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# HPV vaccination is cancer prevention

*DON'T WAIT TO VACCINATE*

NAME

DATE



# Presenter Disclosure Information

## NAME

- ➡ I, NAME, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations.
  - ➡ I have no relationships to disclose (or disclose relationships).
- ➡ I may/will discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration.
  - ➡ But in accordance with ACIP recommendations.

## **I want to convince you:**

- 1. HPV vaccination is worth your *passionate* advocacy.**
- 2. HPV vaccine is worth giving long *before exposure*.**
- 3. Your recommendation can make all the difference to the family's acceptance.**

## **The learner should be able to:**

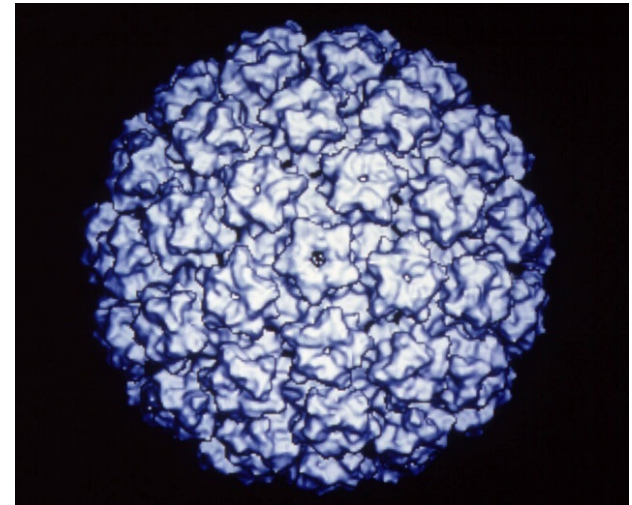
- 1. Explain the importance of HPV vaccination & rates.**
- 2. Discuss the rationale for vaccinating at ages 11 or 12 and including males**
- 3. Provide useful & compelling communication strategies and practical tips to inform parents about HPV**

## Today you will learn

- ▶ HPV infection is more common than you thought, and most of your patients will be exposed
- ▶ HPV vaccination works very well at the recommended age of 11-12 (early vaccination is more effective than later vaccination)
- ▶ HPV vaccination is very, very safe
- ▶ More parents want this vaccine than you think
- ▶ There ARE evidence-based ways to recommend it

## What is HPV?

- A virus that infects human skin and mucosal surfaces
- Transmitted easily by touching
- Classified as a carcinogen
- Most females and males will be infected with at least one type of mucosal HPV at some point in their lives



HPV

## What is the morbidity from HPV?

- ➡ 3 million Americans seek medical care for HPV each year
- ➡ 27,000 develop HPV-related cancers
- ➡ HPV currently causes as many deaths annually as measles did in the pre-vaccine era

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



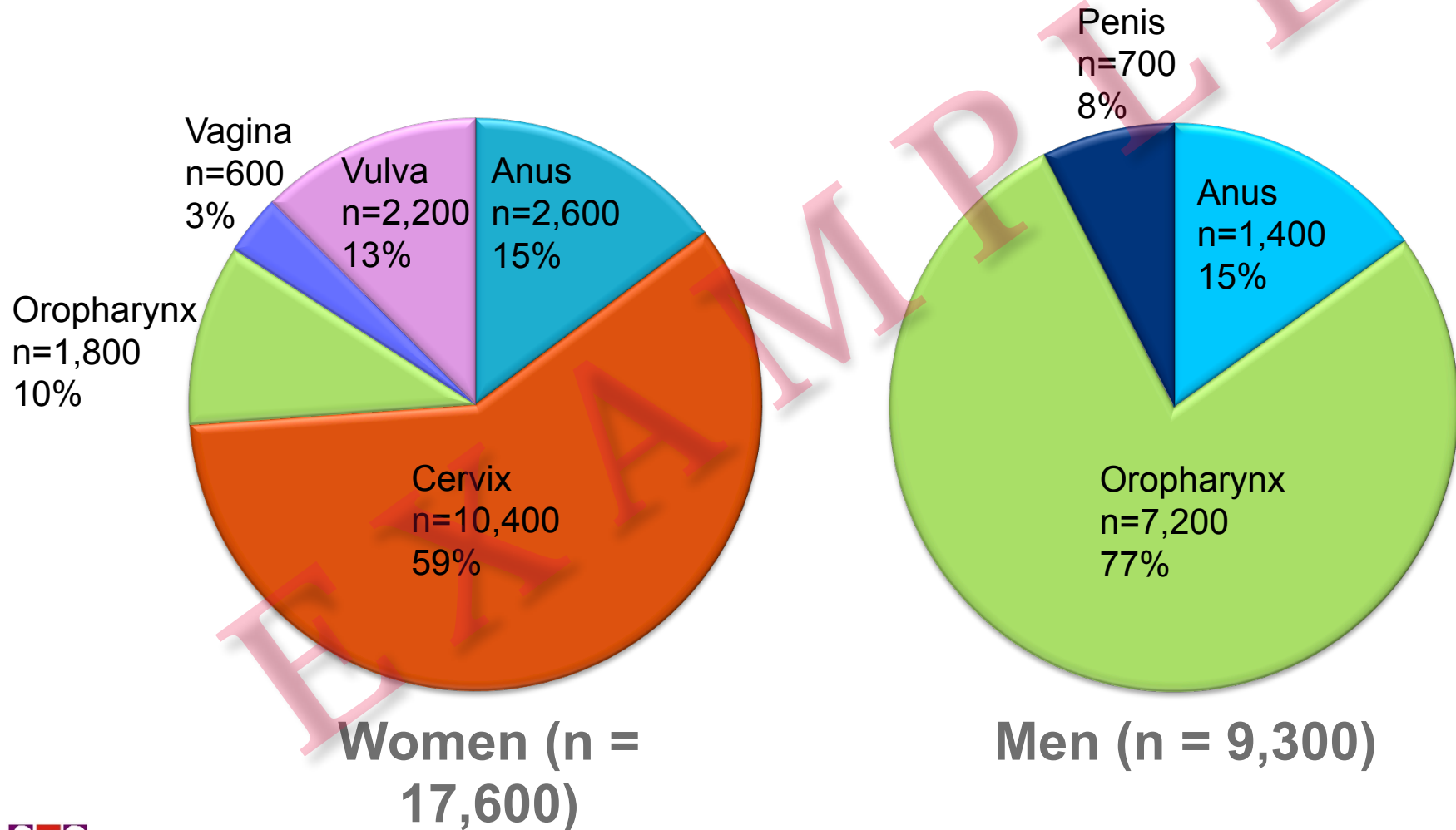
That's 1 case every 20 minutes

## Why do we vaccinate?

- To prevent HPV infections
- To prevent HPV-associated cancers
- Because screening is not available/  
recommended for many HPV  
related cancers



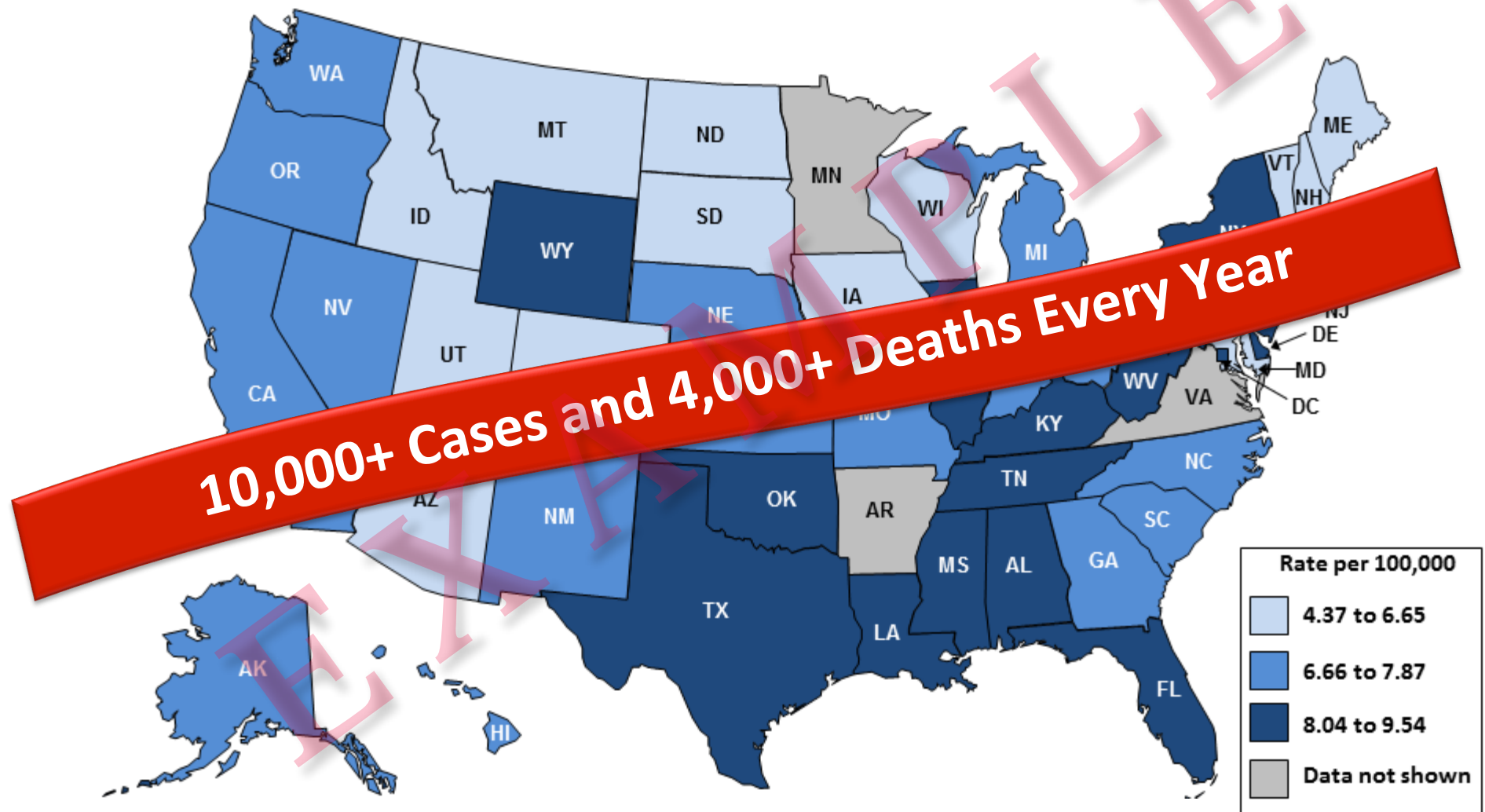
# Average number of new cancers probably caused by HPV, by sex, United States 2006-2010



