





# You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease, the Importance of the HPV Vaccine Recommendation, and Communicating about HPV Vaccination

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### Disclosure

I have no financial disclosures related to this presentation



### **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.



# Three reasons you should care about HPV vaccine

- HPV causes lots of cancer
- HPV vaccine prevents cancer



We are doing a terrible job of immunizing our population with HPV vaccine to prevent cancer



# HPV Types Differ in their Disease Associations

Mucosal Cutaneous ~40 Types ~ 80 Types sites of infection sites of infection High risk (oncogenic) Low risk (non-oncogenic) **HPV 16, 18 most common HPV 6, 11 most common Cervical Cancer Genital Warts** "Common" **Anogenital Cancers Oropharyngeal Cancer Laryngeal Papillomas** Hand and Foot **Cancer Precursors Low Grade Cervical Disease Warts** 

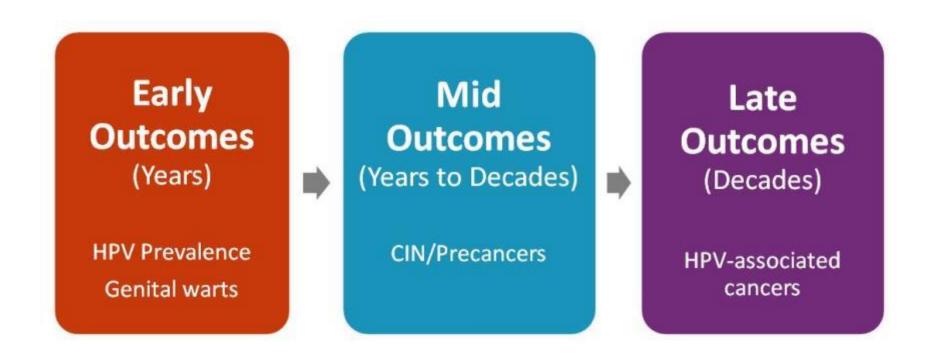
**Low Grade Cervical Disease** 



#### **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





Monitoring Impact of HPV Vaccine Programs on HPV-Associated Outcomes

#### **HPV VACCINE IMPACT**



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



# That's 1 case every 20 minutes



# Cancers Caused by HPV, U.S.

Canaan aita	Average nu proba	Percentage		
Cancer site	Male	Female	<b>Both Sexes</b>	per year
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	

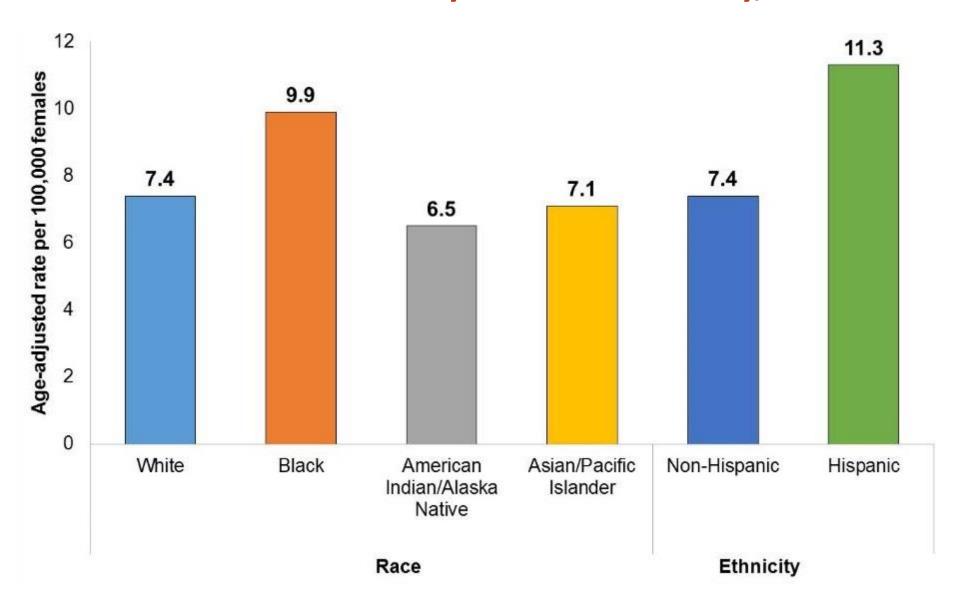


### **Cervical Cancer**

- Cervical cancer is the most common HPVassociated 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



