



You are the Key to HPV Cancer Prevention

Jill B Roark, MPH

Lead, Adolescent Immunization Communications

Health Communication Science Office

National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention

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Disclosures

- ▶ CDC, our planners, and our presenter wish to disclose they have no financial interests or other relationships with manufacturers of commercial products, suppliers of commercial services, or commercial supporters.

Disclosures

- ➔ Content will not include any discussion of unlabeled use of a product or a product under investigational use with the exception of the discussion of use of HPV vaccines in the manner recommended by the Advisory Committee on Immunization Practices, but not approved by the Food and Drug Administration.
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Target Audience

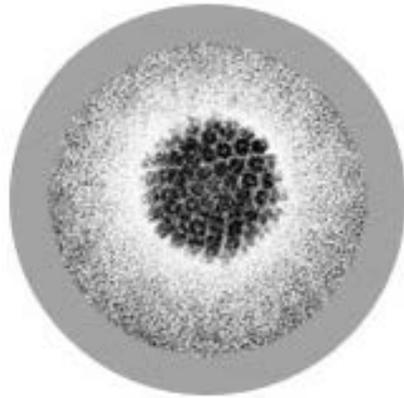
- **Physicians, Nurses, Nurse Practitioners, Pharmacists, Physician's Assistants, DoD Paraprofessionals, Medical Students, etc.**

Continuing Education

- ▶ Continuing education credit is available for this course until **February 26, 2016**.
- ▶ Information about the course can be located at
www.cdc.gov/vaccines/ed/hpv/default.htm