## Pap history in women diagnosed with cervical cancer

Pap smear within 3 years of cancer diagnosis	% women diagnosed with cervical cancer
None	53%
<b>Normal</b>	<b>28%</b>
Abnormal with f/u	9%
Abnormal, no f/u	4%

# HPV-Associated Cervical Cancer Incidence Rates by State, United States, 2006-2010



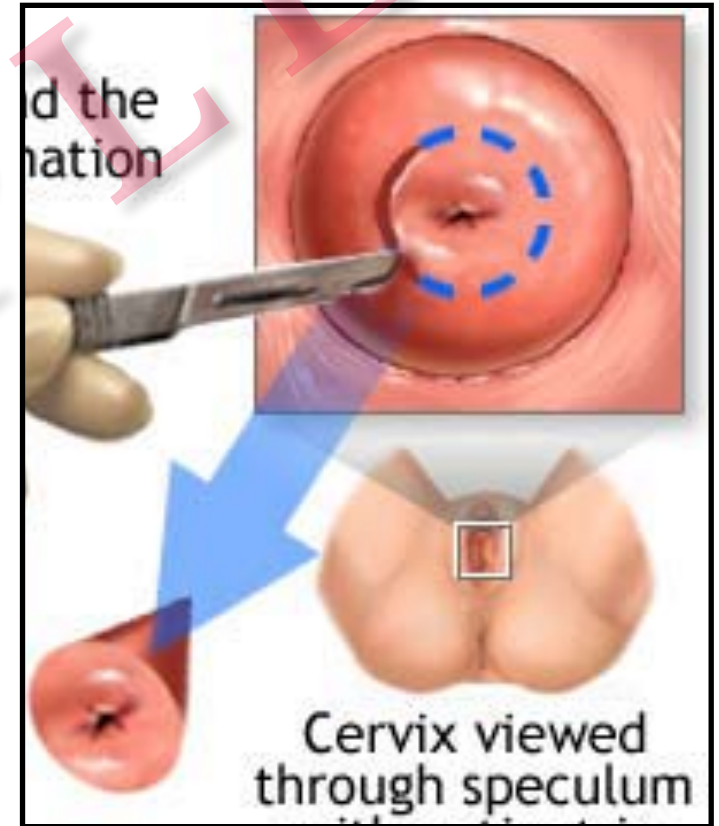
[www.cdc.gov/cancer/npcr](http://www.cdc.gov/cancer/npcr)



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CANCER PREVENTION**

# Treatment of cervical precancerous lesions can lead to increased risk of preterm delivery

- ▶ 330,000 women undergo cone/LEEP procedures every year
- ▶ LEEP/HPV infection associated with obstetric morbidity
  - ▶ Preterm delivery
  - ▶ Preterm rupture of membranes
  - ▶ Low birth weight
  - ▶ *Long term developmental outcomes, neonatal intensive care costs*



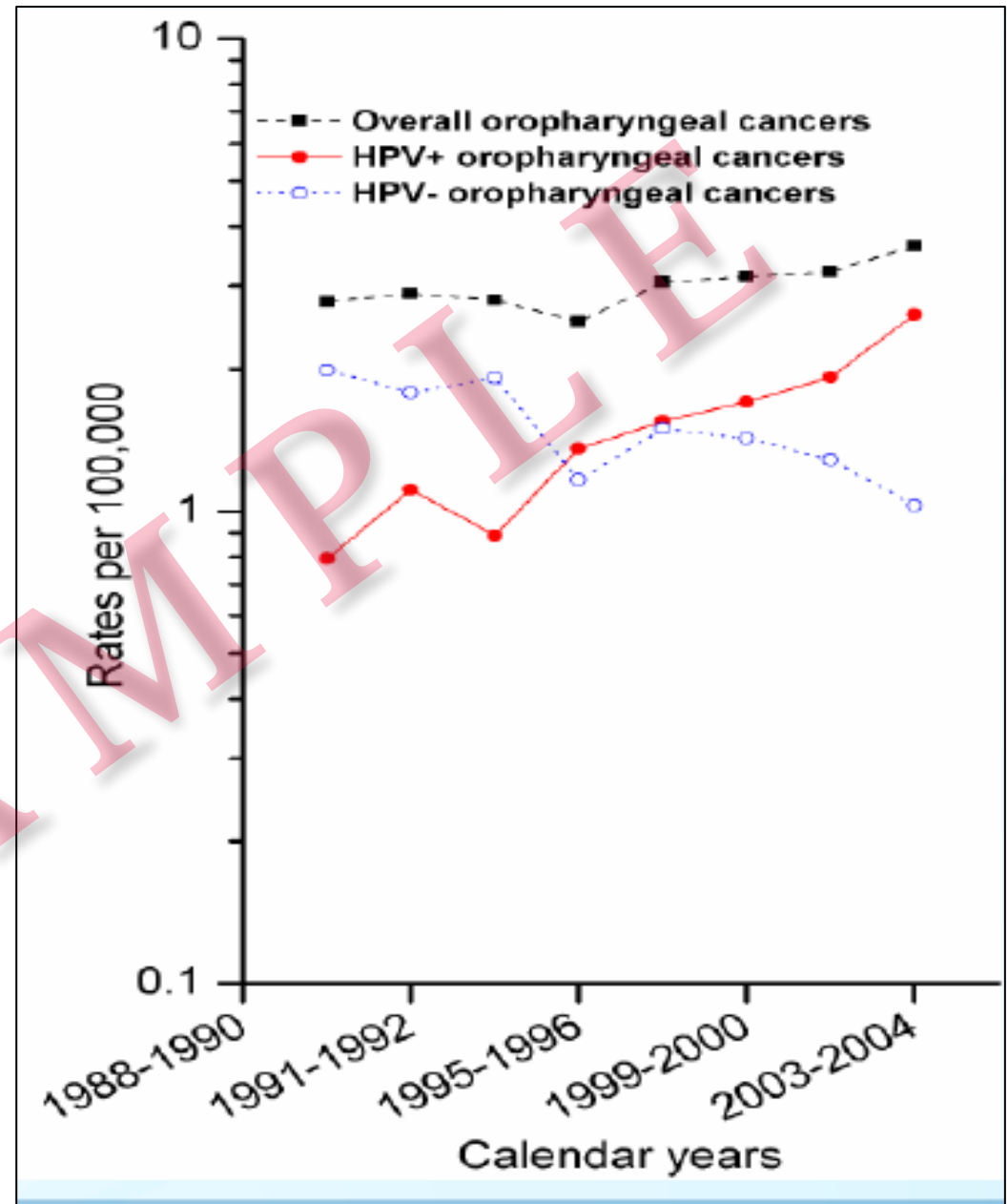
# Why do we want to protect boys from HPV?

- ➡ Oropharyngeal cancers more common in men
  - ➡ No screening test for oropharyngeal cancers
- ➡ Genital warts
- ➡ Anal cancer
- ➡ Penile cancer

The incidence of oropharyngeal cancers increased in the past 20 years

During this time:

- Smoking and alcohol-related cancers decreased 50%
- HPV-related cancers increased by 225%

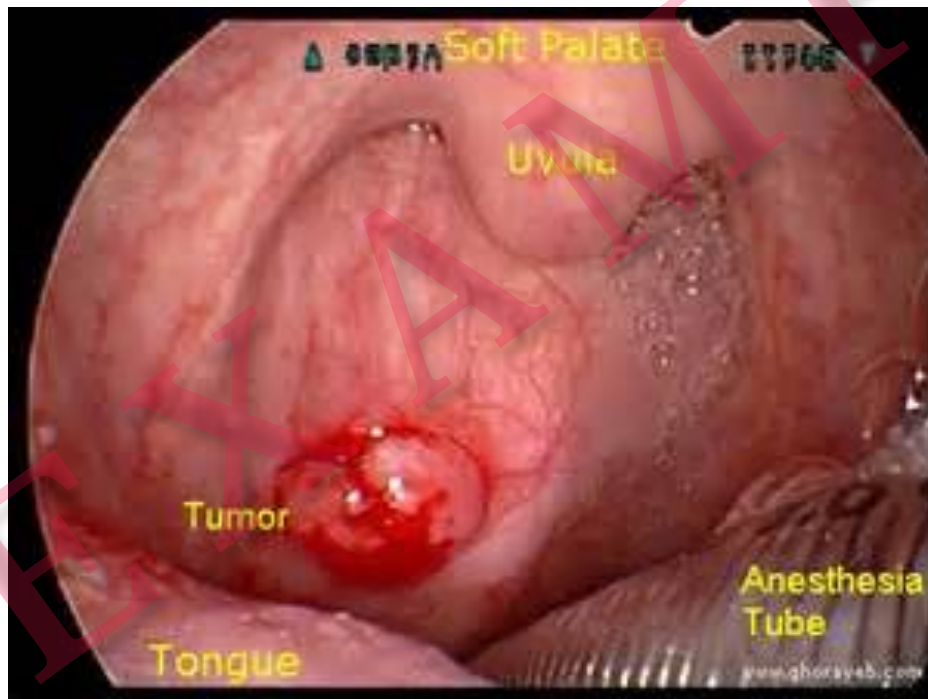


# Oropharyngeal Cancer

11,000 cases annually, 7,000 in men

Will be more common than cervical cancer by 2020

Rise in incidence and changing patient demographics due to HPV



<http://www.ghorayeb.com/OropharyngealCarcinoma.html>

J Clin Oncol 29:4294-4301. © 2011 by American Society of Clinical Oncology





# RISK OF HPV ACQUISITION

*Almost everyone will be exposed to HPV*

*Many infections will clear on their own, others may persist and some will reactivate decades after initial exposure*



