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# You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease and the  
Importance of the HPV Vaccine Recommendation

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# Objectives

- ➔ HPV Infection and Disease
- ➔ HPV vaccine for girls and for boys
- ➔ Talking about HPV vaccine

Understanding the Burden

# HPV INFECTION & DISEASE

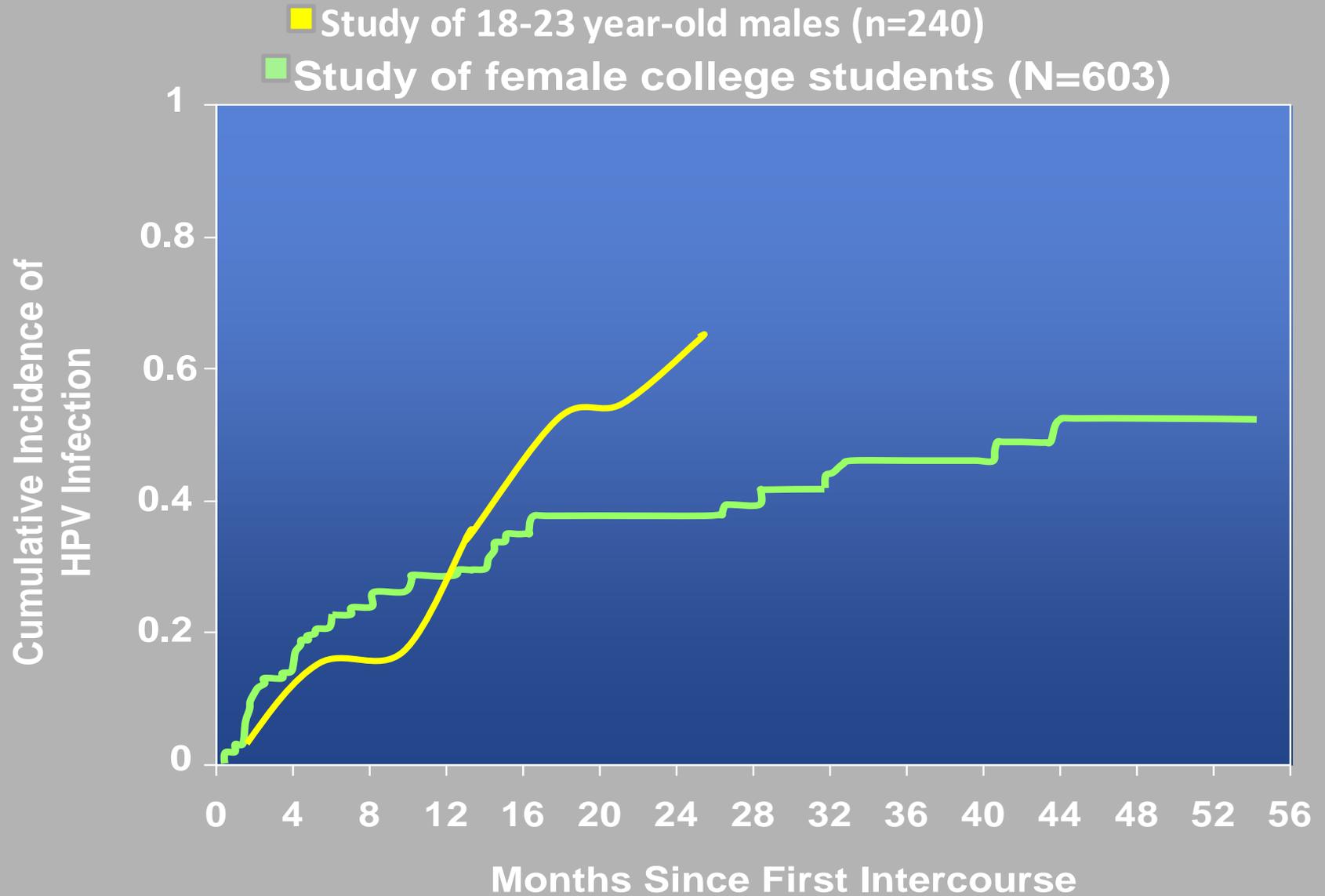
# HPV Infection

- ▶ **Almost all females and males will be infected with at least one type of 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**

# HPV Transmission

- ▶ HPV exposure can occur with any type of intimate sexual contact
- ▶ Intercourse is not necessary to become infected
- ▶ Nearly 50% of high school students have already engaged in sexual (vaginal-penile) intercourse
  - ▶ 1/3 of 9th graders and 2/3 of 12th graders have engaged in sexual intercourse
  - ▶ 24% of high school seniors have had sexual intercourse with 4 or more partners

# Rapid acquisition of HPV in following sexual debut



From Winer RL, Lee S-K, Hughes JP, Adam DE, Kiviat NB, Koutsky LA. Genital human papillomavirus infection: incidence and risk factors in a cohort of female university students. *Am J Epidemiol.* 2003;157:218–226. Reprinted with the permission of Oxford University Press.

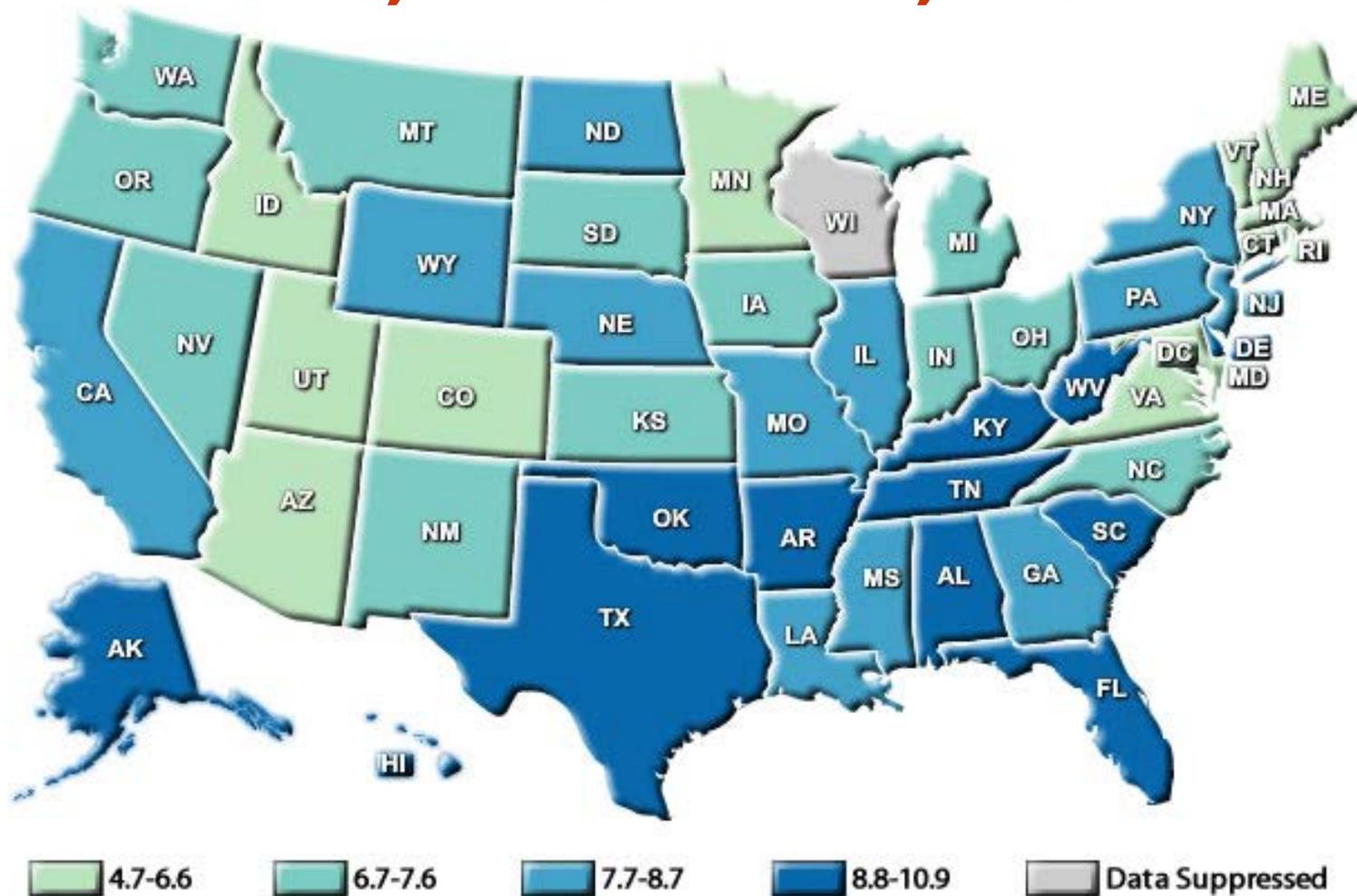
# HPV is found in virgins

- ▶ Study examined the frequency of vaginal HPV and the association with non-coital sexual behavior in longitudinally followed cohort of adolescent women without prior vaginal intercourse
- ▶ HPV was detected in 46% of women prior to first vaginal sex
- ▶ 70% of these women reported non-coital behaviors that may in part explain genital transmission