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

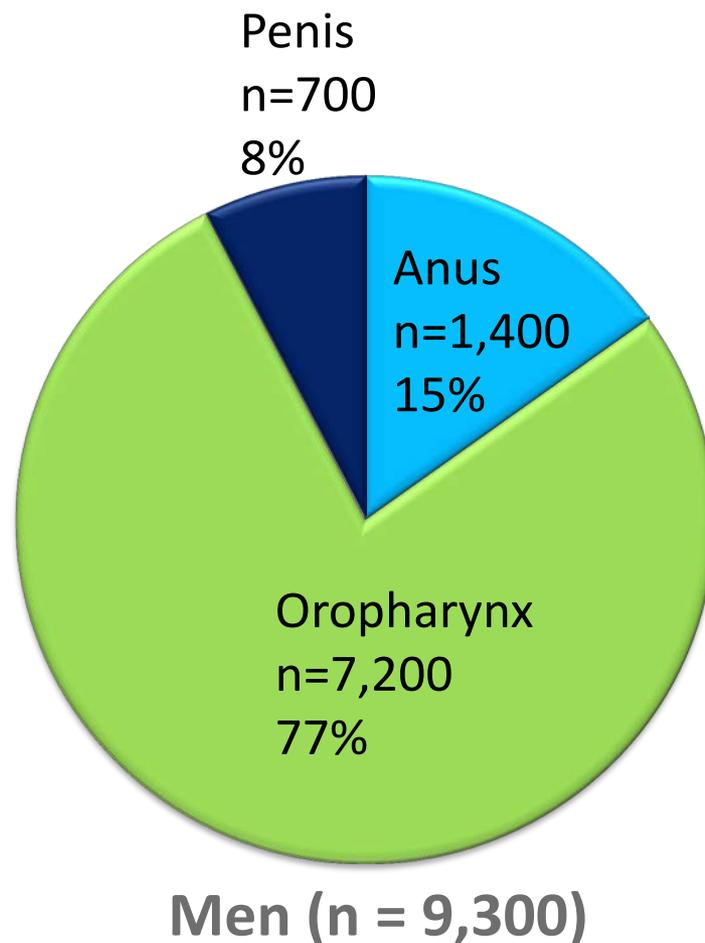
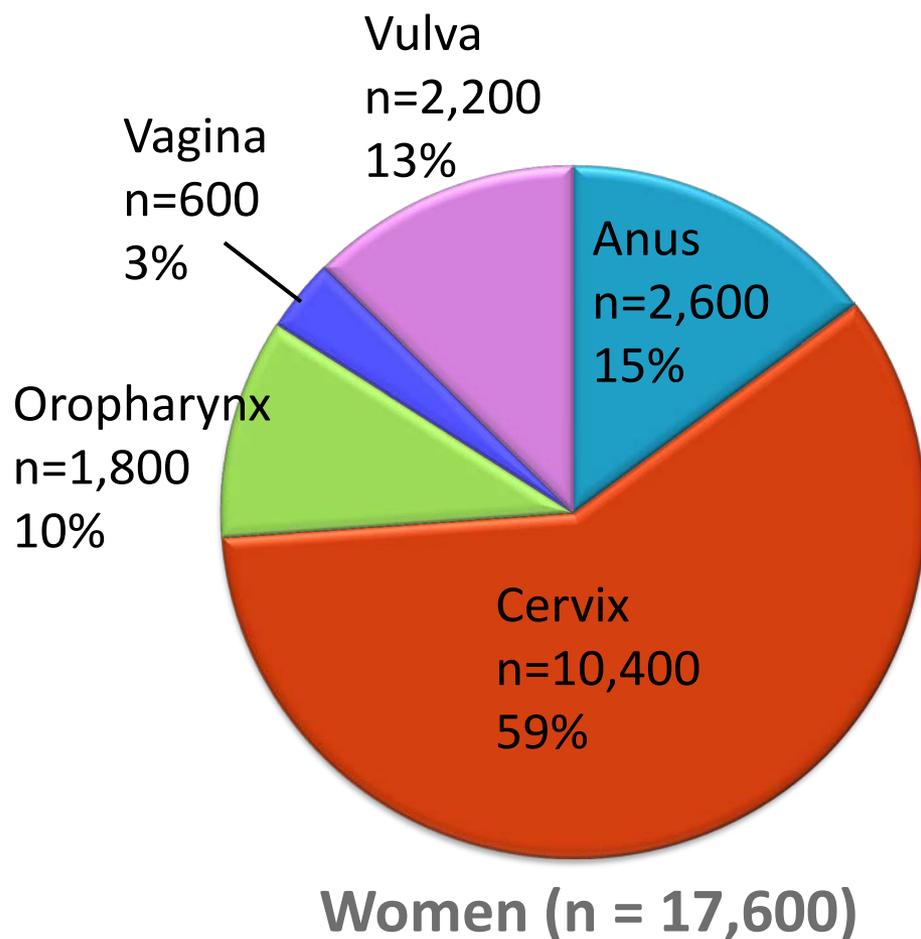
- ▶ **Most females and males will be infected with at least one type of mucosal HPV at some point in their lives**
 - ▶ Estimated 79 million Americans currently infected
 - ▶ 14 million new infections/year in the US
 - ▶ HPV infection is most common in people in their teens and early 20s
- ▶ **Most people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

