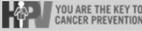




**You are the Key
to HPV Cancer Prevention**
Understanding the Burden of HPV Disease,
the Importance of the HPV Vaccine Recommendation,
and Successfully Communicating about HPV Vaccination

Margaret C. Jones, RN, BSN, BS Ed
Kentucky Immunization Program Manager

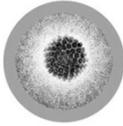
August 2016



Objectives

1. Define the importance of HPV vaccination for cancer prevention and the rationale for vaccinating at ages 11 or 12.
2. List the recommendations for HPV vaccine for girls and for boys.
3. Provide useful and compelling information about HPV vaccine to parents to aid in making the decision to vaccinate.
4. Locate resources relevant to current immunization practice.

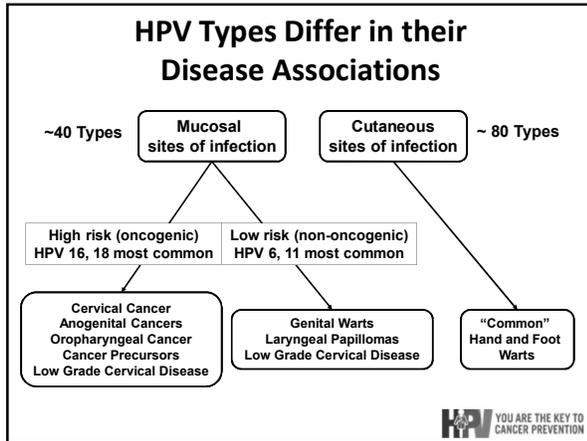




HPV
(Human papillomavirus)

Understanding the Burden
HPV INFECTION & DISEASE





HPV Infection

- ▶ **Most females and males will be infected with at least one type of mucosal HPV at some point in their lives**
 - ▶ Estimated 79 million Americans currently infected
 - ▶ 14 million new infections/year in the US
 - ▶ HPV infection is most common in people in their teens and early 20s
- ▶ **Most people will never know that they have been infected**

Jemal A et al. J Natl Cancer Inst 2013;105:175-201

HPV YOU ARE THE KEY TO CANCER PREVENTION

Every year in the United States 27,000 people are diagnosed with a cancer caused by HPV

20 min.

That's 1 case every 20 minutes

HPV YOU ARE THE KEY TO CANCER PREVENTION

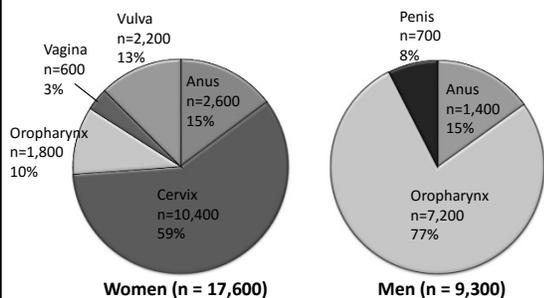
Cancers Caused by HPV, U.S.