# Cervical Cancer

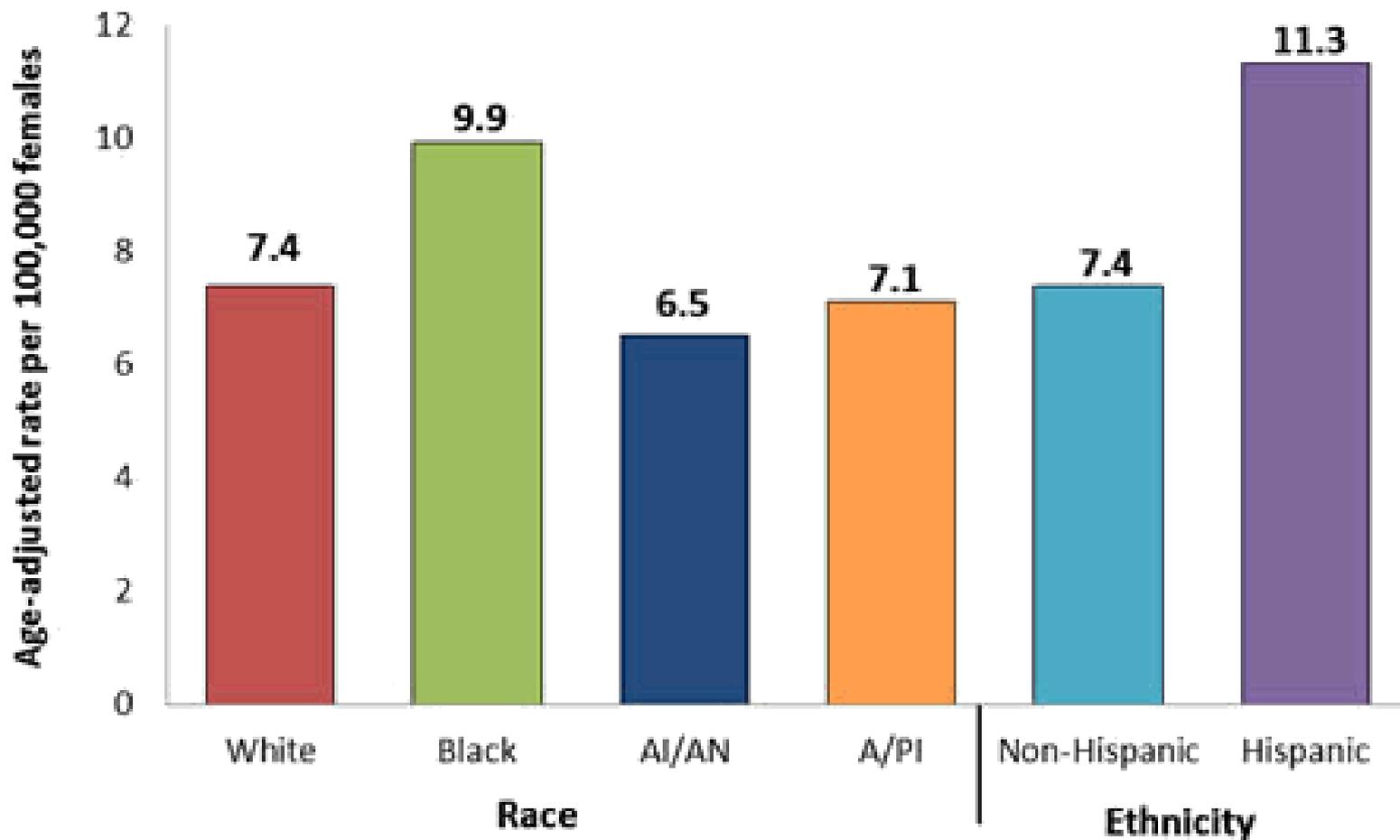
- ▶ **Cervical cancer is the most common HPV-associated cancer among women**
  - ▶ 500,000+ new cases and 275,000 attributable deaths world-wide in 2008
  - ▶ 12,000+ new cases and 4,000 attributable deaths in 2011 in the U.S.
- ▶ **25.9% cervical cancers occur in women who are between the ages of 35 and 44**
  - ▶ 14% between 20 and 34
  - ▶ 23.9% between 45 and 54

# HPV-Associated Cervical Cancer Rates by State, United States, 2009



United States Cancer Statistics: 1999–2009 Incidence and Mortality Web-based Report. Atlanta (GA): DHHS, CDC, and NCI; 2013. Available at: <http://www.cdc.gov/uscs>.

# HPV-Associated Cervical Cancer Rates by Race and Ethnicity, United States, 2004–2008

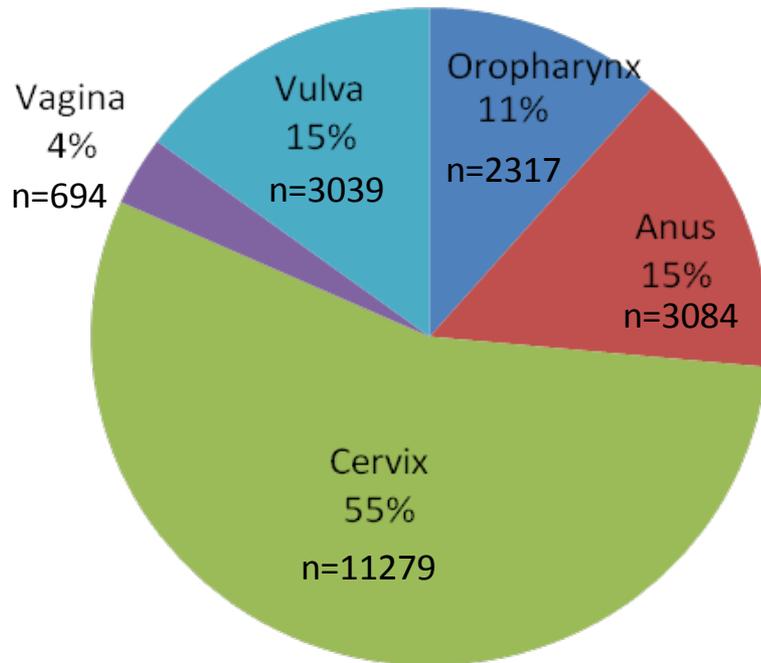


# Annual Report to the Nation on the Status of Cancer: HPV-Associated Cancers

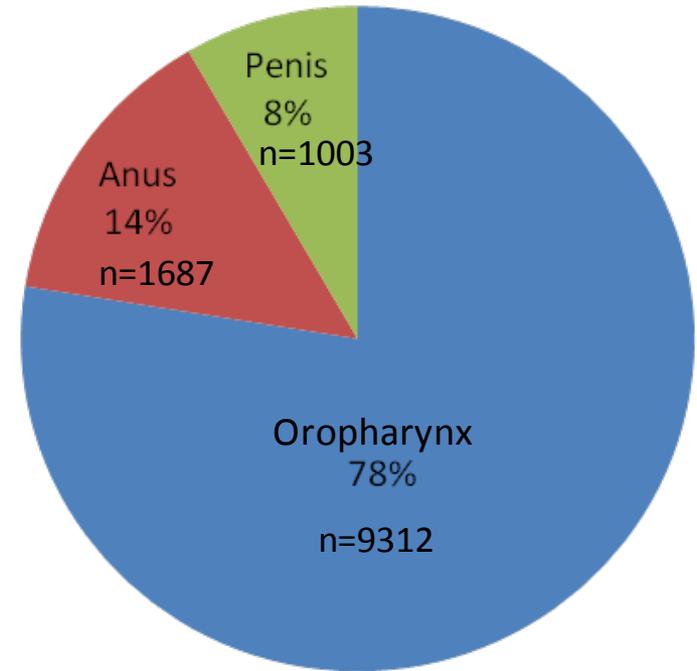
- From 2000 to 2009, oral cancer rates increased
  - 4.9% for Native American men
  - 3.9% for white men
  - 1.7% for white women
  - 1% for Asian men
- Anal cancer rates doubled from 1975 to 2009
- Vulvar cancer rates rose for white and African-American women
- Penile cancer rates increased among Asian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