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



That's 1 case every 20 minutes

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



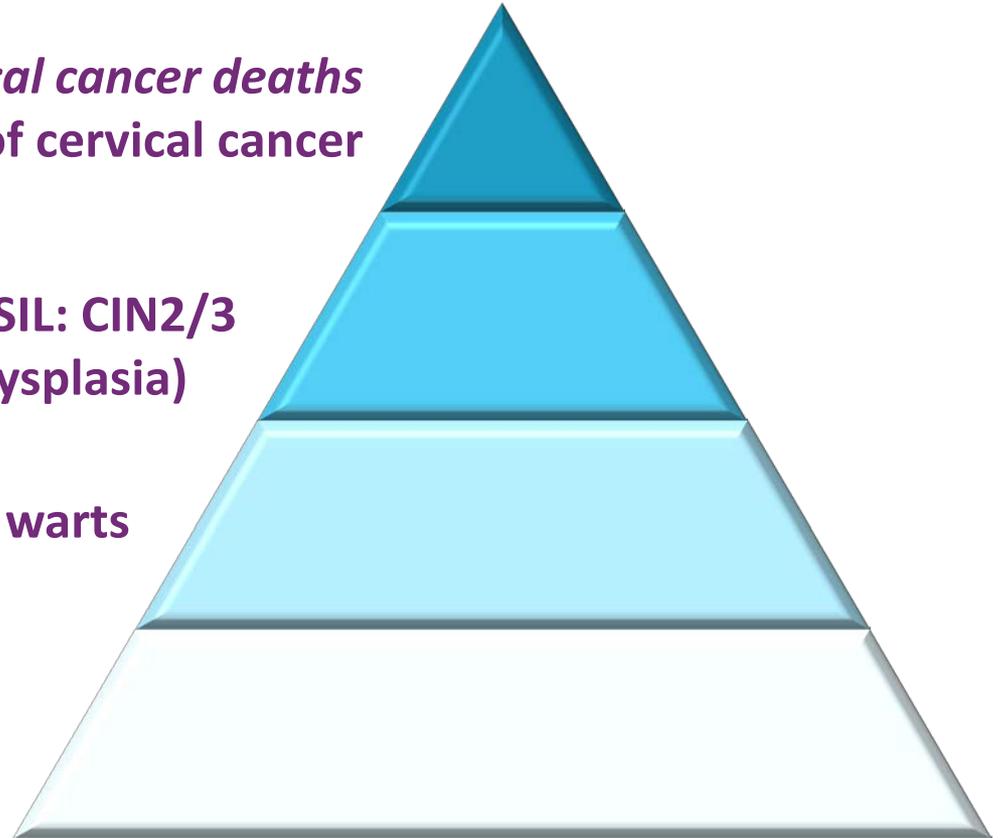
Without vaccination, annual burden of genital HPV-related disease in U.S. *females*:

4,000 cervical cancer deaths
10,846 new cases of cervical cancer

330,000 new cases of HSIL: CIN2/3
(high grade cervical dysplasia)

1 million new cases of genital warts

1.4 million new cases of LSIL: CIN1
(low grade cervical dysplasia)



Nearly 3 million cases and \$7 billion

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

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



HPV vaccine is cancer prevention.