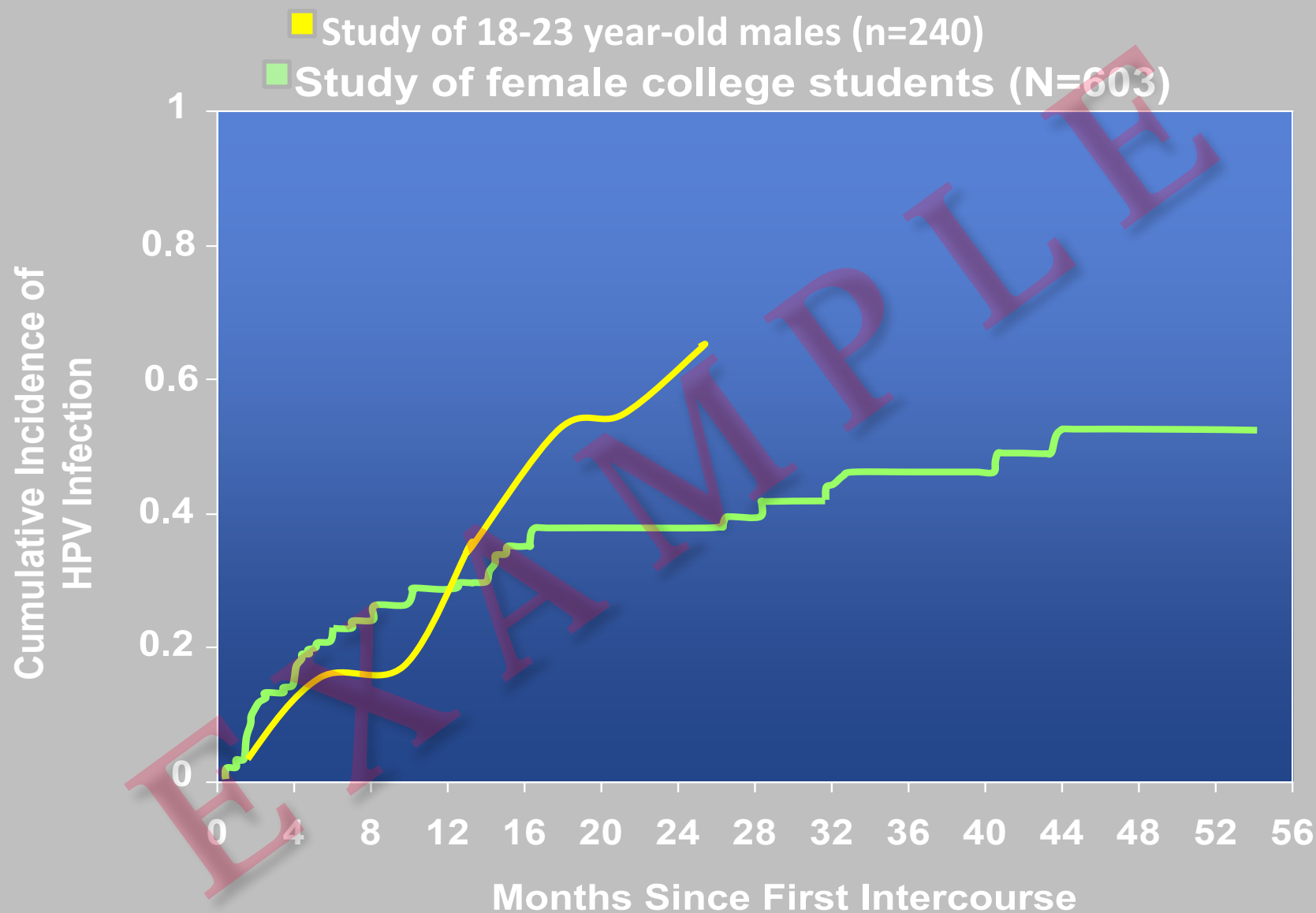
## HPV transmission

- ➡ Most females and males will be infected with at least one type of mucosal HPV at some point in their lives
- ➡ Most common route is sexual intercourse
  - ➡ genital-genital, anal-genital, oral-genital, manual-genital
- ➡ 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

# HPV can be transmitted without "having sex"

- ▶ 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 has been detected in women prior to first vaginal sex. The percentage ranges from 9 to 46%, depending on the study.
- ▶ 70% of these women reported non-coital behaviors that may in part explain genital transmission

## Rapid acquisition of HPV following sexual debut



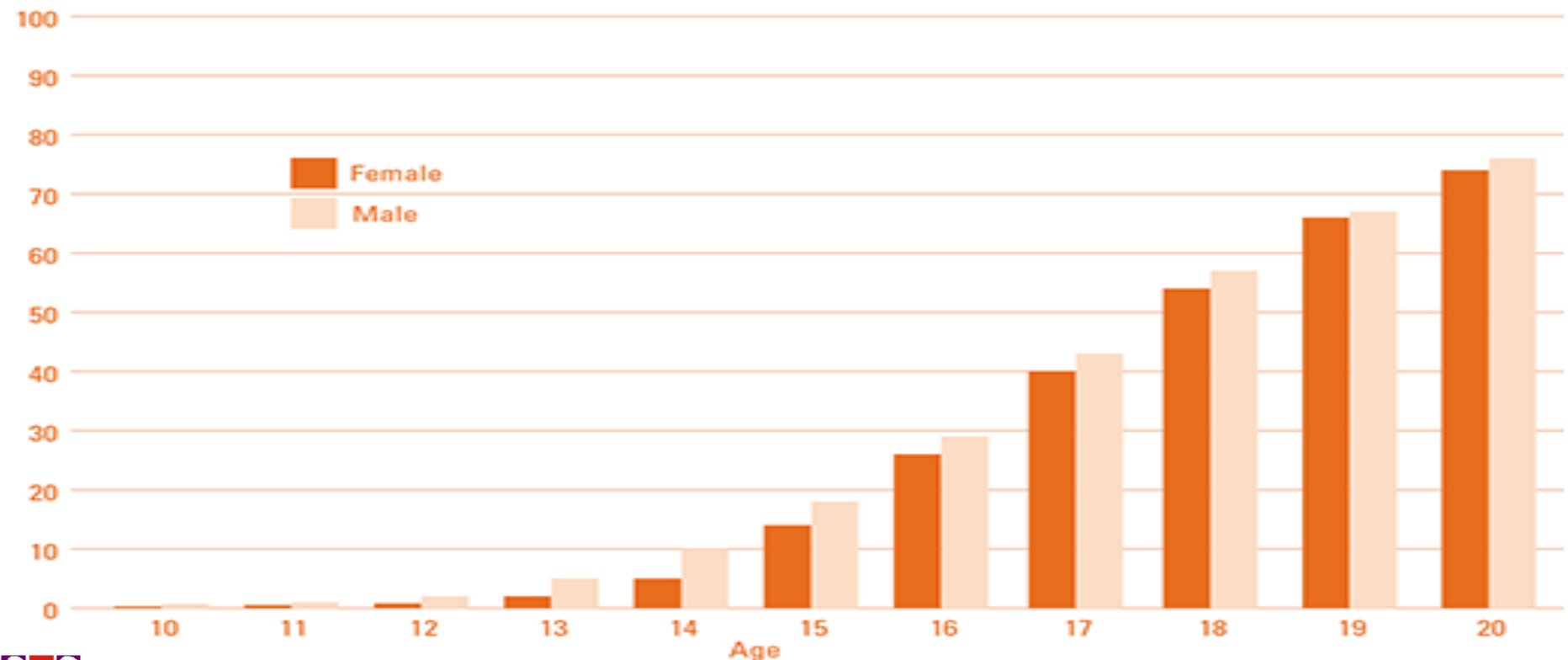
From Winer RL, Lee S-K, Hughes JP, Adam DE, Kiviat NB, Koutsky LA. Genital human papillomavirus infection: incidence and risk factors in a cohort of female university students. *Am J Epidemiol.* 2003;157:218–226. Reprinted with the permission of Oxford University Press. Partridge, JID 2007

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

## Teen Sexual Activity

Adolescence is a time of rapid change.

% of adolescents who have had sex by each age



## HPV may never go away

- ➡ 700 women aged 35-60
- ➡ Only 13% of incident infections attributed to new sexual partners
- ➡ 85% of incident infections occurred during periods of abstinence or monogamy

*Early vaccination can prevent initial infection*

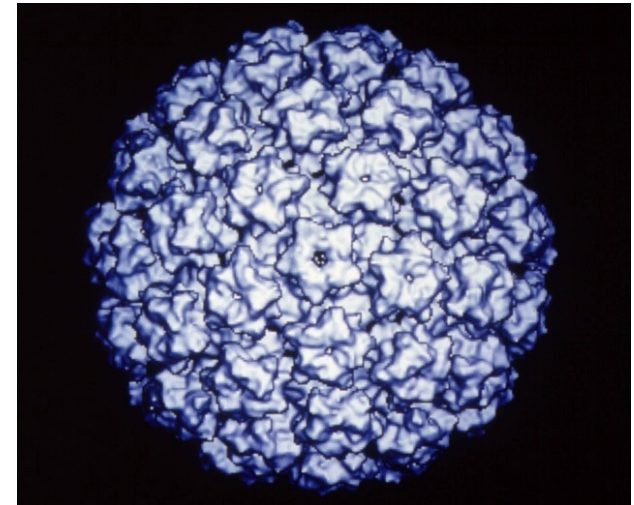
# Recommendations, Safety, Impact, & Coverage Rates

## 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

# 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
<b>Females</b>	✓	✓	✓
<b>Males</b>	✓	✓	



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

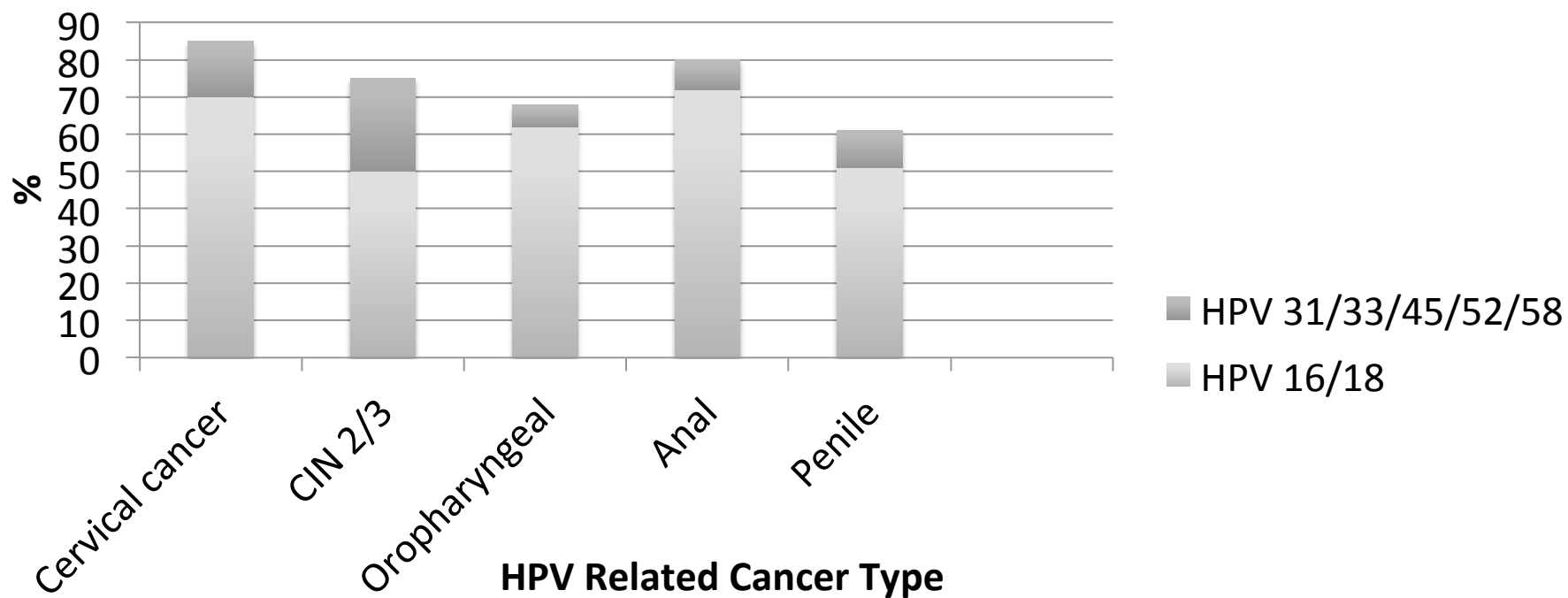




## 9vHPV Vaccine Safety

- ➡ 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

## Percentage of HPV types found in common HPV related cancers, US Data



**Overall improvement in cancer prevention for 9-valent vaccine over quadrivalent and bivalent:  
14% for females, 4% for males**

## Clinician questions

### ➡ Do I need to restart the series if a dose is late?

No, just ensure the recommended minimum intervals are met.