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

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



New Cancers Caused by HPV per Year United States 2006-2010



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

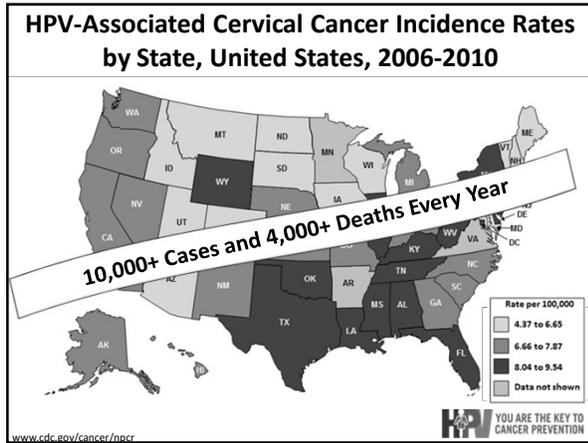


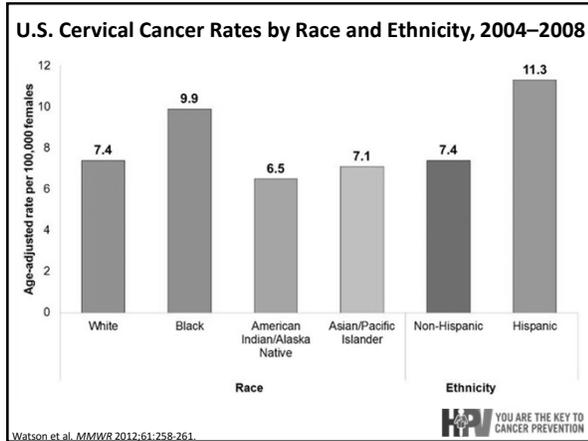
Cervical Cancer

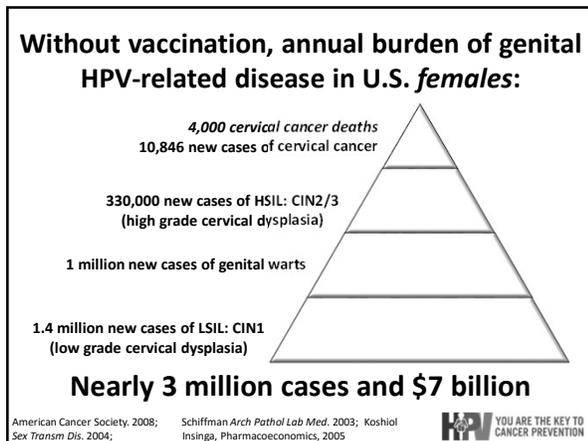
- ▶ **Cervical cancer is the most common HPV-associated cancer among women**
 - ▶ 500,000+ new cases and 275,000 attributable deaths world-wide in 2008
 - ▶ 11,000+ new cases and 4,000 attributable deaths in 2011 in the U.S.
- ▶ **37% cervical cancers occur in women who are between the ages of 20 and 44**
 - ▶ 13% (or nearly 1 in 8) between 20 and 34
 - ▶ 24% (or nearly 1 in 4) between 35 and 44

CDC. HPV-associated cancers—US, 2004–2008. MMWR 2012;61(15):258–261. Cervical Cancer Counts by Age. US Cancer Statistics data from 2010, CDC.gov.









Annual Report to the Nation on the Status of Cancer: HPV-Associated Cancers

- ▶ From 2000 to 2009, oral cancer rates increased
 - ▶ 4.9% for Native American men
 - ▶ 3.9% for white men
 - ▶ 1.7% for white women
 - ▶ 1% for Asian men
- ▶ Anal cancer rates doubled from 1975 to 2009
- ▶ Vulvar cancer rates rose for white and African-American women
- ▶ Penile cancer rates increased among Asian men

Jemal A et al. J Natl Cancer Inst 2013;105:175-201



{ HPV vaccine is cancer prevention. }



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

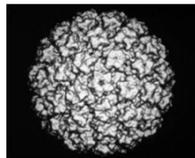
#UCanStopHPV

Evidence-Based HPV Disease Prevention

HPV VACCINE

HPV Prophylactic Vaccines

- ▶ Recombinant L1 capsid proteins that form “virus-like” particles (VLP)
- ▶ Non-infectious and non-oncogenic
- ▶ Produce higher levels of neutralizing antibody than natural infection



HPV Virus-Like Particle



HPV Vaccination is Routinely Recommended

- ▶ **HPV vaccination is recommended for both females and males ages 11-12 years**
 - ▶ HPV vaccine series should be completed before the 13th birthday

Routine immunization for 11- and 12-year-olds includes HPV vaccination.

Clinicians should recommend HPV vaccine on the same day and in the same way as the other vaccines for preteens.