# Average Number of New HPV-Associated Cancers by Sex, in the United States, 2005-2009

## Women (N=20,413)



## Men (N=12,002)



# HPV-Associated Oropharyngeal Cancers

- Prevalence increased from 16.3% (1984-89) to **71.7%** (2000-04)
- Population-level incidence of HPV-positive cancers increased by **225%** while HPV-negative cancers declined by 50%

*If trends continue, the annual number of HPV-positive oropharyngeal cancers is expected to surpass the annual number of cervical cancers by the year 2020*

# Economic Impact Related to HPV-Associated Disease, 2010

Event	Cost (\$ billions)
Cervical cancer screening*	6.6
Cervical cancer	0.4
Other anogenital cancers	0.2
Oropharyngeal cancer	0.3
Anogenital warts	0.3
RRP**	0.2
<b>TOTAL</b>	<b>8.0</b>

\*Cervical cancer screening costs: ~ 80% routine screening, ~20% follow-up

\*\*RRP costs: ~ 70% juvenile-onset, ~ 30% adult-onset



# HPV Vaccine



Quadrivalent/HPV4 (Gardasil)	Name	Bivalent/HPV2 (Cervarix)
Merck	<b>Manufacturer</b>	GlaxoSmithKline
<b>6, 11, 16, 18</b>	<b>Types</b>	16, 18
<b>Females:</b> Anal, cervical, vaginal and vulvar precancer and cancer; Genital warts <b>Males:</b> Anal precancer and cancer; Genital warts	<b>Indications</b>	<b>Females:</b> Cervical precancer and cancer <b>Males: Not approved</b> for use in males
Pregnancy Hypersensitivity to yeast	<b>Contraindications</b>	Pregnancy Hypersensitivity to latex (latex only contained in pre-filled syringes, not single-dose vials)
3 dose series: 0, <b>2</b> , 6 months	<b>Schedule (IM)</b>	3 dose series: 0, <b>1</b> , 6 months



# New HPV Vaccine

HPV4 (Gardasil)	Name	HPV9 (Gardasil 9)
Merck	Manufacturer	
<b>6, 11, 16, 18</b>	Types	<i>PLUS 31, 33, 45, 52 and 58</i>
<p><b>Females:</b> Anal, cervical, vaginal and vulvar precancer and cancer; Genital warts</p> <p><b>Males:</b> Anal precancer and cancer; Genital warts</p>	Indications	<ul style="list-style-type: none"> <li>• <b>Approved for use in females ages 9 through 26 and males ages 9 through 15</b></li> <li>• <b>Additional types cause approximately 20 percent of cervical cancers and are not covered by previously FDA-approved HPV vaccines</b></li> </ul>
<p>Pregnancy</p> <p>Hypersensitivity to yeast</p>	Contraindications	
3 dose series: 0, 2, 6 months	Schedule (IM)	

# ACIP Recommendation and AAP Guidelines for HPV Vaccine

- ➔ Routine HPV vaccination recommended for both males and females ages 11-12 years
- ➔ Catch-up ages 13-21 years for males; 13-26 for females
- ➔ Permissive use ages 9-10 years for both males and females; 22-26 for males
- ➔ For males- GARDASIL

# HPV Vaccine Safety

- The most common adverse events reported were considered mild
- For serious adverse events reported, no unusual pattern or clustering that would suggest that the events were caused by the HPV vaccine
- These findings are similar to the safety reviews of MCV4 and Tdap vaccines
- 57 million doses of HPV vaccine distributed in US since 2006

# HPV Vaccine Safety Data Sources

- Post-licensure safety data (VAERS)<sup>1</sup>
- Post-licensure observational comparative studies (VSD)<sup>2</sup>
- Ongoing monitoring by CDC and FDA
- 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>3</sup>
  - Institute of Medicine's report on adverse effects and vaccines, 2011<sup>4</sup>

<sup>1</sup>Vaccine Adverse Events Reporting System, <http://vaers.hhs.gov/index>

<sup>2</sup>Vaccine Safety Datalink, <http://www.cdc.gov/vaccinesafety/Activities/VSD.html>

<sup>3</sup>[http://www.who.int/vaccine\\_safety/Jun\\_2009/en/](http://www.who.int/vaccine_safety/Jun_2009/en/)

<sup>4</sup><http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

# HPV Vaccine Impact: HPV Prevalence Studies

## ➤ NHANES Study

- National Health and Nutrition Examination Survey (NHANES) data used to compare HPV prevalence before the start of the HPV vaccination program with prevalence from the first four years after vaccine introduction
- In 14-19 year olds, vaccine-type HPV prevalence decreased 56 percent, from 11.5 percent in 2003-2006 to 5.1 percent in 2007-2010
- Other age groups did not show a statistically significant difference over time
- The research showed that **vaccine effectiveness** for prevention of infection was an estimated 82 percent

# HPV Vaccine Impact: HPV Prevalence Studies, continued

## ➤ Clinic-Based Studies

- Significant decrease from 24.0% to 5.3% in HPV vaccine type prevalence in at-risk sexually active females 14-17 years of age attending 3 urban primary care clinics from 1999-2005, compared to a similar group of women who attended the same 3 clinics in 2010
- Significant declines in vaccine type HPV prevalence in both **vaccinated and unvaccinated** women aged 13-26 years who attended primary care clinics from 2009-2010 compared to those from the pre-vaccine period (2006-2007)

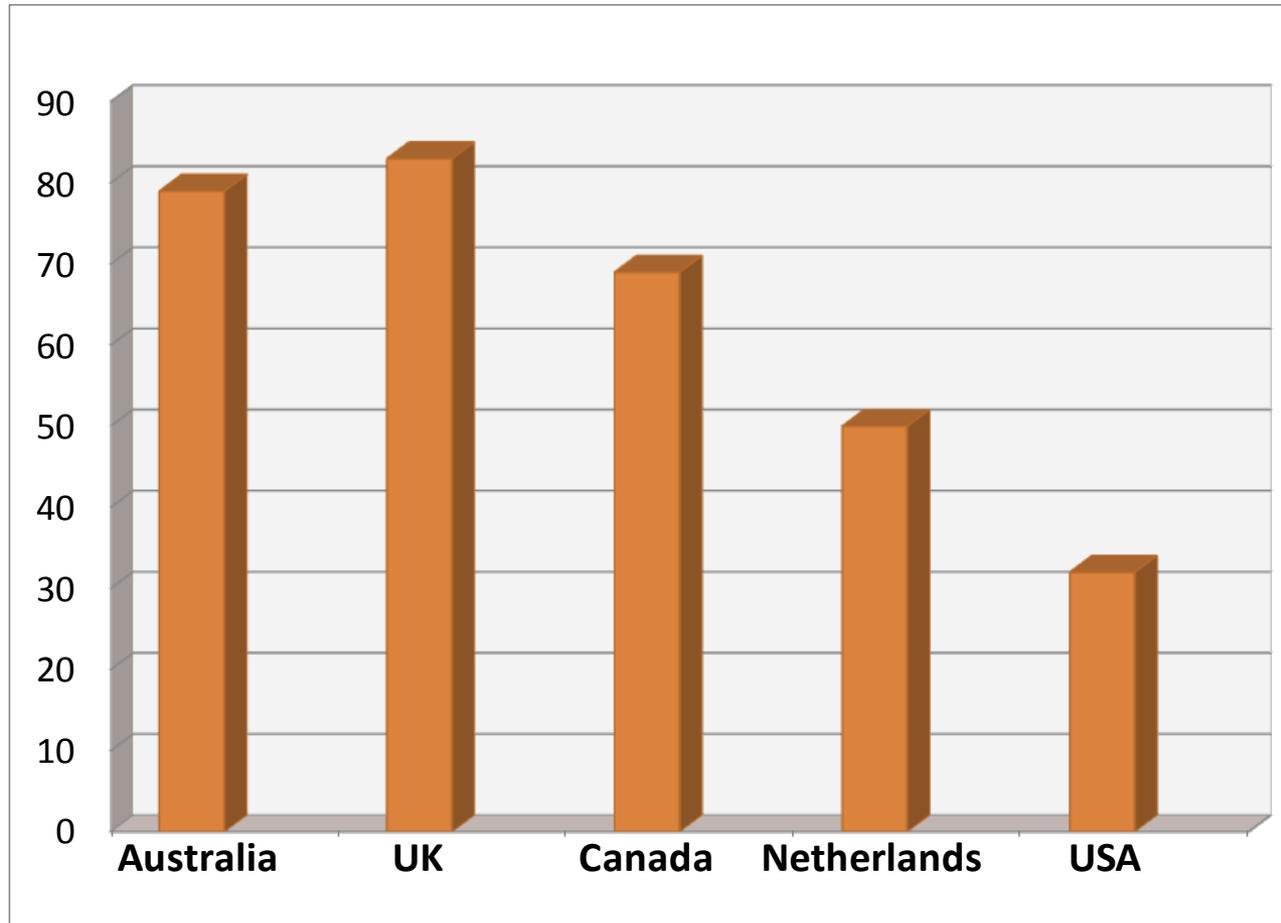
# HPV Vaccine Impact: Genital Warts Studies