### ➡ Can I vaccinate someone over age 26?

Vaccination is safe, but disease may not be reduced. Insurance is unlikely to reimburse.

### ➡ How long does immunity last?

At least 10 years, studies are ongoing

### ➡ Should I vaccinate after an abnormal Pap?

Yes, they will be protected from HPV types they don't already have.

### ➡ Should I re-vaccinate with HPV-9 after HPV-4?

No formal recommendation, not cost-effective.

Parents and adolescents want to know...

**IS IT SAFE?**

**DOES IT WORK?**

**WILL IT CHANGE MY CHILD'S BEHAVIOR?**



# HPV VACCINE SAFETY



# 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 long-term safety data

## *No increased risk of:*

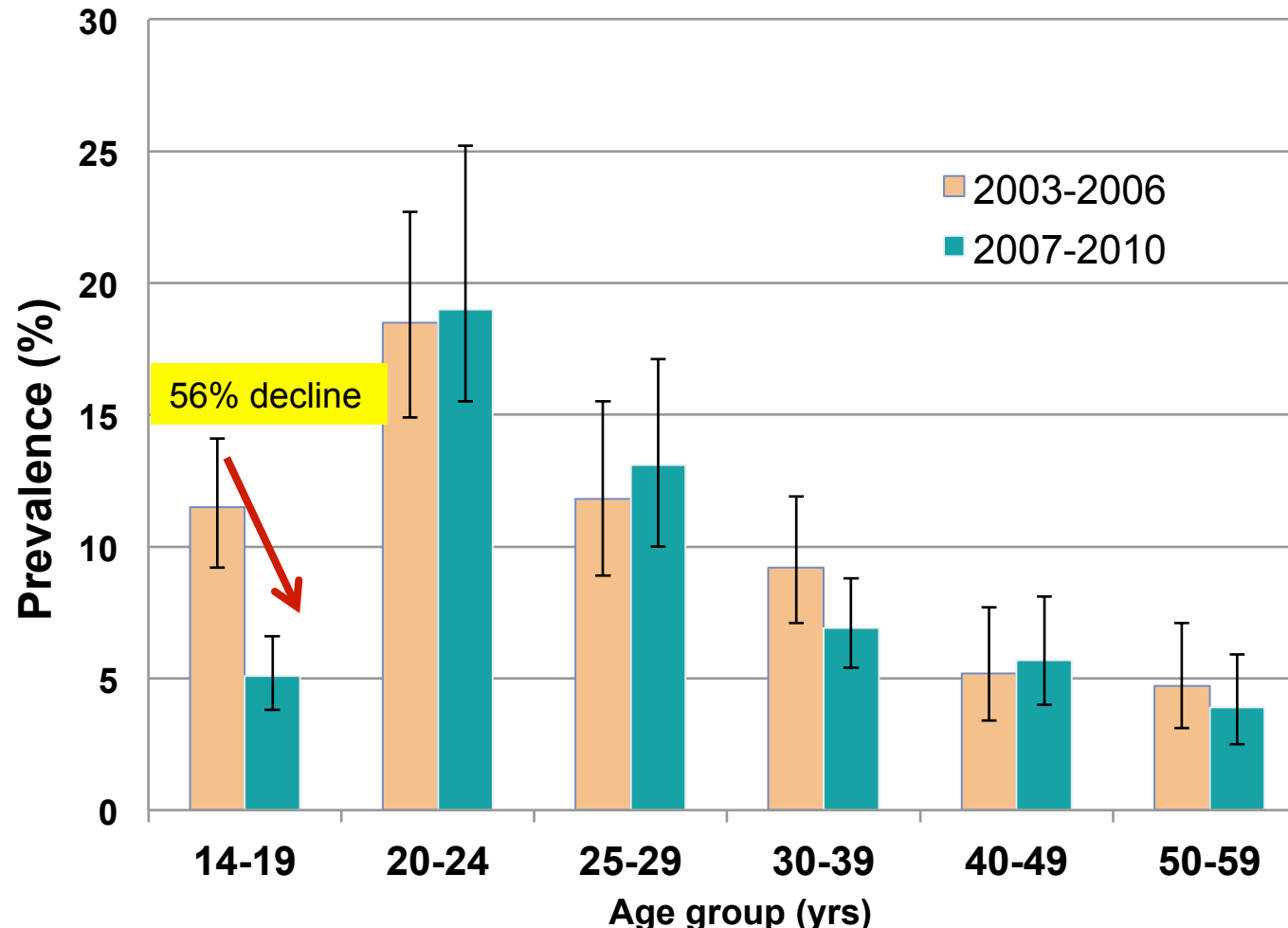
- ☐ 2011- allergic reactions, anaphylaxis, Guillain–Barré Syndrome, stroke, blood clots, appendicitis, or seizures (than unvaccinated or who received other vaccines)
  - ☐ 2013 – (almost 1 million girls) blood clots or AEs related to the immune & CNS
  - ☐ 2014 – (>1 million women) venous thromboembolism or blood clots
  - ☐ 2012 and 2014 – (2 studies) autoimmune disorders
  - ☐ 2015 – Multiple sclerosis or other demyelinating diseases
- 2012 - vaccine 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