MMWR, August 29, 2014, Vol 63, #RR05



Updated ACIP Recommendations

Age

- ▶ **Routine vaccination at age 11 or 12 years***
- ▶ Vaccination recommended through **age 26 for females** and through **age 21 for males** not previously vaccinated
- ▶ Vaccination recommended for men **through age 26** who have sex with men (MSM) or are immunocompromised (including persons HIV-infected)

Formulation by gender (assuming availability)

	9vHPV	4vHPV	2vHPV
Females	✓	✓	✓
Males	✓	✓	

*vaccination series can be started at 9 years of age
MMWR 2015;64:300-4



Updated ACIP Recommendations: Formulations

- ▶ 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.
- ▶ 9vHPV targets **five additional** cancer causing types, which account for about 15% of cervical cancers.
- ▶ 4vHPV and 9vHPV also protect against HPV **6 and 11**, types that cause genital warts.

MMWR 2015;64:300-4



**Updated ACIP Recommendations:
Interchangeability**

If vaccination providers do not know, or do not have available the HPV vaccine product previously administered, or are in settings transitioning to 9vHPV:

For protection against HPV 16 and 18,

- Females: Any HPV vaccine product may be used to continue or complete the series
- Males: 4vHPV or 9vHPV may be used to continue or complete the series

MMWR 2015;64:300-4



**ACIP Recommendations:
Timing of the Series**

■ **2vHPV, 4vHPV and 9vHPV are each administered in a 3-dose schedule**

- Interval between doses 1 → 2: 1-2 months
- Interval between doses 1 → 3: 6 months

■ **If the vaccine schedule is interrupted, the series does not need to be restarted**

MMWR 2015;64:300-4



**HPV Vaccination Is Safe, Effective,
and Provides Lasting Protection**

■ **HPV Vaccine is SAFE**

- Benefits of HPV vaccination far outweigh any potential risks
- Safety studies findings for HPV vaccination similar to safety reviews of MCV4 and Tdap vaccination

■ **HPV Vaccine WORKS**

- Population impact against early and mid outcomes have been reported in multiple countries

■ **HPV Vaccine LASTS**

- Studies suggest that vaccine protection is long-lasting
- No evidence of waning protection

Garland et al, Prev Med 2011; Ali et al, BMJ 2013; Markowitz JID 2013; Nsouli-Maktabi MSMR 2013



HPV VACCINE SAFETY

HPV YOU ARE THE KEY TO CANCER PREVENTION

HOW A VACCINE'S SAFETY CONTINUES TO BE MONITORED

FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects).

Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

VACCINE ADVERSE EVENT REPORTING SYSTEM

VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

VACCINE SAFETY DATALINK

Network of healthcare organizations across the U.S.

Healthcare information available for a population of over 9 million people.

Scientists use VSD to conduct studies to evaluate the safety of vaccines and determine if possible side effects are actually associated with vaccination.

Vaccine recommendations may change if safety monitoring shows that the vaccine risks outweigh the benefits (like if scientists detect a new serious side effect).

cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html

VAERS: HPV Vaccine Safety Monitoring

- ▶ Ongoing safety monitoring has shown most reports are non-serious
- ▶ Among the 7.6% of reports coded as “serious,” most frequently cited possible side effects are headache, nausea, vomiting, and fever
- ▶ Syncope (fainting) continues to be reported following vaccination among adolescents
 - ▶ Adherence to a 15-minute observation period after vaccination is encouraged

MMWR. 2014;63(RR05):1-30

HPV YOU ARE THE KEY TO CANCER PREVENTION

VSD Rapid Cycle Analysis (RCA), 4vHPV

- ▶ RCA allows VSD to detect adverse events following vaccination in near real time
- ▶ After approx. 600,000 HPV4 doses among females, **no significant risk** for any of the *pre-specified adverse events* after vaccination (including GBS, seizures, syncope, appendicitis, stroke, venous thromboembolism, and allergic reactions)

Gee J et al, Vaccine 2011;29:8279-8284.