#### U.S. Cervical Cancer Rates by Race and Ethnicity, 2004–2008







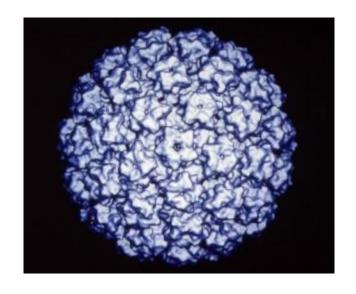
**Evidence-Based HPV Disease Prevention** 

### **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 Vaccines Currently Licensed in U.S.**

	Bivalent 2vHPV (Cervarix)	Quadrivalent 4vHPV (Gardasil)	9-Valent 9vHPV (Gardasil 9)
Manufacturer	GlaxoSmithKline	Merck	Merck
HPV Types Included	16, 18	6, 11, <b>16, 18</b>	6, 11, <b>16, 18,</b> 31, 33, 45, 52, 58
Contraindications	Hypersensitivity to latex*	Hypersensitivity to yeast	Hypersensitivity to yeast
Dose Schedule	3 dose series: 0, 1, 6 months	3 dose series: 0, 2, 6 months	3 dose series: 0, 2, 6 months

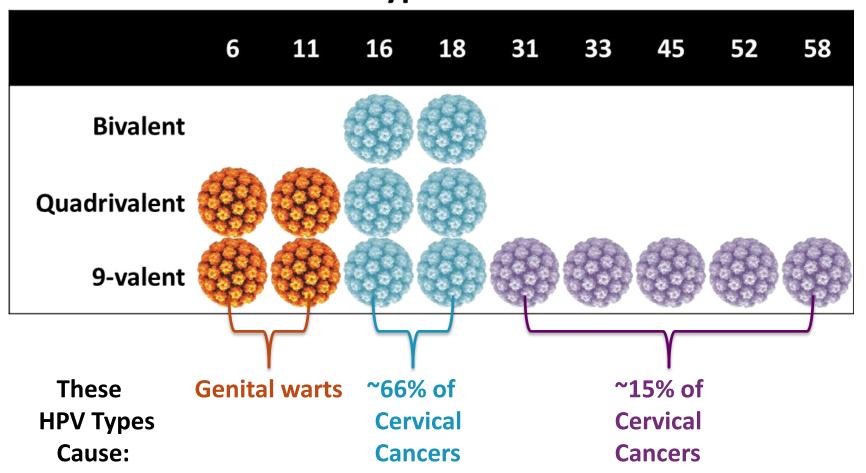


<sup>\*</sup> only contained in pre-filled syringes, not single-dose vials

# **HPV Vaccine**

# **HPV Vaccine Comparison**

#### **HPV Types Included in Vaccine**





# 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



### **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	<b>V</b>	<b>~</b>	<b>✓</b>
Males	<b>V</b>	<b>V</b>	



# **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,

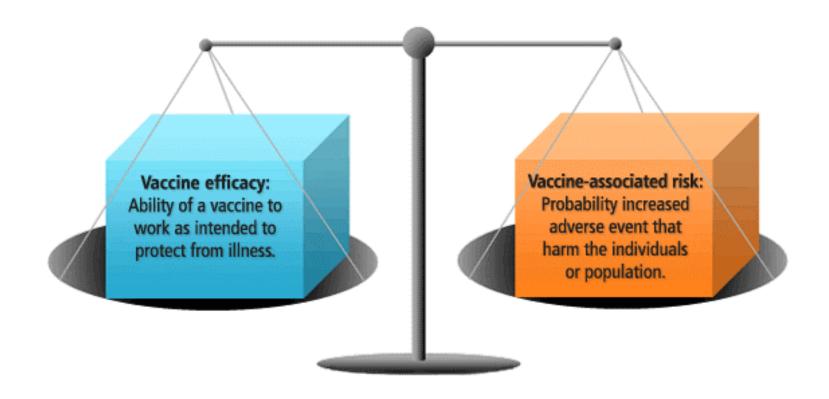
- Females: Any HPV vaccine product may be used to continue or complete the series
- Males: 4vHPV or 9vHPV may be used to continue or complete the series