# HPV VACCINE EFFECTIVENESS



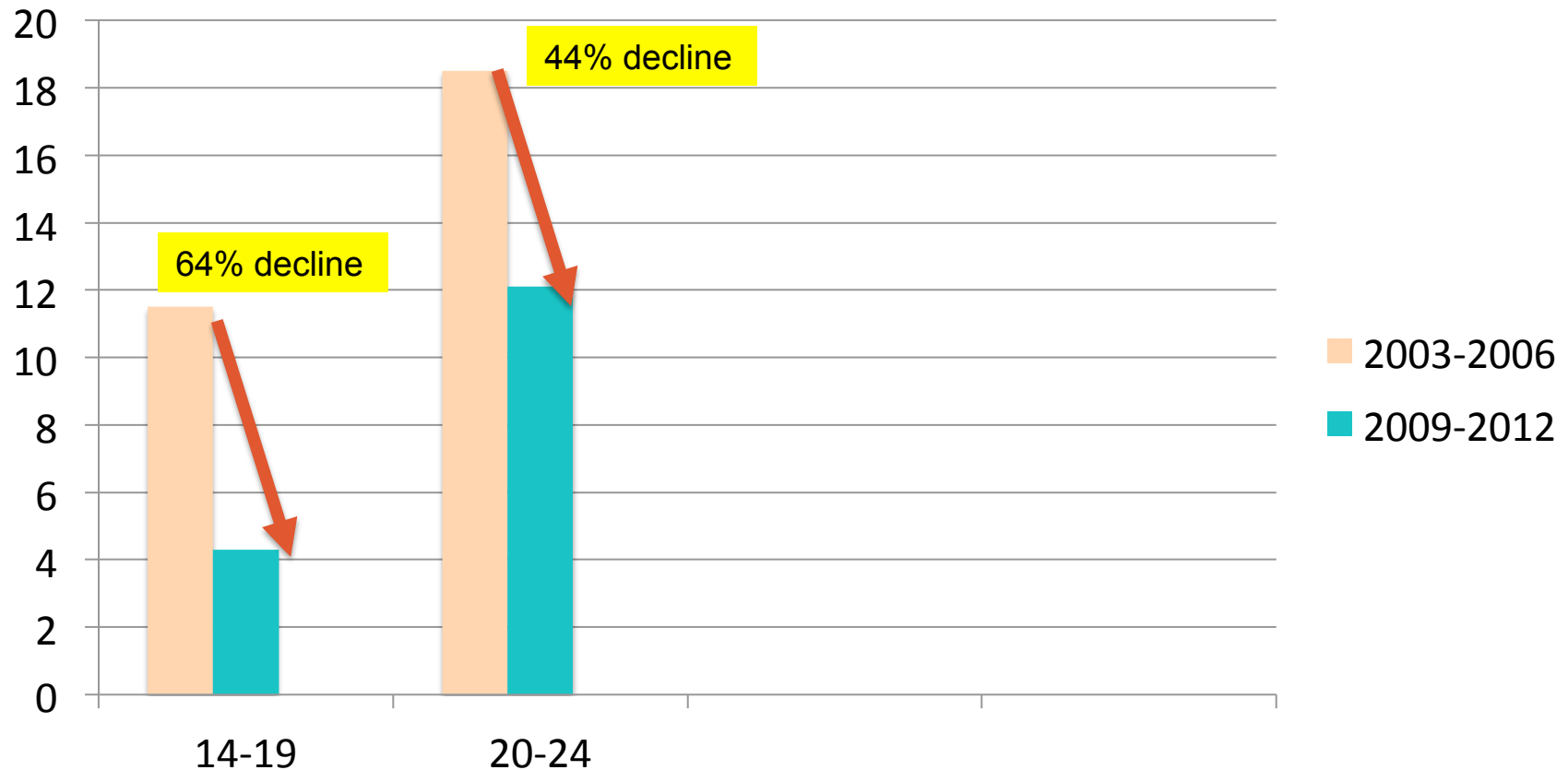
# HPV vaccine impact: US in 2013

Prevalence of vaccine type HPV decreased 56%

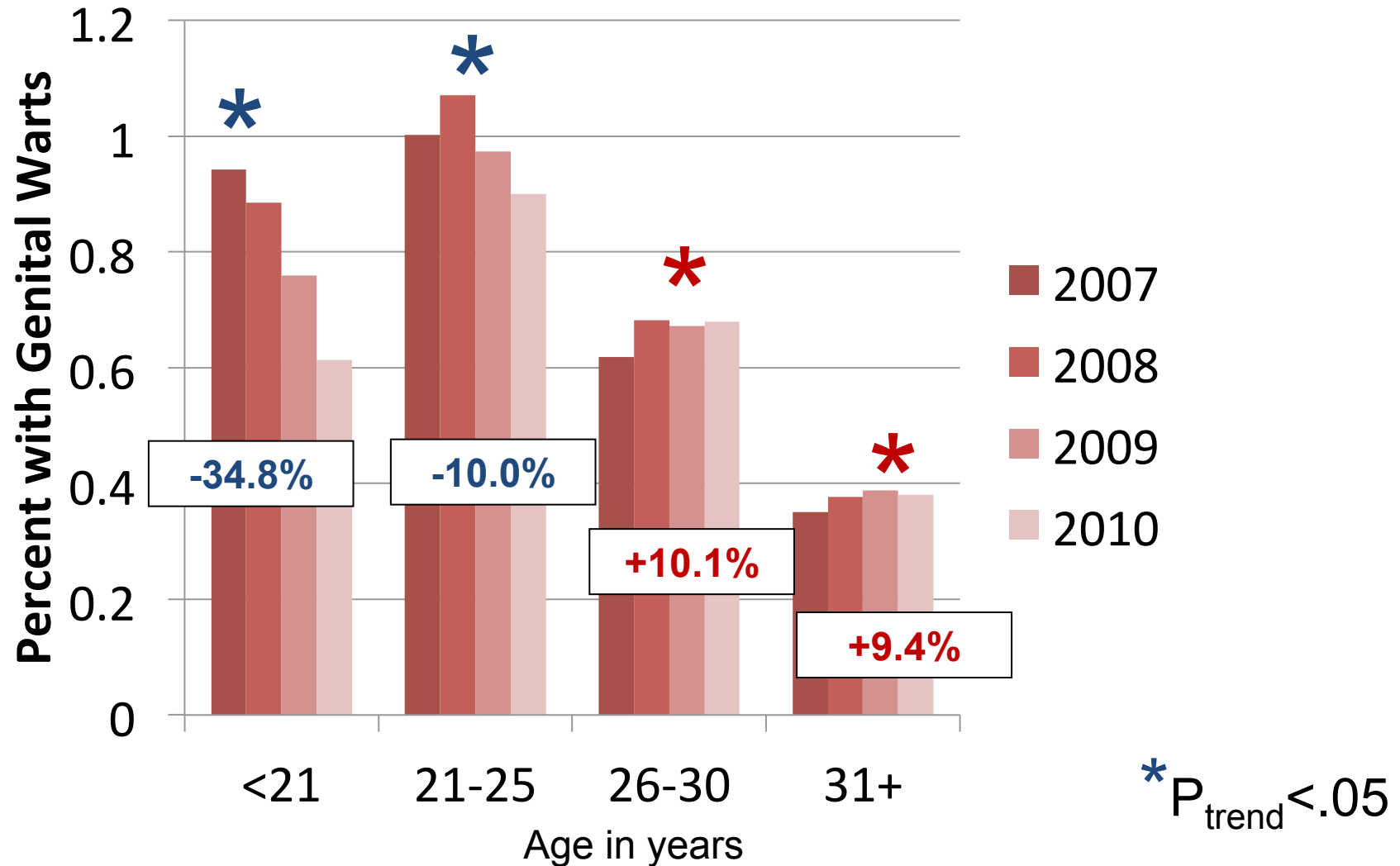


# HPV vaccine impact: US in 2016

**Prevalence of vaccine type HPV decreased 64% and 44%**

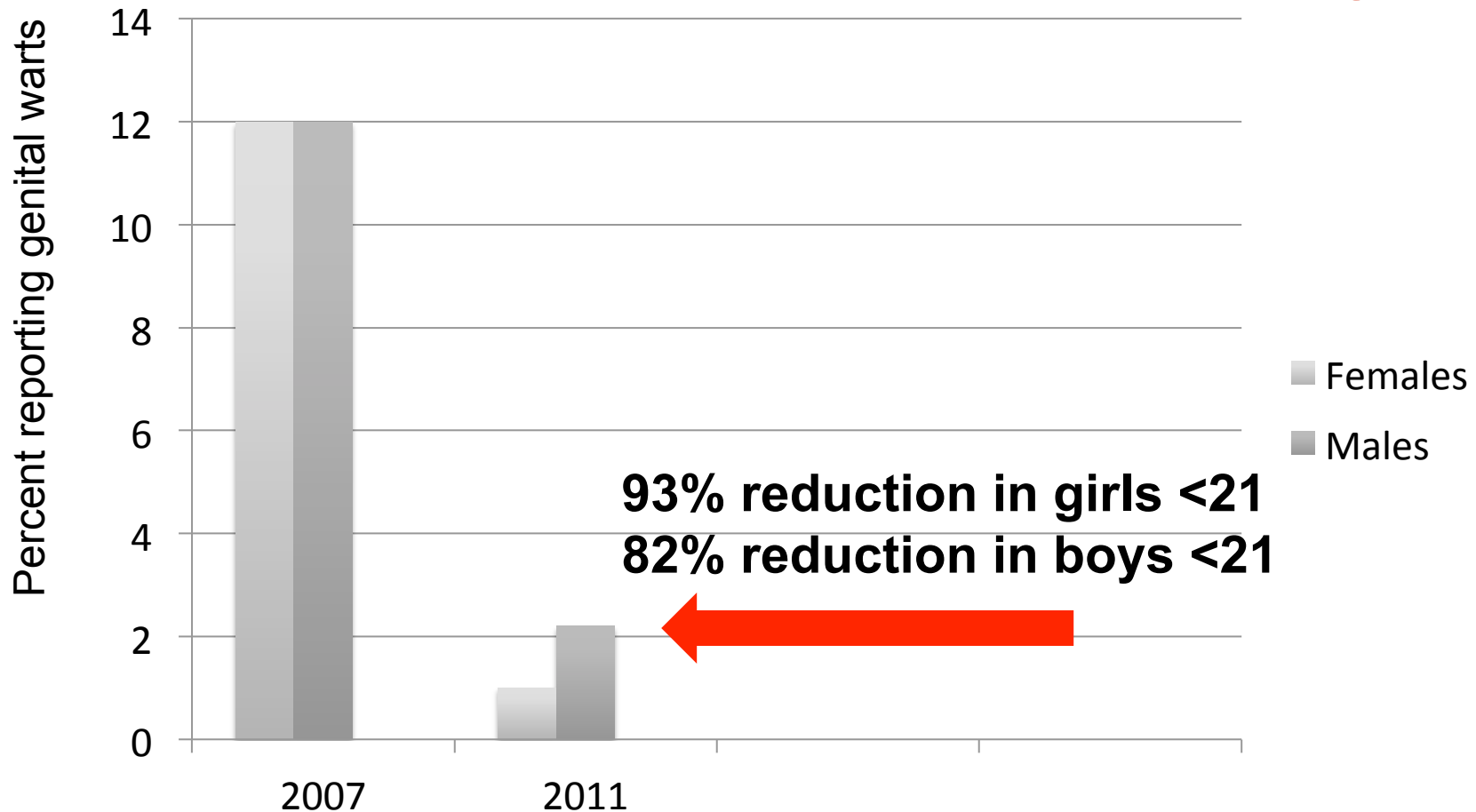


# Genital warts among females by age group, CA Family PACT 2007-2010

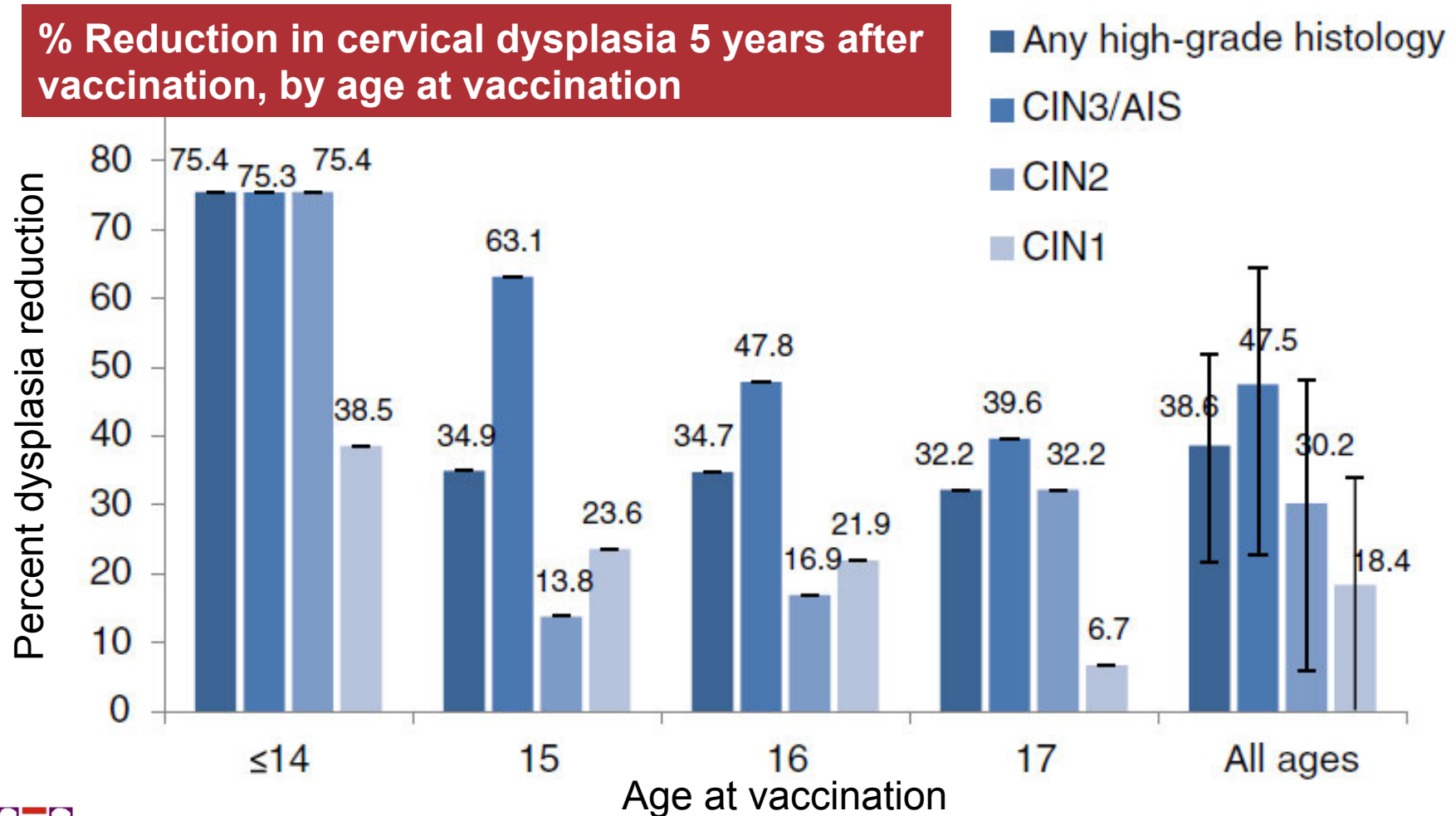


# Near-disappearance of genital warts in Australia following introduction of HPV vaccination

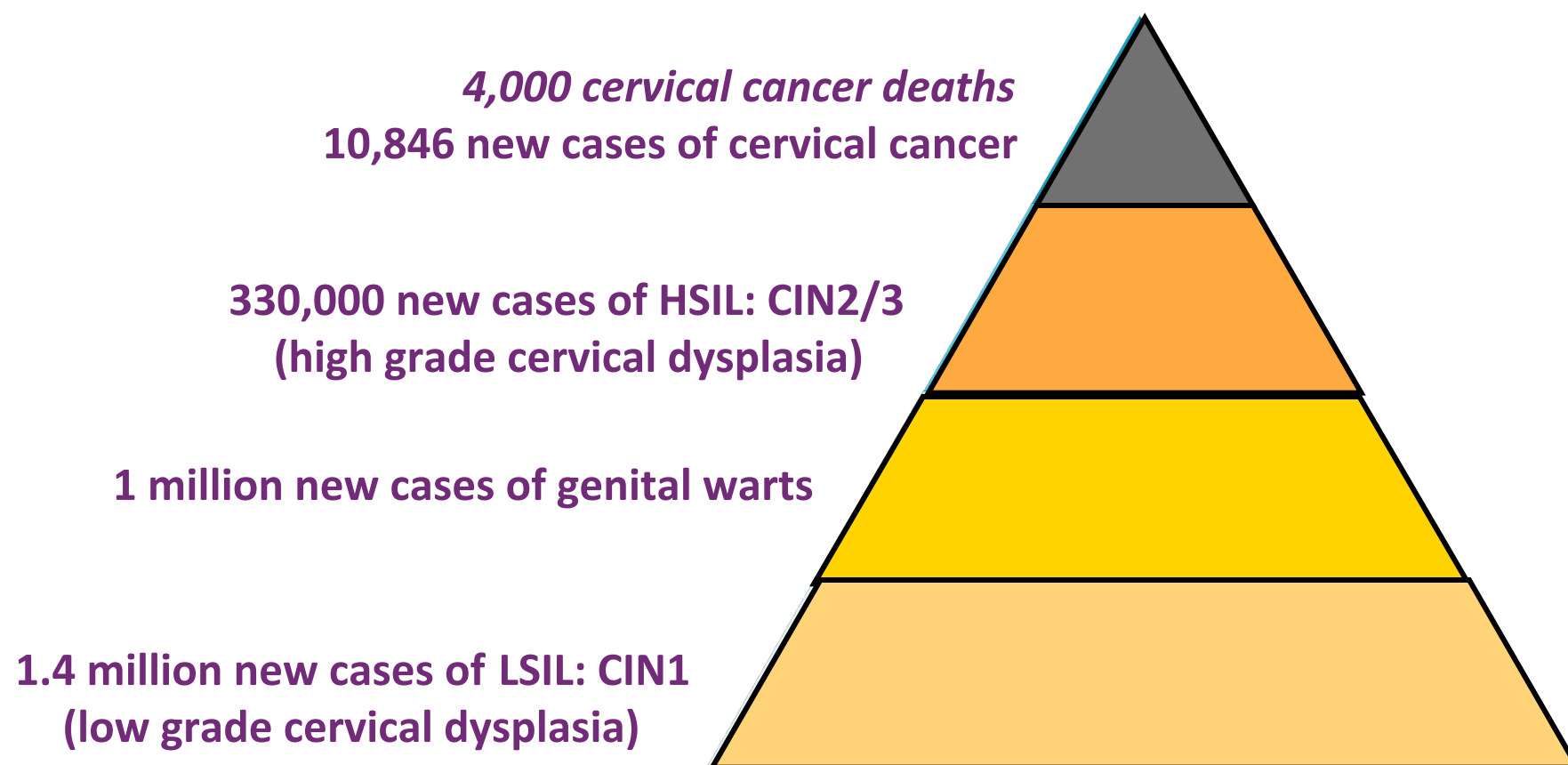