Ongoing HPV Safety Activities at CDC

- ▶ Review of reports to VAERS to search for unusual adverse events or changing patterns of adverse events
- ▶ VSD addressing HPV vaccine safety in special populations:
 - ▶ Safety of 4vHPV among males
 - ▶ Inadvertent 4vHPV vaccination during pregnancy
- ▶ VSD addressing HPV vaccine safety concerns that may arise from case reports and/or the media



Non-CDC HPV Vaccine Safety Activities

- ▶ Post-licensure commitments from manufacturers
 - ▶ Vaccine in pregnancy registries
 - ▶ Long term follow-up in Nordic countries
- ▶ Official reviews
 - ▶ WHO's Global Advisory Committee on Vaccine Safety¹
 - ▶ Institute of Medicine's report on adverse effects and vaccines, 2011²

¹www.who.int/vaccine_safety/Jun_2009/en/
²www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx



Key Findings – CDC and Non-CDC

- **Venous thromboembolism (VTE)¹**
 - Study evaluating the risk of VTE in vaccinated persons age 9-26 years
 - *Found no increased risk of VTE following 4vHPV*
- **Autoimmune and neurologic conditions²**
 - Study addressing concerns about autoimmune and neurologic disease following 4vHPV vaccination.
 - *Found no association between 4vHPV vaccination and 16 autoimmune conditions*
- **Injection site reactions and syncope³**
 - 4vHPV vaccination may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received
 - *No major safety concerns found*

¹ Gee et al., Vaccine 2011
²Chao C. et al. J Intern Med 2012
³Klein NP, et al., Arch Pediatr Adolesc Med. 2012 Dec; 166(12):1140-8.



IOM Review: Syncope & Anaphylaxis

- **IOM reviewed possible associations between 8 vaccines and adverse health events. Key findings:**
 - Evidence “favors acceptance” of a causal relationship between HPV vaccine and anaphylaxis (rare)
 - Evidence “convincingly supports” a causal relationship between the injection of a vaccine and syncope
- **Inadequate evidence was found for causal relationships between HPV vaccination and 12 other specific health events studied**

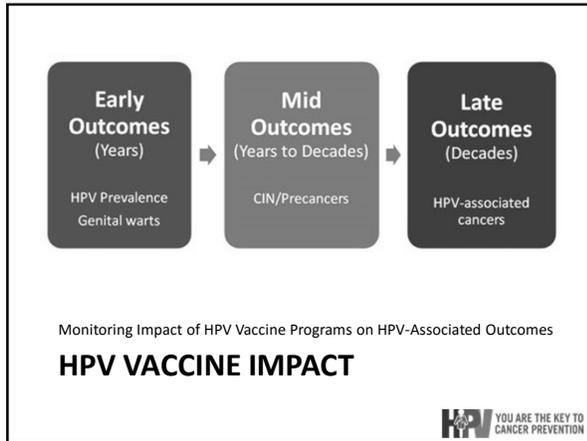
Institute of Medicine. The National Academies Press, 2012.



9vHPV Vaccine Safety

- **Seven pre-licensure studies including 15,000 males and females**
- **Generally well tolerated**
 - Adverse event profile similar to that of 4vHPV across age, gender, race, and ethnicity
 - More injection-site reactions expected among those who receive 9vHPV





HPV vaccine impact monitoring

- Post licensure evaluations are important to evaluate real world effectiveness of vaccines
- Population impact against early and mid outcomes have been reported:
 - Genital warts**
 - Australia, New Zealand, Denmark, Sweden, Germany, Quebec, US
 - HPV prevalence**
 - Australia, Norway, Denmark, Sweden, UK, US
 - Cervical lesions**
 - Australia, British Columbia, Denmark, Sweden, US