- ▶ **Ecologic analysis used to examine trends in anogenital warts from 2003-2010 among a large group of private health insurance enrollees**
  - ▶ Significant declines in females aged 15-19 year (38% decrease from 2.9/1000 PY in 2006 to 1.8/1000 PY in 2010)
  - ▶ Smaller declines observed among those 21-30 years
- ▶ **Genital wart trends in males and females attending public family planning clinics**
  - ▶ Significant decrease of 35% (.94% to .61%) in females < 21 yrs
  - ▶ Significant decrease of 19% decrease in males < 21 yrs

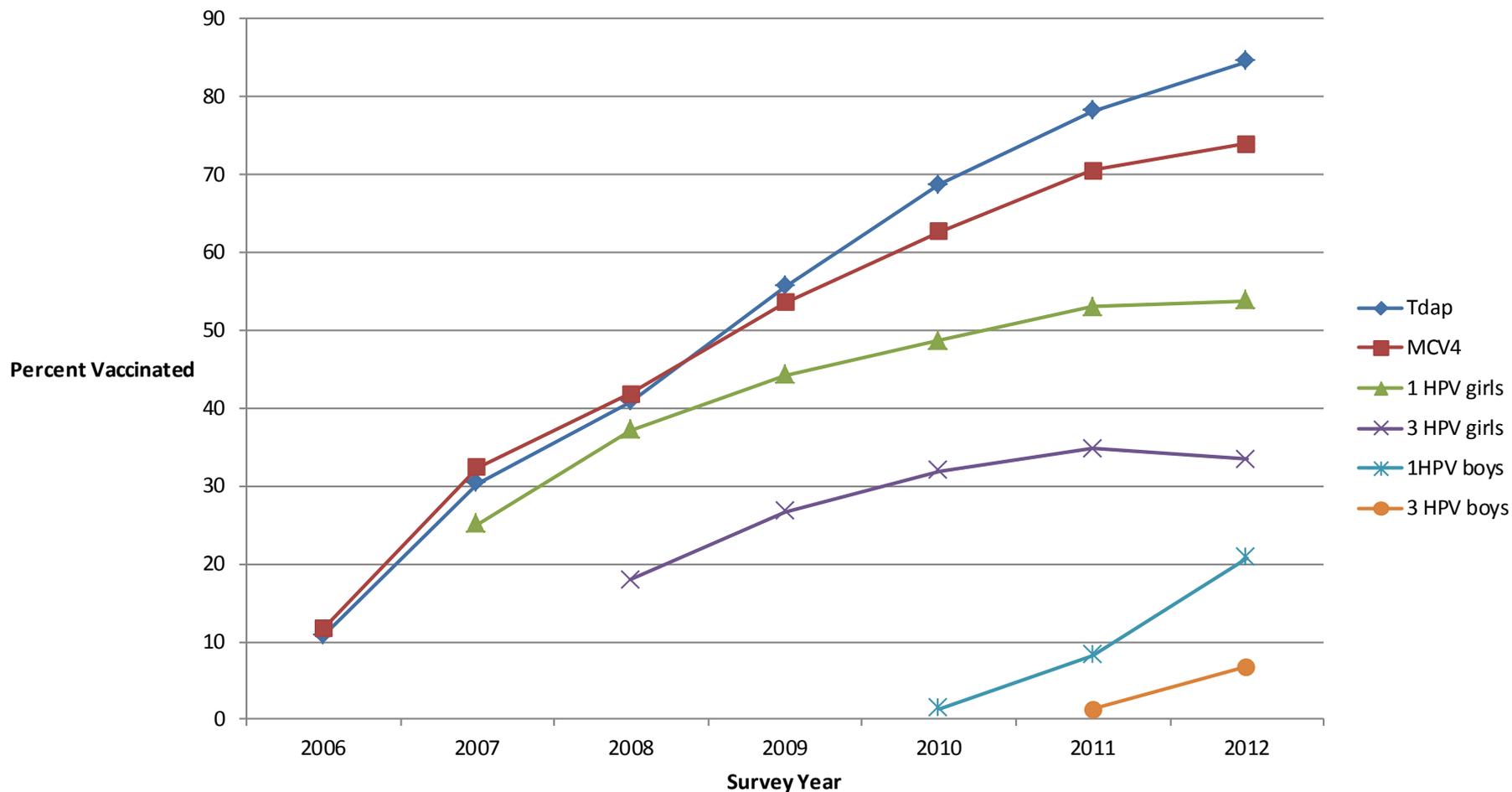
# HPV Vaccine Impact: High HPV Vaccine Coverage in Australia

- ➔ 80% of school-age **girls** in Australia are fully vaccinated
- ➔ High-grade cervical lesions have declined in women less than 18 years of age
- ➔ For vaccine-eligible females, the proportion of genital warts cases declined dramatically by 93%
- ➔ Genital warts have declined by 82% among males of the same age, indicating herd immunity