**\*70% vaccination rate for females only**



# Higher effectiveness with vaccination at younger ages



# Without vaccination, annual burden of genital HPV-related disease in U.S. *females*:



## 3 million cases and \$7 billion



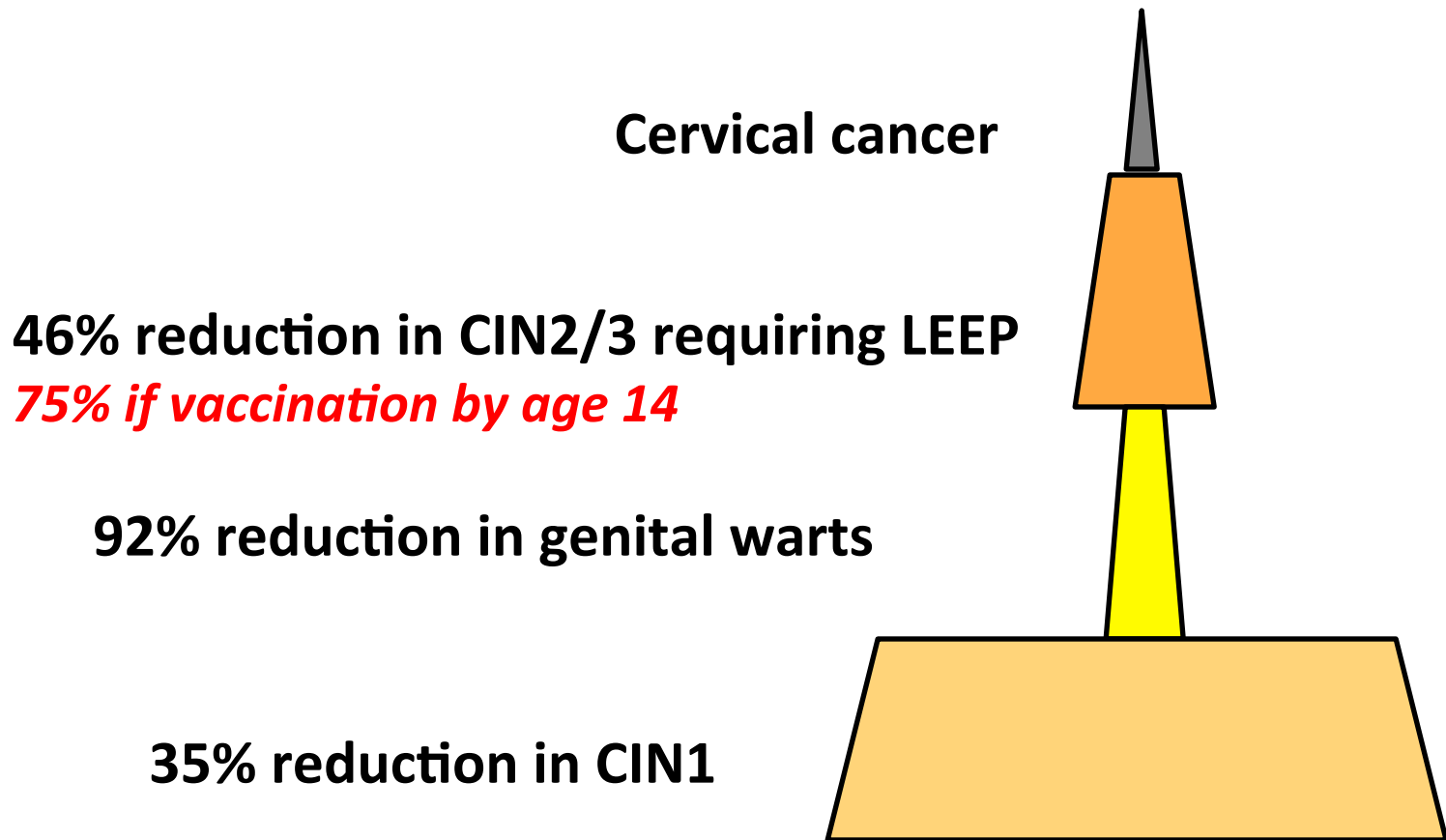
American Cancer Society. 2008;  
*Sex Transm Dis.* 2004;

Schiffman *Arch Pathol Lab Med.* 2003; Koshiol  
Insinga, *Pharmacoeconomics*, 2005



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# Extrapolating the prior pyramid with projections of vaccine efficacy based on Australian data



Gertig, D. M., J. M. Brotherton, et al. (2013). "Impact of a population-based HPV vaccination program on cervical abnormalities: a data linkage study" BMC Med 11: 227.