HPV YOU ARE THE KEY TO CANCER PREVENTION

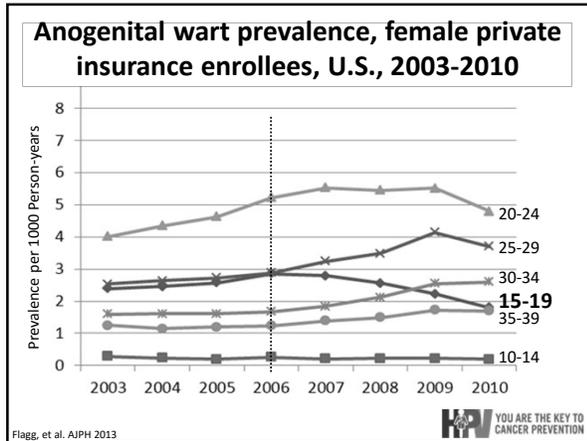
NHANES HPV Prevalence Studies

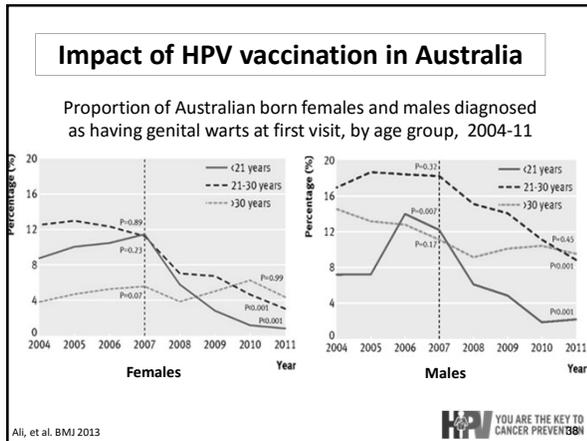
- National Health and Nutrition Examination Survey (NHANES) data used to compare HPV prevalence
 - Before the start of the HPV vaccination program (2003-2006) &
 - From the first 4 years after vaccine introduction (2007-2010)
- Results
 - In **14-19 year olds**, vaccine-type HPV prevalence **decreased 56%** (11.5% in 2003-2006 to 5.1% in 2007-2010)
 - Other age groups** did not show a statistically significant difference over time

Vaccine effectiveness for prevention of infection was an estimated 82%

Markowitz, et al. J Infect Dis 2013

HPV YOU ARE THE KEY TO CANCER PREVENTION





Systematic Review and Meta-Analysis: Population-Level Impact of HPV Vaccination

- Review of 20 studies in 9 high income countries
- In countries with >50% coverage, among 13-19 yr olds
 - HPV 16/18 prevalence **decreased at least 68%**
 - Anogenital warts decreased by ~61%
- Evidence of herd effects
- Some evidence of cross protection against other types

HPV YOU ARE THE KEY TO CANCER PREVENTION

Drolet et al. Lancet Infect Dis 2015

Challenges in Monitoring HPV Vaccine Impact on Cervical Lesions

- ▶ Detected through cervical cancer screening
- ▶ Changing screening recommendations
- ▶ Lack of cervical cancer screening registries in some countries
- ▶ Incomplete linkages with vaccination registries



HPV Vaccine Duration of Immunity

- ▶ Studies suggest that vaccine protection is long-lasting; no evidence of waning immunity
 - ▶ *Available evidence* indicates protection for *at least* 8-10 years
 - ▶ Multiple cohort studies are in progress to monitor the duration of immunity