# International uptake of 3 doses HPV vaccine

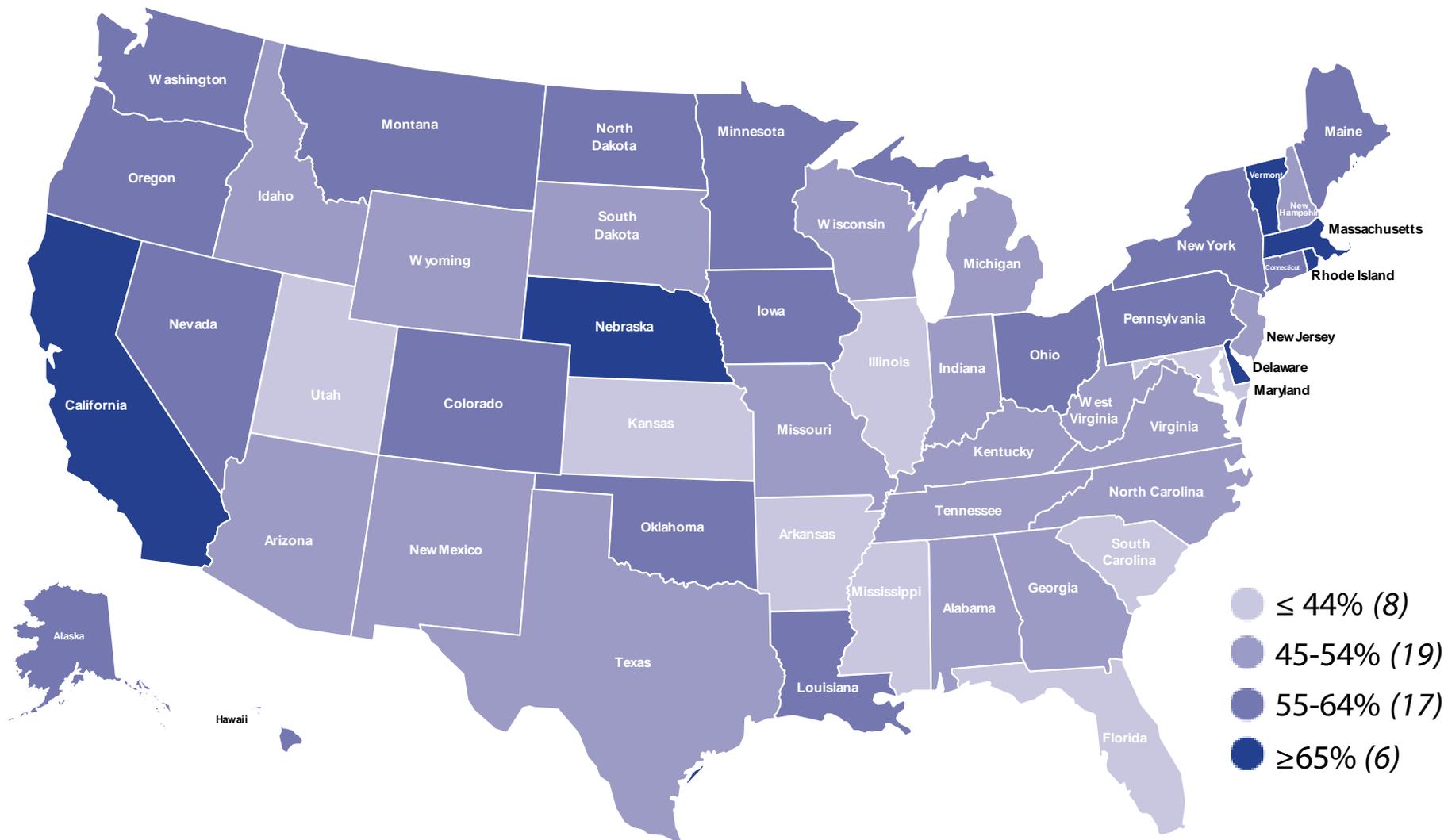


# National Estimated Vaccination Coverage Levels among Adolescents 13-17 Years, National Immunization Survey-Teen, 2006-2012

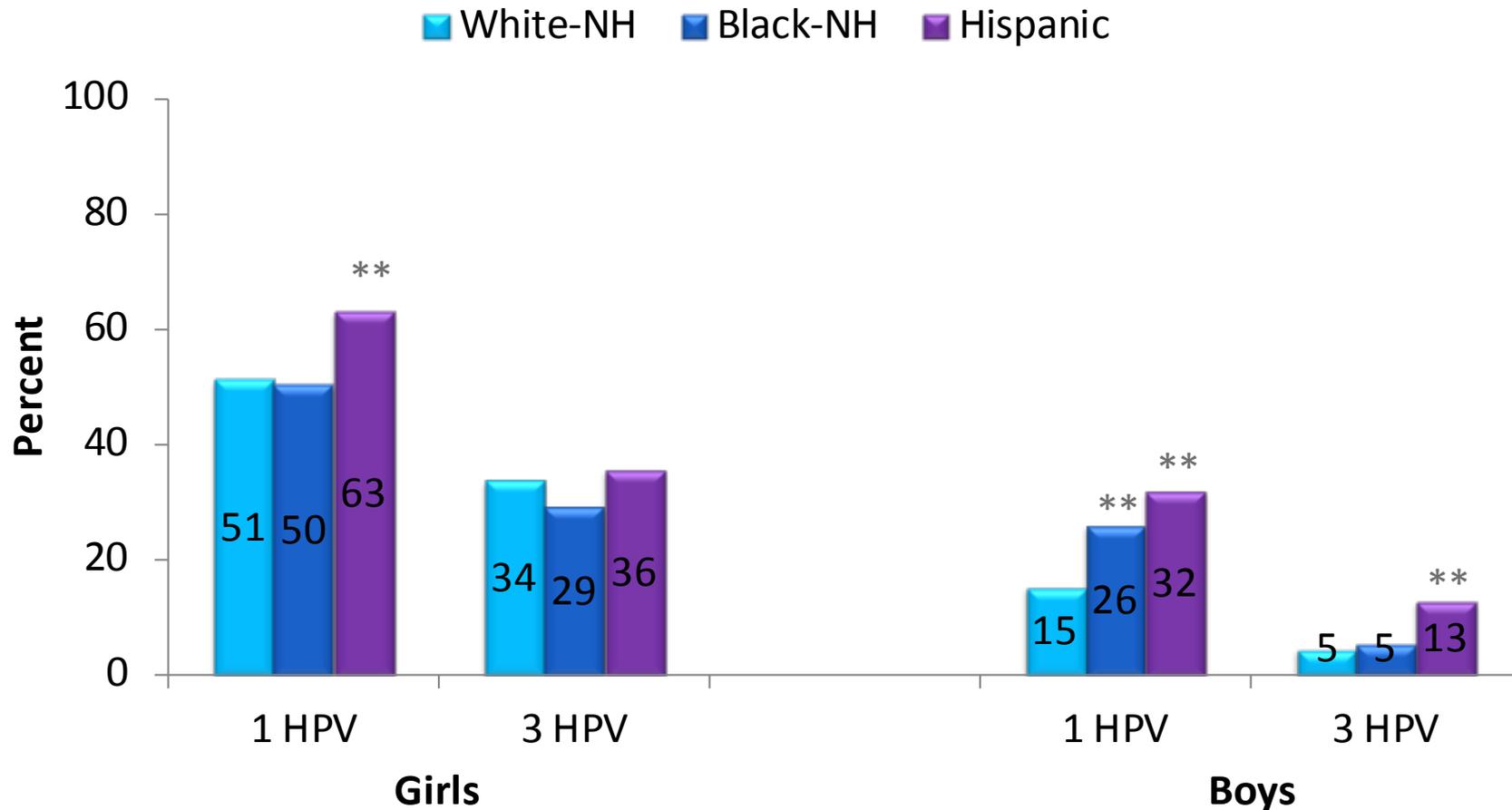


Tdap: tetanus, diphtheria, acellular pertussis vaccine.  
 MCV4: meningococcal conjugate vaccine  
 HPV: human papillomavirus vaccine