# Impact of HPV vaccine on oral HPV infection

7,466 women 18-25 years of age randomized to receive HPV or hepatitis A (control) vaccine

➡ 5,840 gave oral specimens at the end of the 4-year study

➡ Control vaccine group: 15 HPV 16/18 infections

➡ HPV vaccine group: 1 HPV 16/18 infections

***Estimated vaccine efficacy against oral HPV infection:  
93.3%***

Herrero R, et al. Reduced prevalence of oral human



papillomavirus (HPV) 4 years after bivalent HPV vaccination in a randomized clinical trial in Costa Rica. PLOS ONE 2013;8:e68329





**In summary:**

**HPV exposure is ubiquitous**

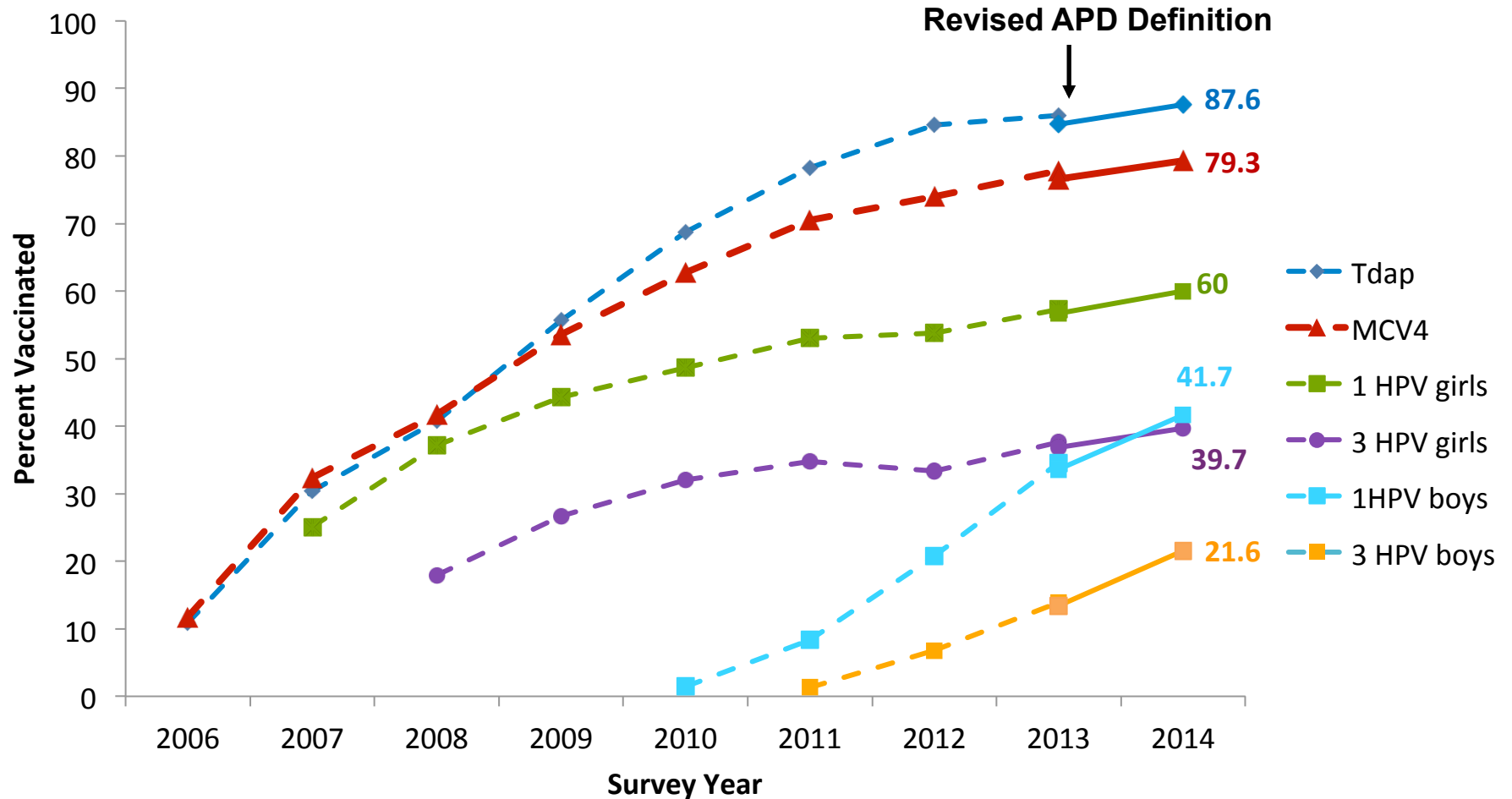
**HPV causes many cancers**

**HPV vaccine is safe**

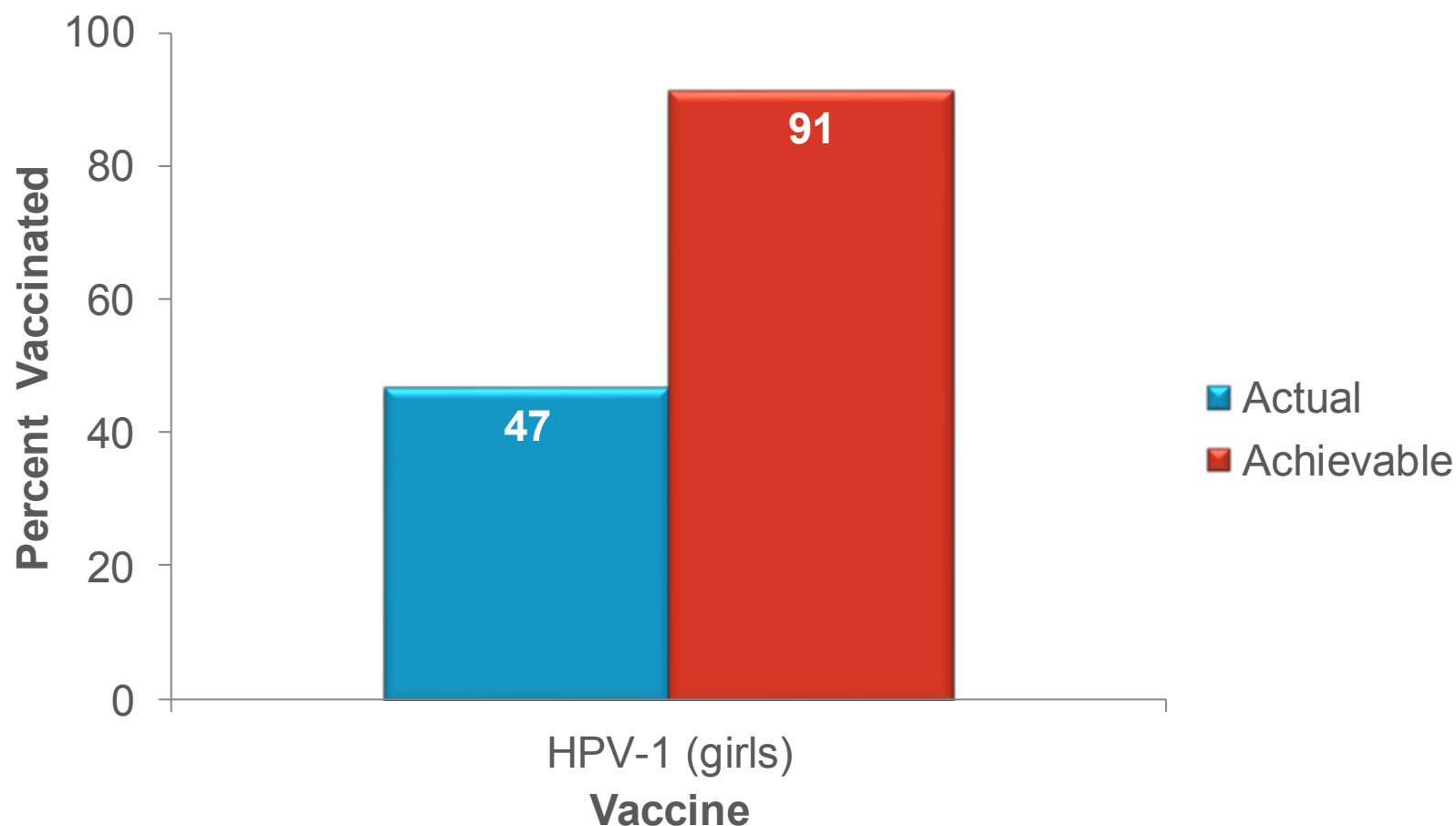
**HPV vaccine is effective**

**WHY ISN'T EVERYONE VACCINATED YET?**

# Adolescent Vaccination Coverage United States, 2006-2014



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



Missed opportunity: Healthcare encounter when some, but not all ACIP-recommended vaccines are given. HPV-1: Receipt of at least one dose of HPV. MMWR. 63(29);620-624.



## A WORD ON SEXUAL PROFILING: *DON'T DO IT*

- 80% of people will be exposed to HPV
- You can't predict who or when



## Delays lead to missed opportunities

Providers introduce HPV vaccination at 11 but do not recommend it strongly

➡ *“I’d honestly say it’s rare that I spend more than 20 seconds on it at 11... So few 11 year olds are physically mature to be sexually active that it’s, I find it’s almost sort of an awkward conversation.”*

Providers and parents may not understand that the vaccine is most effective when all three doses are finished by age 14.

➡ *“I thought that it didn’t really make any difference as long as they had the three vaccines before their 20’s.”*

***And delays intended to be temporary  
may become permanent***



Perkins et al, Pediatrics, 2014



## Each adolescent visit may be the last chance to vaccinate!

- ➡ 30% of adolescents never present for preventive care
- ➡ 1 in 15 adolescent visits is for preventive care
- ➡ Preventive visits decline after age 13
- ➡ Early adolescents (11-14 years old) had 3 times more preventive visits than late adolescents
- ➡ *Use sick and well visits to vaccinate*



Rand et al. Arch Pediatr Adolesc Med



# Evidence-based effective recommendation

## Effective framing

- ➡ “Today your child is due for 3 vaccines: Tdap, HPV, and meningococcal.”

- ➡ *HPV is framed as important*
- ➡ *Many parents just say yes— because they trust you!*

- ➡ Making your job harder
- ➡ “Today your child is due for the Tdap and meningococcal vaccines. We should also talk about the HPV vaccine...”

- ➡ *HPV is framed as “something different”*
- ➡ *Parents sense confusion and your job gets harder*

**Effective framing works at least 10 times better!**



Opel DJ, Pediatrics, 2013



# Why does framing makes a difference

## *Ineffective first discussion*

**Provider:** Meghan and Mark are due for some shots today: Tdap and the meningococcal vaccine. There is also the HPV vaccine...