# ACIP Recommendations: Timing of the Series

- 2vHPV, 4vHPV and 9vHPV are each administered in a 3-dose schedule
  - Interval between doses  $1 \rightarrow 2$ : ~6 weeks (1-2 months)
  - $\blacksquare$  Interval between doses 1  $\rightarrow$  3: 6 months
- If the vaccine schedule is interrupted, the series does <u>not</u> need to be restarted





### **HPV VACCINE SAFETY**



### **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



### 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)



### **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 Safety <sup>1</sup>
- ■Institute of Medicine's report on adverse effects and vaccines, 2011²



# **Key Findings – CDC and Non-CDC**

#### Venous thromboembolism (VTE)<sup>1</sup>

- Study evaluating the risk of VTE in vaccinated persons age 9-26 years
- Found no increased risk of VTE following 4vHPV

#### Autoimmune and neurologic conditions<sup>2</sup>

- 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 syncope<sup>3</sup>

- 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



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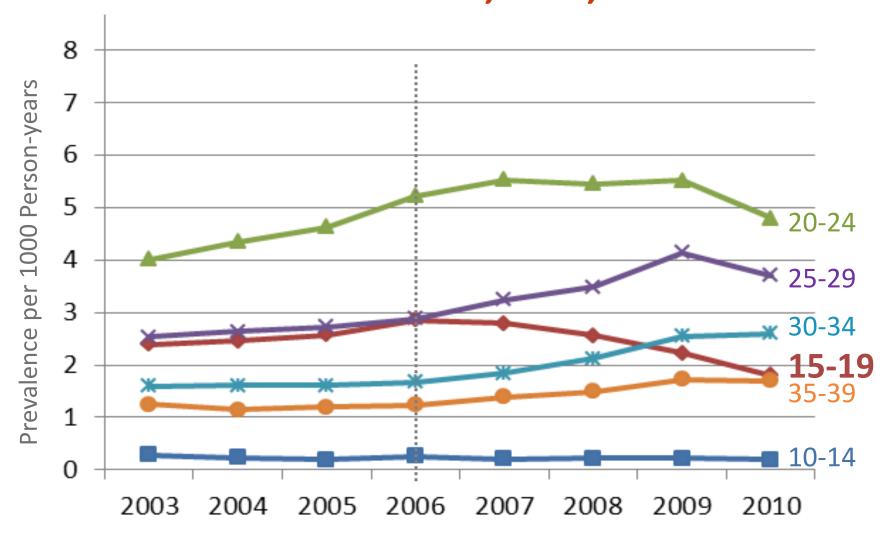
### **NHANES HPV Prevalence Studies**

- 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%



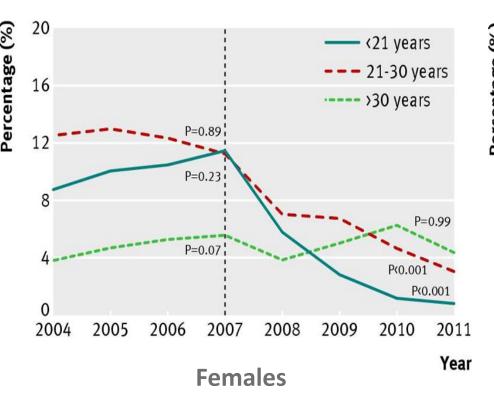
# Anogenital wart prevalence, female private insurance enrollees, U.S., 2003-2010

