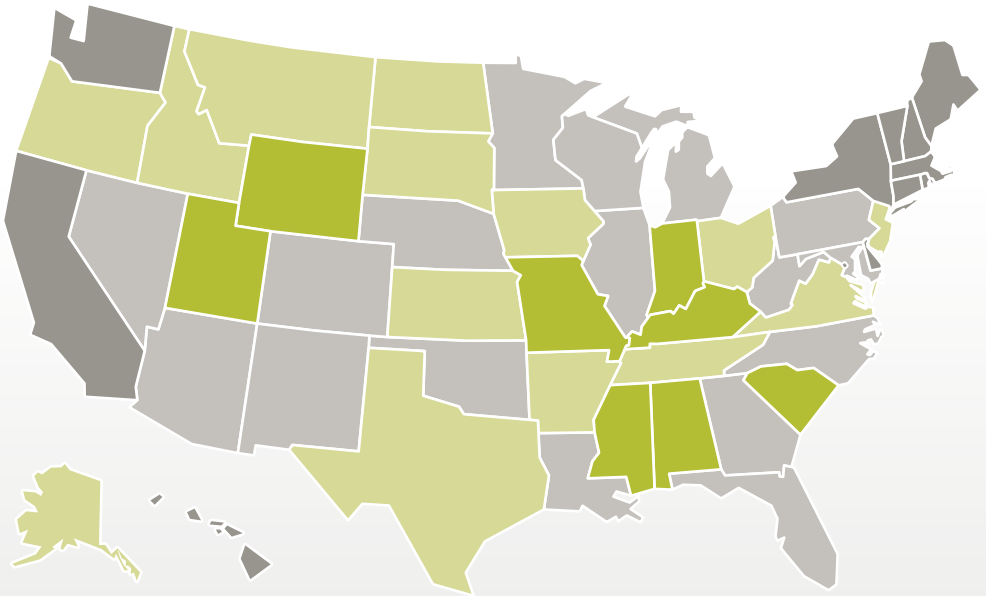


National coverage is 60%
Coverage by state:

- 49% or less
- 50-59%
- 60-69%
- 70% or greater

NATIONWIDE 6 OUT OF 10 BOYS ARE UNVACCINATED

Percentage of adolescent boys who have received one or more doses of HPV vaccine*



National coverage is 42%
Coverage by state:

- 29% or less
- 30-39%
- 40-49%
- 50% or greater

IMPROVING HPV VACCINATION RATES WILL HELP SAVE LIVES.
A high national Tdap vaccination rate of 88% shows that it is possible to achieve high HPV vaccination coverage.

*Estimated coverage with ≥1 dose of Human Papillomavirus (HPV) vaccine, either quadrivalent or bivalent, among adolescents aged 13-17 years, National Immunization Survey–Teen (NIS–Teen), United States, 2014

Source: MMWR July 31, 2015

www.cdc.gov/hpv

NCIRDig524 | July 31, 2015

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



HPV vaccine is cancer prevention.

Talk to your pharmacist about vaccinating your 9-17 year old sons and daughters against HPV.

Stop by Total Care Pharmacy before school starts!

total care pharmacy
diabetes & wellness center

Start the school year by vaccinating your 11-12 year old **sons and daughters** against HPV.

HPV vaccine is cancer prevention.