# Coverage of 1 of More Doses of HPV among Adolescent Girls 13-17 Years by State, NIS-Teen 2012



# HPV Vaccination Estimates among Adolescents 13-17 Years by Race/Ethnicity, NIS-Teen 2012



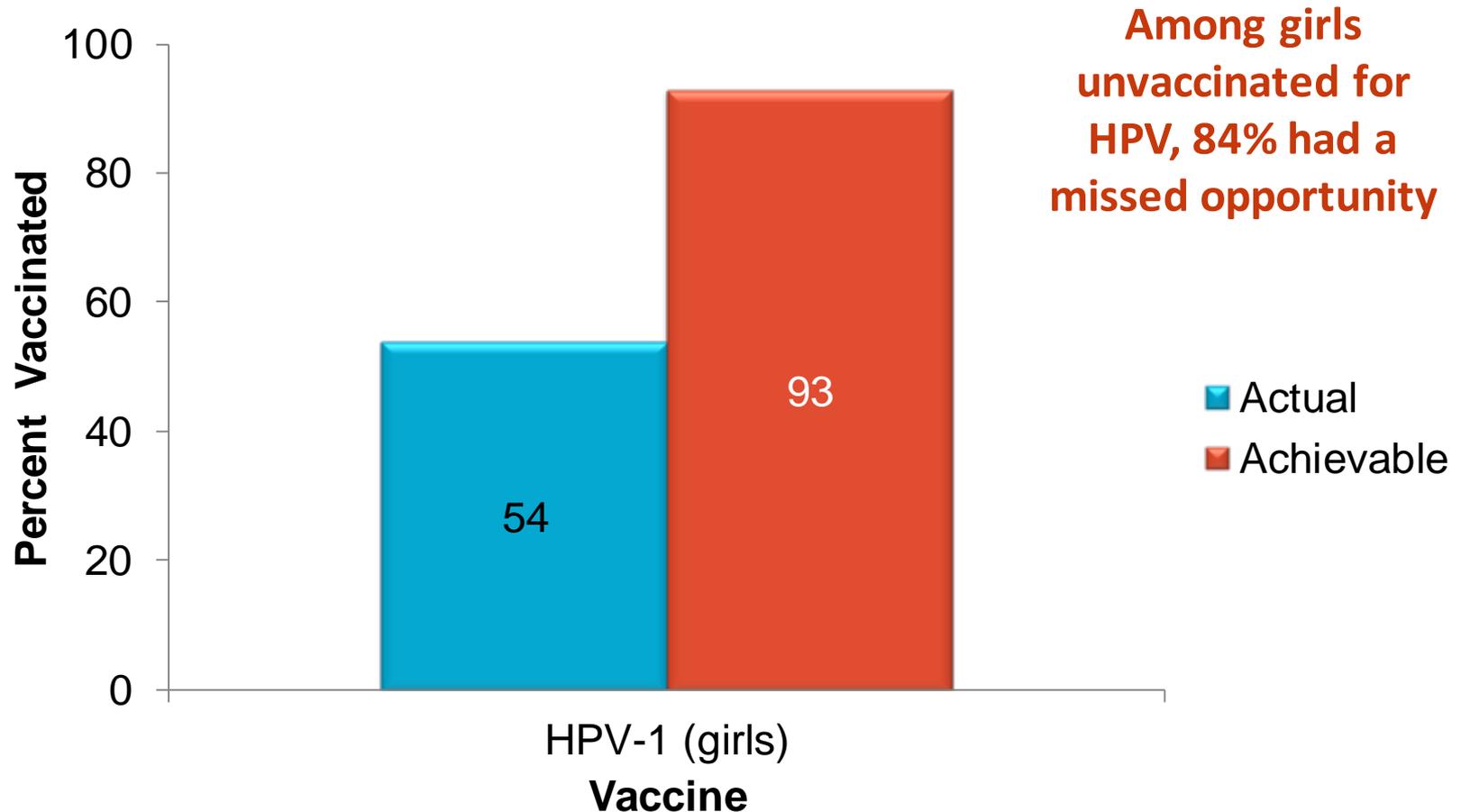
\*\* Statistically different ( $P < 0.05$ ) from White-NH.

# Why We Need to Do Better in HPV Vaccination of 12 year olds

- ▶ Currently 26 million girls <13 yo in the US; If none of these girls are vaccinated then:
  - ▶ 168,400 will develop cervical cancer and
  - ▶ 54,100 will die from it
- ▶ Vaccinating 30% would prevent 45,500 of these cases and 14,600 deaths
- ▶ Vaccinating 80% would prevent 98,800 cases and 31,700 deaths

For each year we stay at 30% coverage instead of achieving 80%, 4,400 future cervical cancer cases and 1400 cervical cancer deaths will occur.

# Actual and Achievable Vaccination Coverage if **Missed Opportunities** Were Eliminated: Adolescents 13-17 Years, NIS-Teen 2012



Missed opportunity: Encounter when some, but not all ACIP-recommended vaccines are given.

HPV-1: Receipt of at least one dose of HPV.

# Avoid Missed Opportunities

- ➔ HPV vaccine can safely be given at the same time as the other recommended adolescent vaccines
- ➔ Provide HPV vaccine during routine sports, or camp physicals
- ➔ Review immunization record even at acute care visits
- ➔ Systems interventions depend on clinician commitment- determine what would work best for YOUR practice- Give me a call, I am happy to help.

# The Perfect Storm

## ► Why is HPV vaccine different?

- HPV vaccine issues sensationalized by popular media
- Different reasons for why some girls and boys don't get the first shot and why some don't finish all 3 shots
- Parents think sexuality instead of cancer prevention
- Some clinicians aren't giving strong recommendations
- Parents have questions that are seen as hesitation by some doctors
- Phased girls-then-boys recommendations initially confusing to parents
- Systems interventions to improve coverage rates depend on clinician commitment

Talking about HPV vaccine

# FRAMING THE CONVERSATION

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

Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. For example, you can say “Your child needs these shots today,” and name all of the vaccines recommended for the child’s age.

Parents may be interested in vaccinating, yet still have questions. Taking the time to listen to parents’ questions helps you save time and give an effective response. CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver.



## CDC RESEARCH SHOWS:

The “HPV vaccine is cancer prevention” message resonates strongly with parents. In addition, studies show that a strong recommendation from you is the single best predictor of vaccination.

## TRY SAYING:

HPV vaccine is very important because it prevents cancer. I want your child to be protected from cancer. That’s why I’m recommending that your daughter/son receive the first dose of HPV vaccine today.

## CDC RESEARCH SHOWS:

Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against.

## TRY SAYING:

HPV can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men. There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine. There are also many more precancerous conditions requiring treatment that can have lasting effects.

## CDC RESEARCH SHOWS:

Parents want a concrete reason to understand the recommendation that 11–12 year olds receive HPV vaccine.

## TRY SAYING:

We’re vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity. We vaccinate people well before they are exposed to an infection, as is the case with measles and the other recommended childhood vaccines. Similarly, we want to vaccinate children well before they get exposed to HPV.

## CDC RESEARCH SHOWS:

Parents may be concerned that vaccinating may be perceived by the child as permission to have sex.

## TRY SAYING:

Research has shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.

## CDC RESEARCH SHOWS:

Parents might believe their child won’t be exposed to HPV because they aren’t sexually active or may not be for a long time.

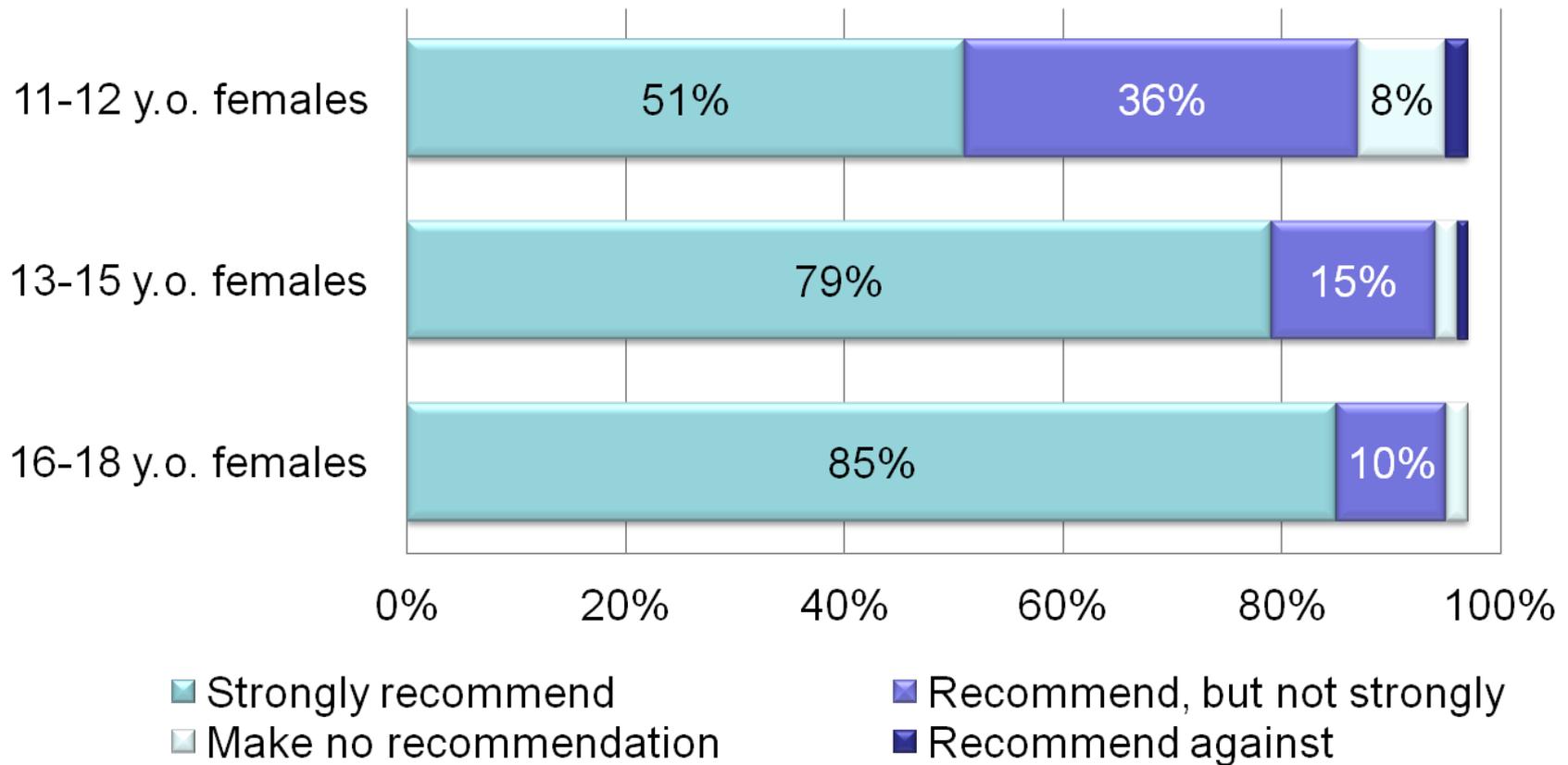
## TRY SAYING:

HPV is so common that almost everyone will be infected at some point. It is estimated that 70 million Americans are currently infected with

# What's in a recommendation?

- ▶ **Studies consistently show that a strong recommendation from you is the single best predictor of vaccination**
  - ▶ In focus groups and surveys with moms, having a doctor/health care professional recommend or not recommend the vaccine was an important factor in parents' decision to vaccinate their child with the HPV vaccine
  - ▶ Not receiving a recommendation for HPV vaccine was listed a barrier by mothers

# Strength of HPV Vaccine Recommendation for Female Patients, Pediatricians and Family Physicians (N=609)

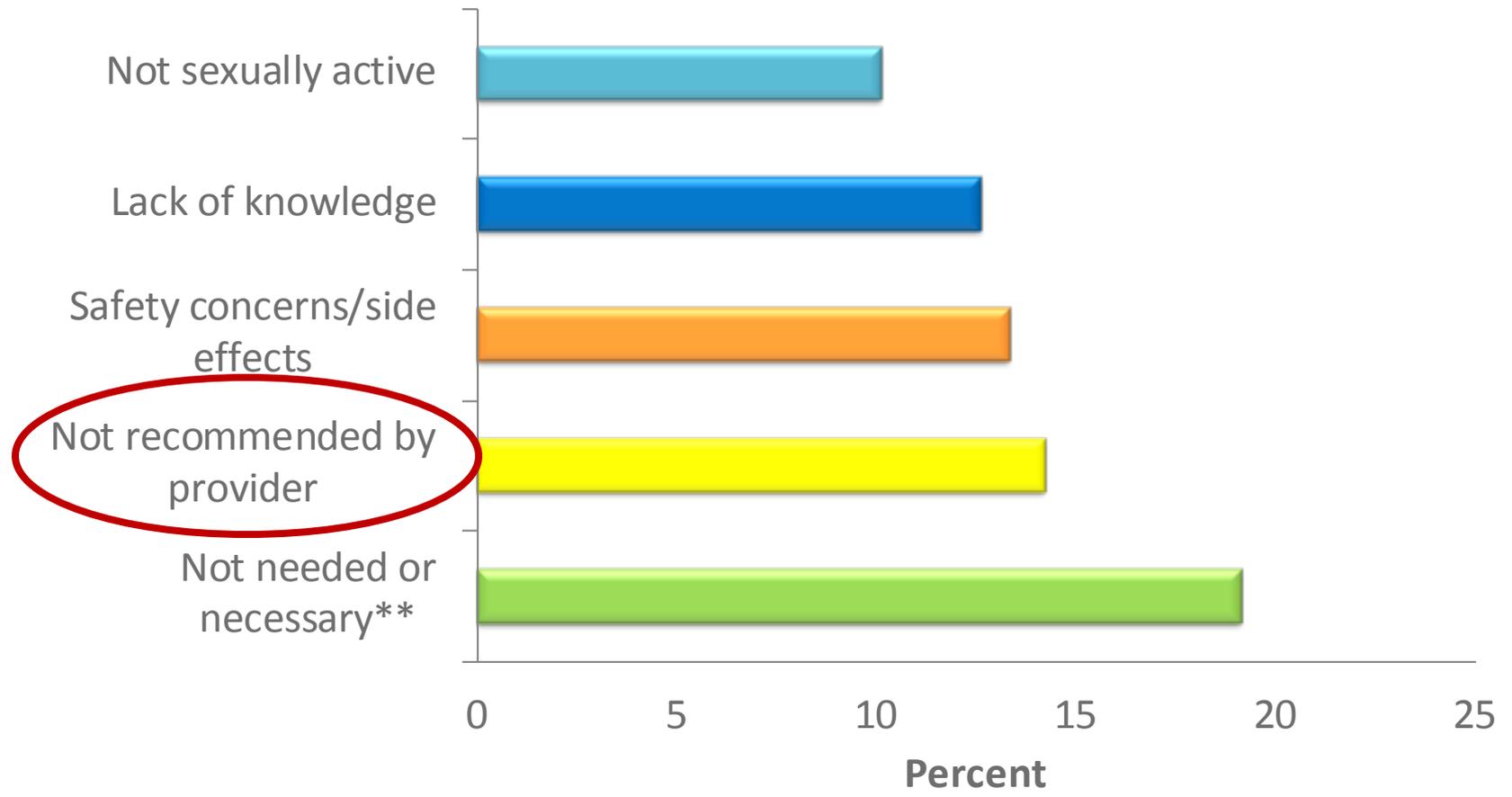


Allison et al. <https://cdc.confex.com/cdc/nic2011/webprogram/Paper25181.html>

# Just another adolescent vaccine

- ▶ Successful recommendations group **all** of the adolescent vaccines
  - ▶ Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines
  - ▶ Moms in focus groups who had not received a doctor's recommendation stated that they questioned why they had not been told or *if the vaccine was truly necessary*
  - ▶ Many parents responded that they trusted their child's doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

# Top 5 reasons for not vaccinating daughter, among parents with no intention to vaccinate in the next 12 months, NIS-Teen 2012



\* Not mutually exclusive.

\*\* Did not know much about HPV or HPV vaccine.



# Try saying:

*Your child needs three shots today: HPV vaccine, meningococcal vaccine and Tdap vaccine.*

*You child will get three shots today that will protect him/her from the cancers caused by HPV, as well as to prevent tetanus, diphtheria, pertussis and meningitis.*

# A case of vaccine hesitancy?

- ▶ **Parents may be interested in vaccinating, yet still have questions**
  - ▶ Many parents didn't have questions or concerns about HPV vaccine
  - ▶ A question from a parents does not mean they are refusing or delaying
  - ▶ Taking the time to listen to parents' questions helps you save time and give an effective response
  - ▶ CDC research shows these straightforward messages work with parents when discussing HPV vaccine—and are easy for you or your staff to deliver

# An anti-cancer vaccine

- ▶ The “HPV vaccine is cancer prevention” message resonates strongly with parents
  - ▶ In focus groups and online panels, mothers wanted more information on the types of HPV cancers
  - ▶ In focus groups mothers stated they were influenced to vaccinate their child because HPV vaccine prevents cancer, they had a family history of cervical cancers, and/or because they had a personal experience with cervical cancer

# Try saying:

*HPV vaccine is very important because it prevents cancer.*

*I want your child to be protected from cancer.*

*That's why I'm recommending that your daughter/son receive the first dose of the HPV vaccine series today.*

# Tell me doctor, how bad is it?

- ▶ **Disease prevalence is not understood, and parents are unclear about what the vaccine actually protects against**
  - ▶ Parents in focus groups knew HPV vaccine can prevent cervical cancers, however they lacked knowledge about indications for HPV vaccine other than cervical cancer for girls, all HPV vaccine indications for boys, and the recommended ages to receive HPV vaccine