HPV Vaccine Three-Dose Coverage

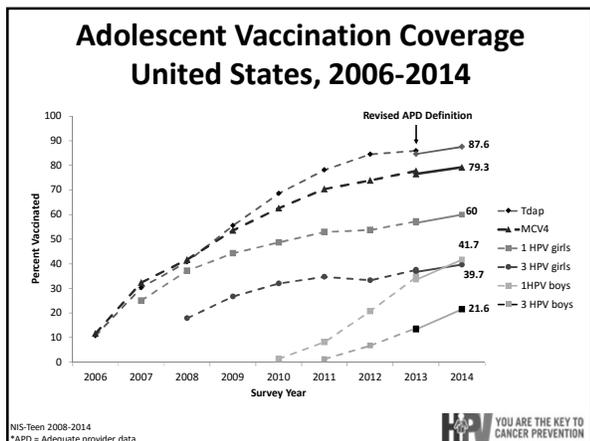


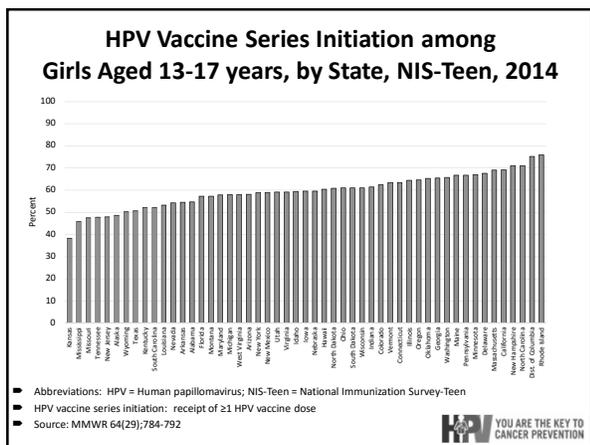
Among Girls in High-Income Countries

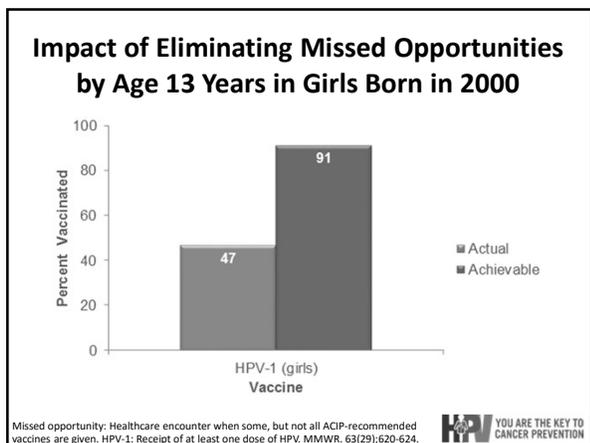
United States

HPV VACCINE COVERAGE



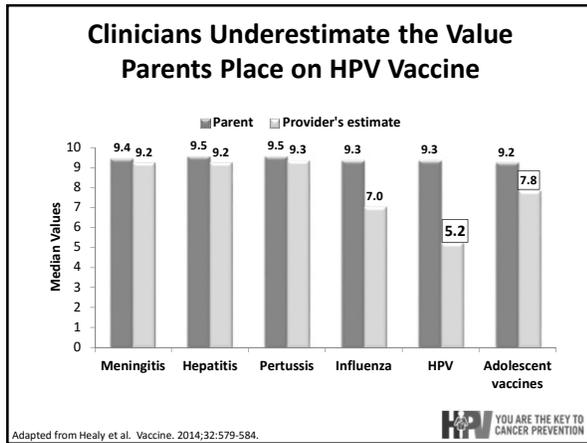






Talking about HPV vaccine
FRAMING THE CONVERSATION

HPV YOU ARE THE KEY TO CANCER PREVENTION



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

Give a Strong Recommendation to Receive HPV Vaccine at Ages 11 or 12

Reason	Percent
Not sexually active	~12
Not recommended	~14
Safety concern/Side effects	~15
Not needed or necessary	~15
Lack of knowledge	~16

- **A strong recommendation from you is the main reason parents decide to vaccinate**
- Many moms in focus groups stated that they trust their child's doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

MMWR 2014; 63(29):625-633; Unpublished CDC data, 2013.

HPV YOU ARE THE KEY TO CANCER PREVENTION

Talking to parents about HPV VACCINE



Make a Bundled Recommendation

- Recommend HPV vaccine the same way and on the same day you recommend Tdap and meningococcal vaccines. A strong recommendation from you is the main reason parents decide to vaccinate.
- You can say "your preteen needs three vaccines that provide protection against meningitis, HPV cancers, and pertussis."
- Hearing "HPV vaccine is cancer prevention" helps parents make the decision to vaccinate. Parents don't want to talk about HPV vaccine in the context of sexuality or sexual transmission.

Address Parents' Questions

- Help them understand why the vaccine is needed at age 11 or 12, let them know that like any other vaccine, they want their children protected long before exposure.
- Emphasize your personal belief in the importance of HPV vaccine to help parents feel secure in their decision. Let them know you have given/will give it to the children in your life.