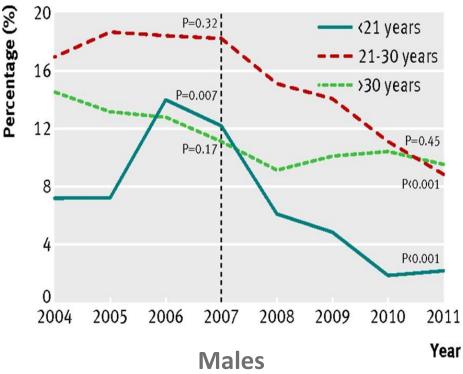




### Impact of HPV vaccination in Australia

Proportion of Australian born females and males diagnosed as having genital warts at first visit, by age group, 2004-11







# 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 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



# Three reasons you should care about HPV vaccine

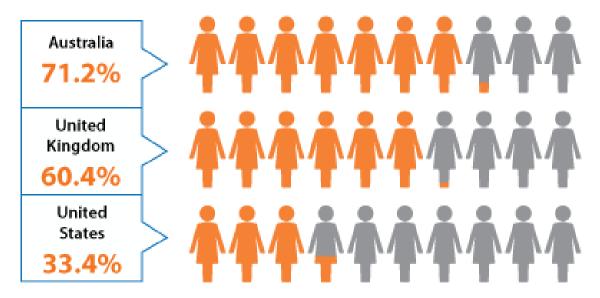
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#### **HPV Vaccine Three-Dose Coverage**



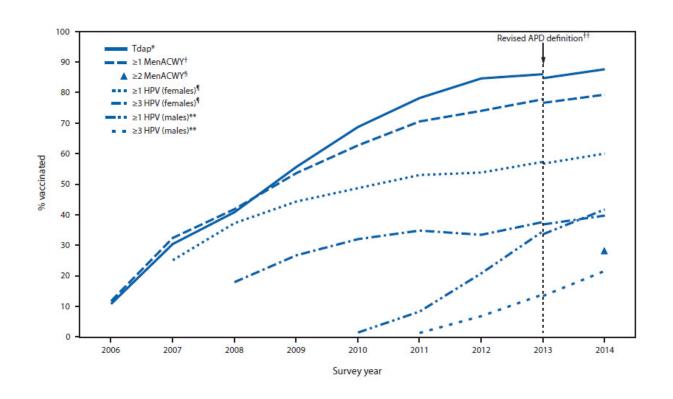
**Among Girls in High-Income Countries** 