# Try saying:

*Persistent HPV infection can cause cancers of the cervix, vagina, and vulva in women, cancer of the penis in men, and cancers of the anus and the mouth or throat in both women and men.*

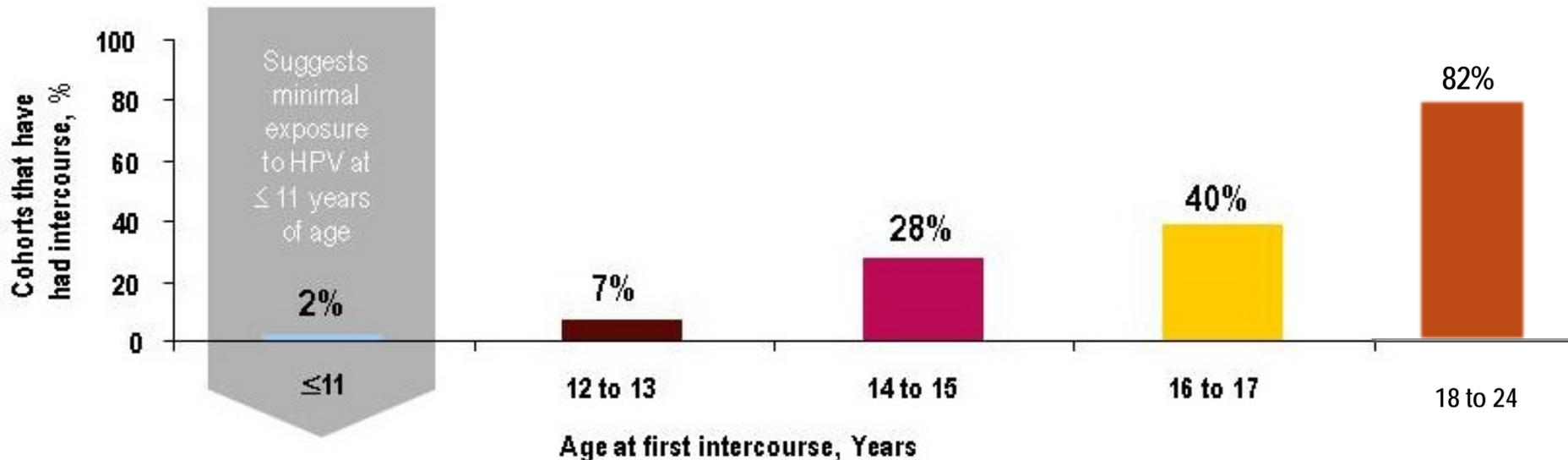
*There are about 26,000 of these cancers each year—and most could be prevented with HPV vaccine.*

*There are also many more precancerous conditions requiring treatment that can have lasting effects.*

# Why at 11 or 12 years old?

- ▶ **Parents want a concrete reason why 11-12 year olds should receive HPV vaccine**
  - ▶ In audience research with moms, almost all respondents were unaware of the correct age range the vaccine was recommended
  - ▶ Respondents also missed the concept of vaccinating before sexual activity

# Rationale for vaccinating early: Protection prior to exposure to HPV



Adapted from Henry J. Kaiser Family Foundation

# Try saying:

*We're vaccinating today so your child will have the best protection possible long before the start of any kind of sexual activity.*

*We vaccinate people well before they are exposed to an infection, as is the case with measles and the other routinely recommended childhood vaccines. Similarly, we want to vaccinate children long before they begin any type of sexual activity and are exposed to HPV.*

*Also HPV vaccine produces a better immune response in preteens than it does in older teens and young women.*

# A green light for sexual activity?

- ▶ **Parents may be concerned that vaccinating may be perceived by the child as permission to have sex**
  - ▶ In focus groups, some parents expressed concern that in getting HPV vaccine for their child, they would be giving their child permission to have sex
  - ▶ This was one of the top four reasons respondents gave when asked why they would not vaccinate their daughter
  - ▶ A few parents expressed that while they wanted their child to “wait to have sex” they understood that might not be the case

# Receipt of HPV vaccine does not increase sexual activity or decrease age of sexual debut

- Kaiser Permanente Center for Health Research
- 1,398 girls who were 11 or 12 in 2006, 30% of whom were vaccinated, followed through 2010
- No difference in markers of sexual activity, including
  - Pregnancies
  - Counseling on contraceptives
  - Testing for, or diagnoses of, sexually transmitted infections

# Try saying:

*Multiple research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active.*

*These studies have also shown that getting the HPV vaccine does not make kids more likely to start having sex a younger age.*

# But she's too young!

- ▶ **Parents might believe their child won't be exposed to HPV because they aren't sexually active or may not be for a long time**
  - ▶ In focus groups, some moms couldn't understand how their child could become infected even if they waited until marriage to have sex
  - ▶ Some moms stated that they didn't think HPV infection was very common because they had never heard what it was or didn't know anyone who had an HPV infection or HPV disease

# Try saying:

*Even if your child waits until marriage to have sex or only has one partner in the future, he/she could still be exposed if his/her future partner has engaged in any type of sexual activity with another person.*

*We don't wait until exposure occurs to give any other routinely recommended vaccine. HPV vaccine is also given when kids are 11 or 12 years old because it produces a better immune response at that age. That's why it is so important to start the shots now and finish them in the next 6 months.*

# Would you give it to your child?

- ▶ **Emphasizing your personal belief in the importance of HPV vaccine helps parents feel secure in their decision**
  - ▶ Some respondents in focus groups stated that they would feel more comfortable knowing that the doctor had vaccinated their own child or was planning to (if the child was <11)
  - ▶ Respondents in an online survey stated that knowing that oncologists supported the recommendation made them more likely to get their child vaccinated

# Try saying:

*I strongly believe in the importance of this cancer-preventing vaccine.*

*I have given HPV vaccine to my son/daughter (or grandchild/niece/nephew/friend's children).*

*Experts, such as the American Academy of Pediatrics, cancer doctors, and the CDC, also agree that getting the HPV vaccine is very important for your child.*

# Scared of side effects

- **Understanding that the side effects are minor and emphasizing the extensive research that vaccines must undergo can help parents feel reassured**
  - Moms in focus groups stated concerns about both short term and long term vaccine safety as a reason that they would not vaccinate their child
  - Respondents were not aware that HPV vaccine was tested in adolescents and adults and were concerned that their child's fertility could be affected by the vaccine

# Try saying:

*HPV vaccine has been very carefully studied by scientific experts and it's safety is continually monitored.*

*This is not a new vaccine and for years HPV vaccine has been shown to be **very effective and very safe**. HPV vaccine has a similar safety profile to the meningococcal and Tdap vaccines.*

*Like other shots, side effects can happen, but most are mild, primarily pain or redness in the arm. This should go away quickly, and HPV vaccine has not been associated with any long-term side effects.*

# Try saying:

*Since 2006, about 57 million doses of HPV vaccine have been distributed in the U.S., and in the years of HPV vaccine safety studies and monitoring, no serious safety concerns have been identified.*

*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 which could cause preterm delivery or problems.*

# When do we come back?

- Many parents do not know that the full vaccine series requires 3 shots
- Your reminder will help them to complete the series
  - In focus groups, most respondents did not know the dosing schedule for HPV vaccine

# How Can Clinicians Help?

- 1. Give a **STRONG** recommendation**
  - ▶ Ask yourself, how often do you get a chance to prevent cancer?
- 2. Start conversation early and focus on **cancer prevention****
  - ▶ Vaccination given well before sexual experimentation begins
  - ▶ Better antibody response in preteens
- 3. Offer a **personal story****
  - ▶ Own children/Grandchildren/Close friends' children
  - ▶ HPV-related cancer case
- 4. Welcome **questions** from parents, especially about safety**
  - ▶ Remind parents that the HPV vaccine is safe and not associated with increased sexual activity

**For more information,  
including free resources for yourself  
and your patients, visit:  
[cdc.gov/vaccines/teens](https://cdc.gov/vaccines/teens)**

**Email questions or comments to  
CDC Vaccines for Preteens and Teens:**

**[bapahud@cmh.edu](mailto:bapahud@cmh.edu)**

**Or**

**[PreteenVaccines@cdc.gov](mailto:PreteenVaccines@cdc.gov)**