HPV YOU ARE THE KEY TO CANCER PREVENTION

Make an Effective Recommendation

- **Same way: Effective recommendations group all of the adolescent vaccines**

Recommend HPV vaccination the *same way* you recommend Tdap & meningococcal vaccines.
- **Same day: Recommend HPV vaccine today**

Recommend HPV vaccination the *same day* you recommend Tdap & meningococcal vaccines.

HPV YOU ARE THE KEY TO CANCER PREVENTION

Unpublished CDC data, 2013.

If a parent were hesitant...

Ask	Clarify & restate their concerns to make sure you understand
Acknowledge	<ul style="list-style-type: none"> •Emphasize it is the parents' decision. •Acknowledge risks and conflicting information sources. •Applaud them for wanting what is best for their child. •Be clear that you are concerned for the health of their child, not just public health safety.
Advise	<ul style="list-style-type: none"> •Clarify their concerns to make sure you understand and are answering the question they actually care about. •Allow time to discuss the pros and cons of vaccines. •Be willing to discuss parents' ideas. •Offer written resources for parents. •Tailor your advice using this sheet or CDC's <i>Tips & Time Savers</i>.
Remember	<ul style="list-style-type: none"> •Declination is not final. The conversation can be revisited. •End the conversation with <u>at least 1 action</u> you both agree on. •Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a <i>Declination Form</i>

HPV YOU ARE THE KEY TO CANCER PREVENTION

Some Parents Need Reassurance

- ▶ Many parents simply accept of this bundled recommendation
- ▶ Some parents may be interested in vaccinating, yet still have questions. Interpret a question as they need additional reassurance from YOU, the clinician they trust with their child’s health care
- ▶ Ask parents about their main concern (be sure you are addressing their real concern)

Unpublished CDC data, 2013.



Clinicians can give a strong and effective HPV vaccine recommendation by announcing:

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



If main concern is “**Why does my child need this vaccine**” try saying:

HPV vaccine is very important because it prevents cancer.

I know we’d like to protect Maureen from cancer and I’d feel better if she got her first dose of the HPV vaccine series today.



If main concern is **“My daughter will wait for marriage/won’t be exposed”**, try saying:

HPV is so common that almost everyone will be infected at some time.

When your daughter marries, she could catch HPV from her husband. He might have been infected before he ever met her.



If main concern is **“why now, let’s wait until child is older,”** try saying:

HPV vaccination provides the best protection when given at age 11 or 12, which is why I recommend starting the HPV vaccine series today.



If main concern is **“HPV vaccine will be a green light for sex,”** try saying:

Studies have shown that getting the HPV vaccine doesn’t make kids more likely have sex, or to have sex at a younger age.



If main concern is **“would you give it to your child,”** try saying:

*Yes, I gave it to my child
(or grandchild, etc) because I think
preventing cancer is very important.*



If main concern is **“side effects,”** try saying:

*Vaccines, like any medication, can cause
side effects. With HPV vaccine most are
mild, primarily pain or redness in the arm.
This should go away quickly.*

*HPV vaccine has not been linked with any
serious or long-term side effects.*



If main concern is **“possible effects on fertility,”** try saying:

*There is no data to suggest that getting HPV
vaccine will have an effect on future fertility.*

*However, persistent HPV infection can cause
cervical cancer and the treatment of cervical
cancer can leave women unable to have
children.*

*Even treatment for cervical pre-cancer can put
a woman at risk for problems with her cervix
during pregnancy causing preterm delivery or
problems.*



Before leaving the exam room, **remind parents when to come back**. Try saying:

*To work, Robert needs the full HPV vaccine series, so . . .
When you check out, please make sure to make an appointment for about 6 weeks from now for the next shot, and put that appointment on your calendar before you leave the office today!*