**United States** 

#### **HPV VACCINE COVERAGE**

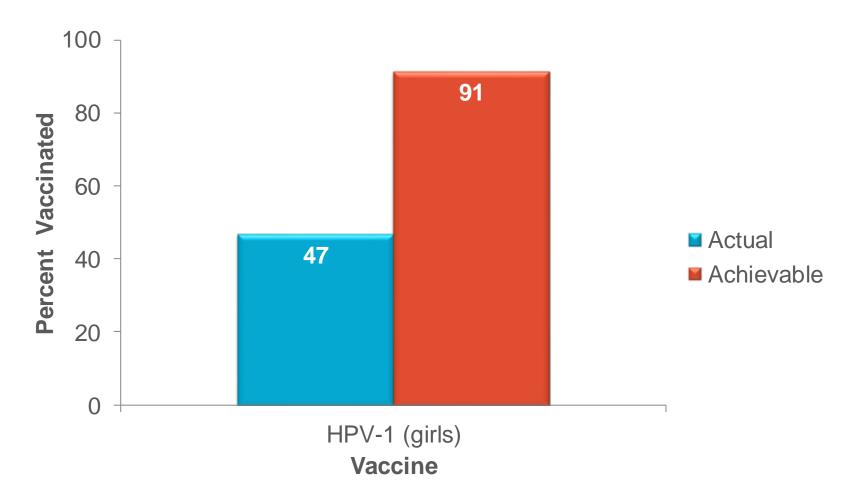


# HPV vaccine coverage rates-United States, 2014

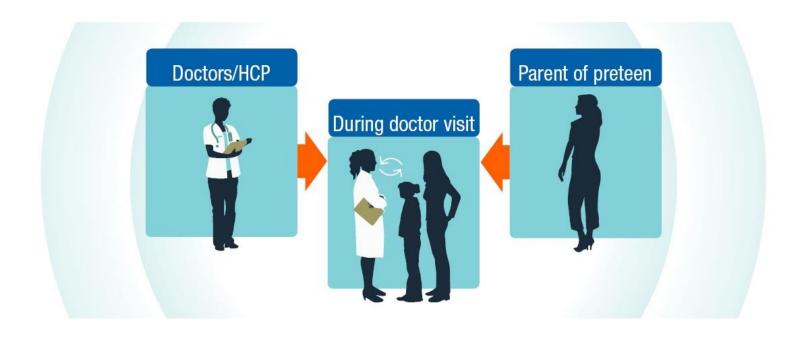




# Impact of Eliminating Missed Opportunities by Age 13 Years in Girls Born in 2000





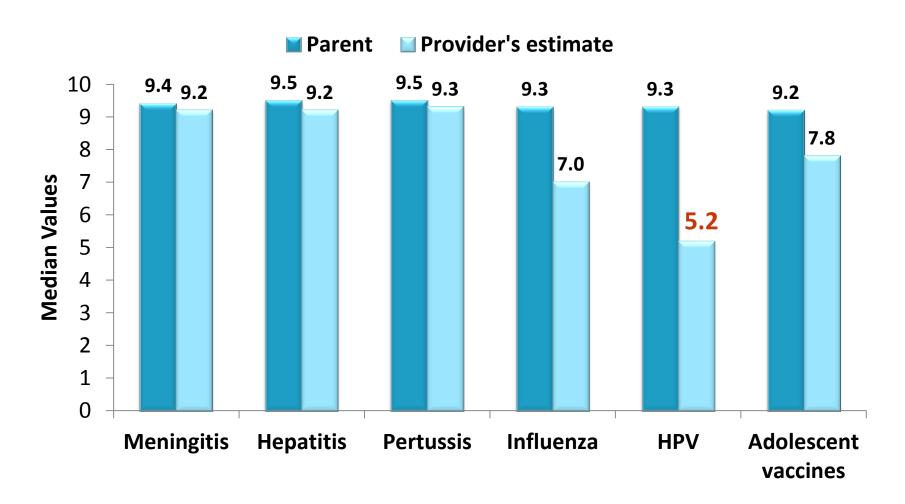


Talking about HPV vaccine

### FRAMING THE CONVERSATION

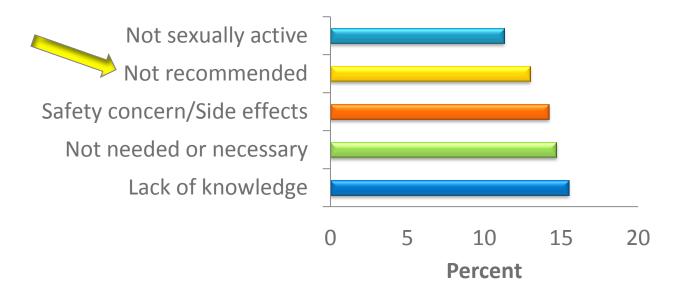


### Clinicians Underestimate the Value Parents Place on HPV Vaccine





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



- 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



#### 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.



## Deaths from vaccine-preventable disease-2014

Disease	Deaths per year in the U.S.
Pertussis	14
Meningococcal disease	43
Influenza	1421
HPV-related cancers	4086



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 "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 vaccine produces a more robust immune response in preteens than in older teens 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 . ..