total care pharmacy
diabetes & wellness center

Visit Total Care Pharmacy
206 W. Main St.
Morehead, KY 40351



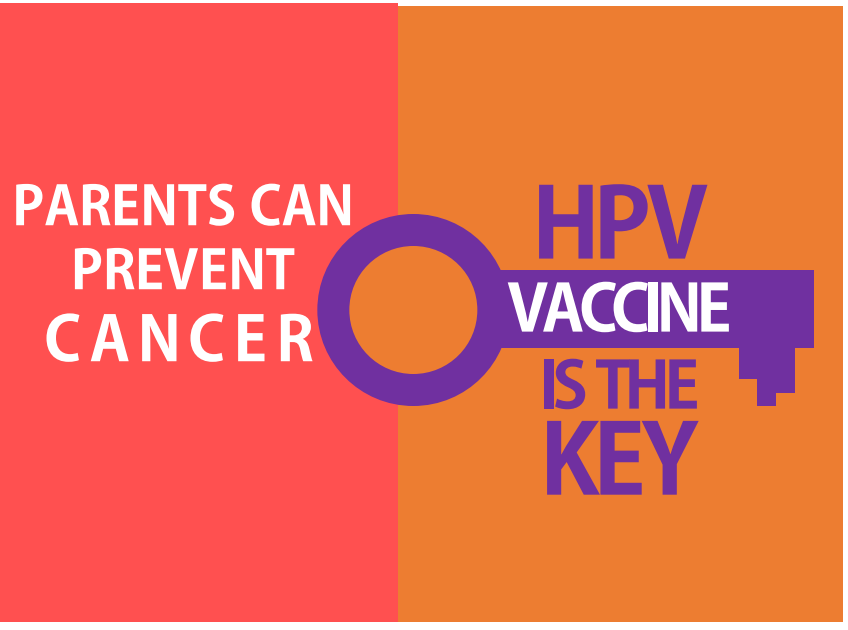


HPV vaccine is cancer prevention.

Start the school year by vaccinating your 11-12 year old **sons and daughters**.

Visit Total Care Pharmacy
206 W. Main St., Morehead, KY 40351

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Talk to your
Total Care Pharmacist
about vaccinating your
adolescent sons and daughters
(ages 9-17) against HPV.

206 W. Main St., Morehead, KY 40351

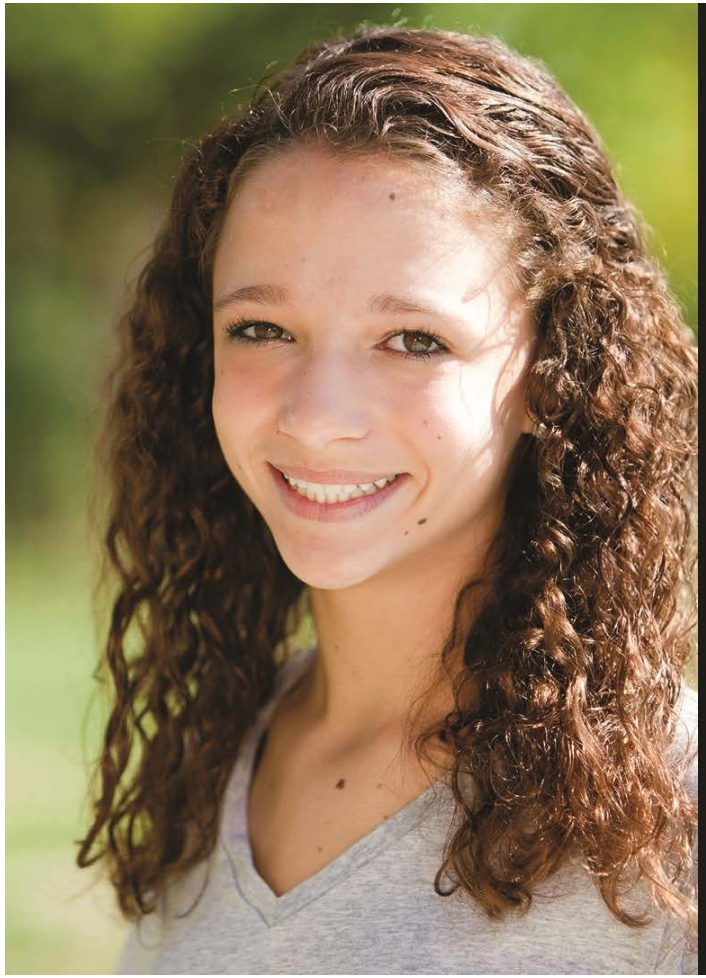
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Talk to your
Total Care
Pharmacist
about vaccinating
your 9-17 year old
sons and daughters
against HPV.

206 W. Main St.
Morehead, KY 40351

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HPV Vaccine is CANCER PREVENTION

Talk to your Total Care Pharmacist about vaccinating your 11-12 year old sons and daughters against HPV today!

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www.totalcarepharmacy.biz

YOU ARE THE KEY TO CANCER PREVENTION

CDC