Increase the number of target patients who come in & leave vaccinated

1. Align office policy with mission – e.g., immunize at every opportunity
2. Align communication with mission
3. Standing orders
4. Prompt the person who is supposed to order the vaccine
 - ▀ Nursing personnel
 - ▀ EHR
 - ▀ Both



Be sure everyone in the office understands the mission



Human stories often influence people more than statistics To understand the human stories behind HPV, listen to survivors

- ▀ Shot By Shot
- ▀ Unprotected People on www.immunize.org



Standing orders

- Empower non-physician personnel to vaccinate patients (after assessing for specific contraindications) without direct physician involvement
- Practices should have on file preapproved orders to vaccinate
- Templates available for all routine vaccines at www.immunize.org/standing-orders/
- To save physicians time, staff have to be aware of the standing orders and be trained to use it



Review Question #1

HPV vaccine is recommended for the following persons:

- A. All adolescents at the 11 to 12 year old visit.
- B. Females only at the 13 year old visit.
- C. Males only at the 11 to 12 year old visit.
- D. Females only at the 11 to 12 year old visit.



Review Question #1

HPV vaccine is recommended for the following persons:

- A. All adolescents at the 11 to 12 year old visit.
- B. Females only at the 13 year old visit.
- C. Males only at the 11 to 12 year old visit.
- D. Females only at the 11 to 12 year old visit.



Review Question #2

Why should males receive HPV vaccine?

- A. Prevention of infection with HPV types 6, 11, 16, 18.
- B. Prevention of genital warts caused by HPV types 6 and 11.
- C. Prevention of anal cancer caused by HPV types 16 and 18.
- D. All of the above.



Review Question #2

Why should males receive HPV vaccine?

- A. Prevention of infection with HPV types 6, 11, 16, 18.
- B. Prevention of genital warts caused by HPV types 6 and 11.
- C. Prevention of anal cancer caused by HPV types 16 and 18.
- D. All of the above.



Review Question #3

Which of the following HPV vaccine recommendations for a child aged 11 or 12 years is the most likely to be successful?

- A. Ask parent if child is sexually active and then discuss importance of HPV vaccination.
- B. Tell parent that their child needs three vaccinations to prevent meningitis, HPV cancers, and pertussis.
- C. Tell parent about the vaccinations that are mandatory for school entry and ask if they also want HPV vaccine.
- D. Ask parent if they want to get HPV vaccination for their child or wait until the child is older.

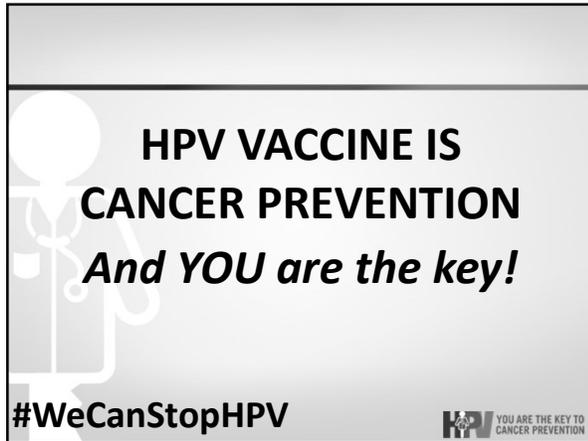


Review Question #3

Which of the following HPV vaccine recommendations for a child aged 11 or 12 years is the most likely to be successful?

- A. Ask parent if child is sexually active and then discuss importance of HPV vaccination.
- B. Tell parent that their child needs three vaccinations to prevent meningitis, HPV cancers, and pertussis.
- C. Tell parent about the vaccinations that are mandatory for school entry and ask if they also want HPV vaccine.
- D. Ask parent if they want to get HPV vaccination for their child or wait until the child is older.





**HPV VACCINE IS
CANCER PREVENTION**
And YOU are the key!

#WeCanStopHPV

HPV YOU ARE THE KEY TO
CANCER PREVENTION

The graphic features a stylized white silhouette of a person with a large white circle above their head, set against a light gray background. The text is centered and uses a mix of bold, uppercase sans-serif and italicized lowercase sans-serif fonts.