Please make sure to make appointments for the next shot on the way out, and put that appointment on your calendar before you leave the office today!



## 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.



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#### 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.



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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.



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cdc.gov/vaccines/YouAreTheKey

#### **HPV PORTAL FOR PROVIDERS**



#### **Continuing Education**



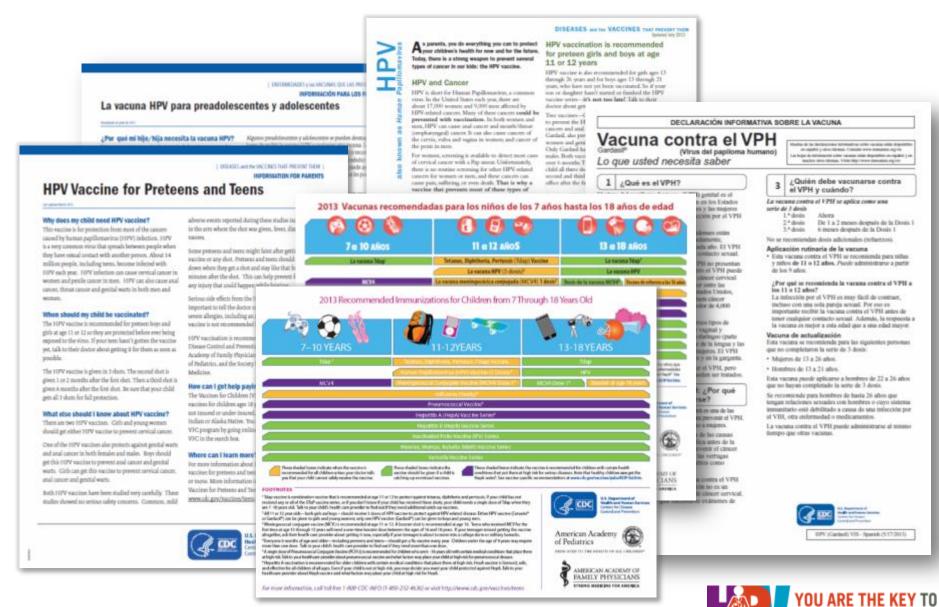






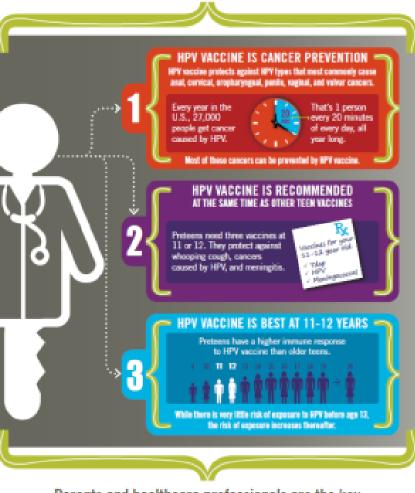


#### Factsheets for Parents in English & Spanish



CANCER PREVENTION

#### **HPV CANCER PREVENTION**



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

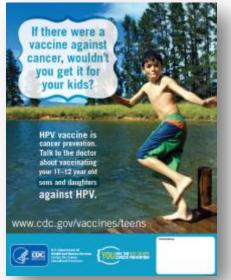
VACCINATE YOUR 11-12 YEAR OLDS.

www.cdc.gov/vaccines/teens





**Free** posters available for ordering in the following sizes: 8.5x11, 11x17, 18x24











### Want to know when we have new resources and tools? Send us an email to request our newsletter: PreteenVaccines@cdc.gov

We can help provide speakers for grand rounds and continuing education events, as well.



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

Complete the program evaluation at <a href="http://bit.do/HPVeval">http://bit.do/HPVeval</a> Receive continuing education credits at <a href="http://bit.do/HPVCE">http://bit.do/HPVCE</a>

\*Note: You must complete the program evaluation to receive credit