- Vaccine perceived as different, optional, unimportant

## *Effective first discussion*

**Provider:** Meghan and Mark are due for some shots today: HPV, meningococcal vaccine, and Tdap.

- Presumption of vaccine uptake
- Vaccination perceived as normative, important

## *Addressing catch-up population*

**Provider:** I see that Meghan and Mark haven't gotten their HPV vaccines yet. We should definitely start that today!

- Presumption of vaccine uptake, conveys message of importance



Perkins et al, Pediatrics, 2014





## Providers overestimate parent's concerns

*“From what I understand the vaccine is safe, efficacious and I’d be a fool and also have amnesia to believe that high schoolers do not engage in unwise sexual practices at times.” —Father of a 12 year-old*

**55-90% of parents and adolescents will follow provider recommendations**

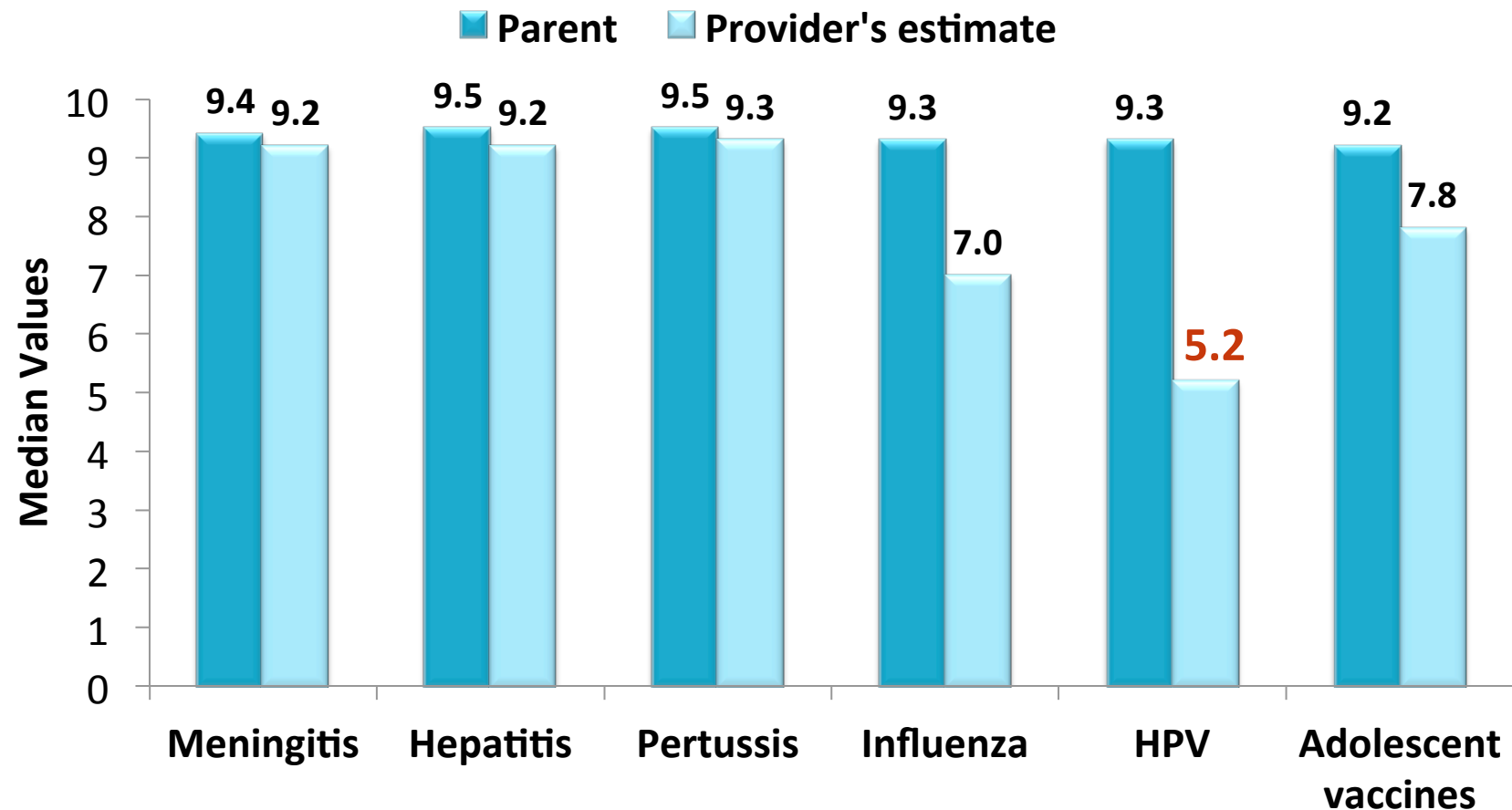
**Most parents also believe their sons and daughters would at some point be at risk for STIs**



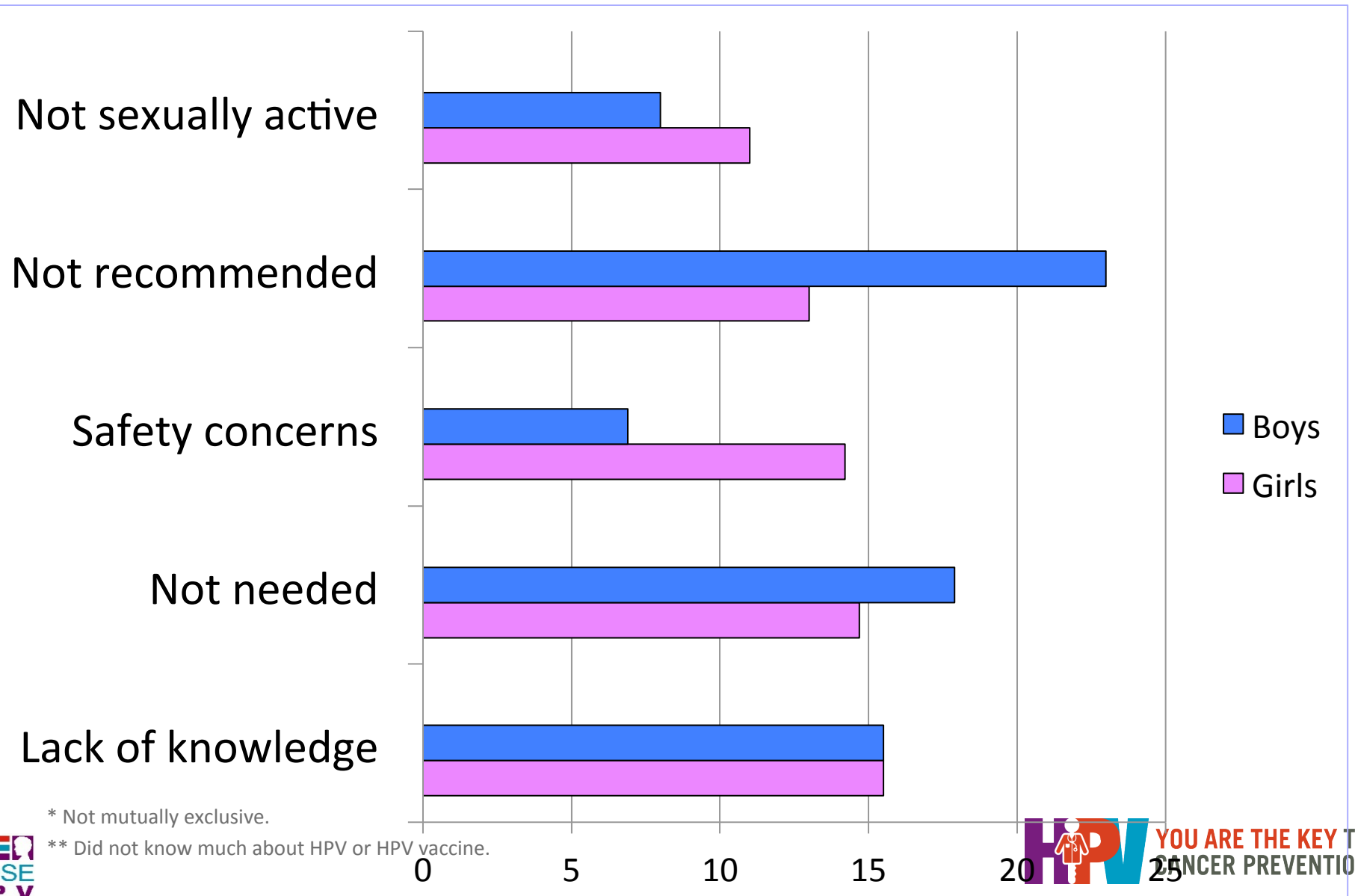
Perkins et al, Pediatrics 2014; Brewer 2007, Prev Med



# Clinicians Underestimate the Value Parents Place on HPV Vaccine



# Parents top 5 reasons for not vaccinating their daughters and sons, NIS-Teen 2013



# You can reassure parents that HPV vaccination does *not* change sexual behavior

- 3 large studies including >200,000 girls & young women
- HPV vaccination NOT associated with
  - Being sexually active
  - Number of sexual partners
  - Receiving counseling on contraceptives
  - Testing for or diagnoses of sexually transmitted infections

Liddon NC, *Am J Prev Med* 2012;42:44

Bednarczyk RA, *Pediatrics* 2012;130:798

Jena AB, *JAMA Intern Med*, 2015



# Addressing all concerns in 45 seconds

**Provider:** Meghan and Mark are due for their HPV vaccine.

**Parent:** Why do they need an HPV vaccine?

**Provider:** The HPV vaccine will help protect them from cancer caused by HPV infection. We know that HPV infection is dangerous— 27,000 people in the US get cancer from HPV every year. And we know that the HPV vaccine is safe— over 100 million doses have been given and there haven't been any serious side effects.

**Parent:** I don't think they need that yet...

**Provider:** Vaccines only work if they're given before exposure—we never wait until a child is at risk to give any recommended vaccines. HPV vaccine is also given as early as possible because it produces a better immune response in younger adolescents. That's why it is so important to start the shots now and finish all of them in the next 6 months.

## Discuss HPV vaccination in the context of mom's cervical cancer

*One doctor says:*

“In your experience with your health right now, you may be screened for cervical cancer by means of a pap smear... because cervical cancer can obviously be something that can be life-threatening but if caught soon, it can be taken care of, and this is how your health is impacted by this virus right now. Well, children now have the option of getting the HPV vaccine which is actually very effective at reducing the risk for contracting that same virus.”



## How does the Chair of ACIP do it?

*“When discussing HPV vaccine with 11 and 12 year-olds and their parents, I will ask the simple question: When do you want your children to put on their bike helmets?”*

- ➡ A. Before they get on their bike
- ➡ B. When they are riding their bike in the street
- ➡ C. When they see the car heading directly at them
- ➡ D. After the car hits them

*I usually end up with a smile and a successfully launched series.”*



Temte JL, Pediatrics 2014, letter to the editor



## HPV is common and dangerous

- ➡ *3 million Americans seek medical treatment for HPV-related disease every year*
- ➡ *More than 12,000 women every year get cervical cancer— 30% of them were screened on time*
- ➡ *More than 20,000 men and women every year get HPV-related cancers for which there are no screening tests*

**We can do better**



## HPV vaccination *IS* high quality care

- ➡ Recommend the HPV vaccine the same way and on the same day you recommend Tdap and meningococcal vaccines.
- ➡ Hearing “HPV vaccine is cancer prevention” helps parents make the decision to vaccinate.

**A strong recommendation is critical**

# Conclusions

Vaccinating all your patients with HPV vaccines will save lives and improve health

For more information,  
including free resources for providers  
and patients:

AAP HPV champion toolkit:

<https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Pages/HPV-Champion-Toolkit.aspx>

[cdc.gov/vaccines/teens](https://cdc.gov/vaccines/teens)