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

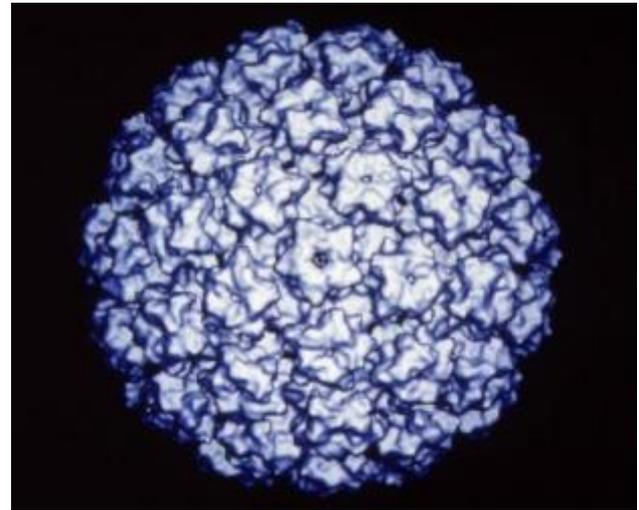
#UCanStopHPV

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

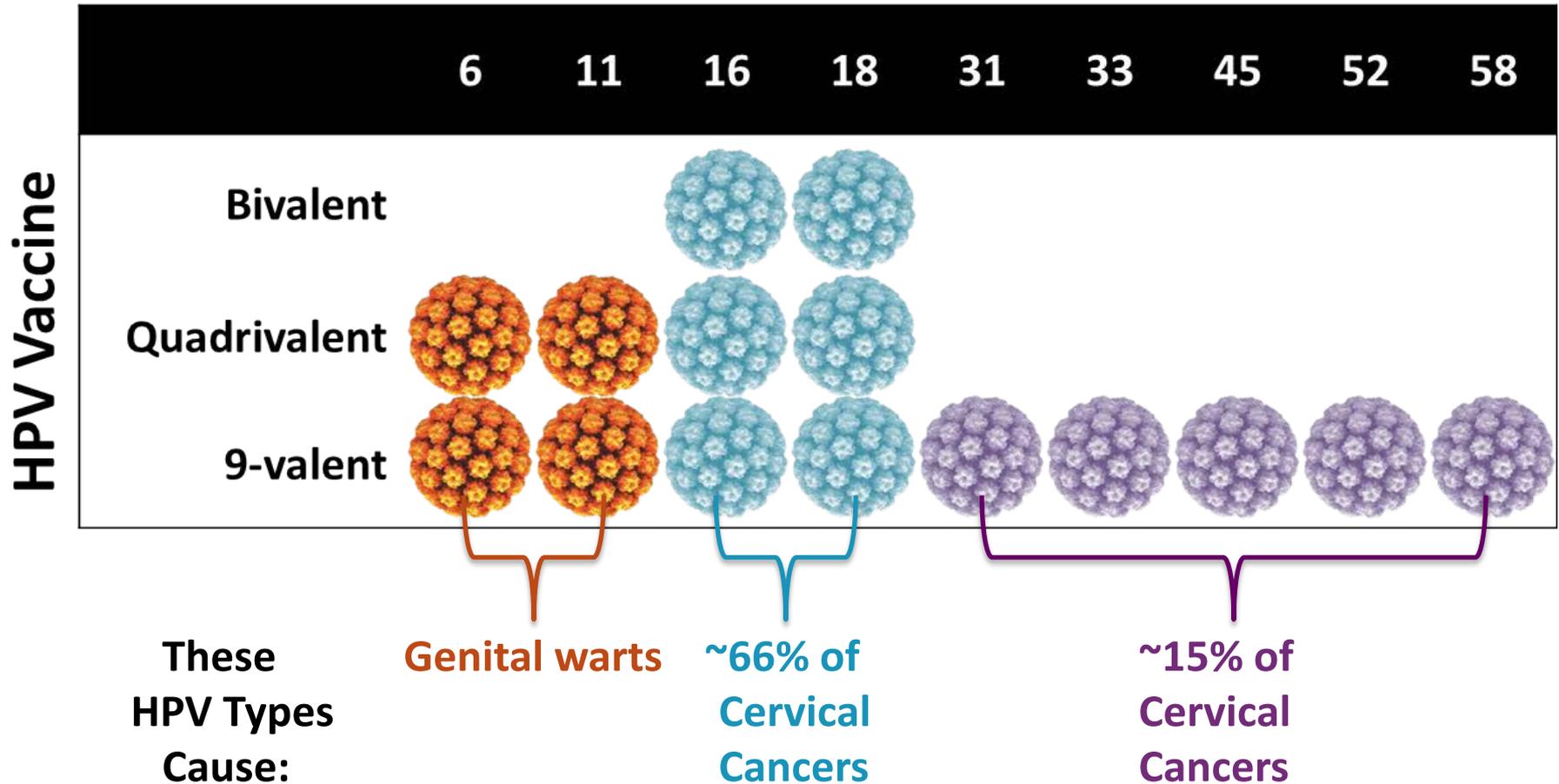
HPV Vaccines Currently Licensed in U.S.

| | Bivalent 2vHPV (Cervarix) | Quadrivalent 4vHPV (Gardasil) | 9-Valent 9vHPV (Gardasil 9) |
|---------------------------|--|--|---|
| Manufacturer | GlaxoSmithKline | Merck | Merck |
| HPV Types Included | 16, 18 | 6, 11, 16, 18 | 6, 11, 16, 18, 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 |

* May be present in tip of pre-filled syringes

HPV Vaccine Comparison

HPV Types Included in Vaccine



HPV Vaccine Recommendation

Girls & Boys can start HPV vaccination at age 9

Preteens should finish HPV vaccine series by 13th birthday



Plus girls 13-26 years old who haven't started or finished HPV vaccine series



Plus boys 13-21 years old who haven't started or finished HPV vaccine series

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: 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 → 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

HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

▶ HPV Vaccine is SAFE

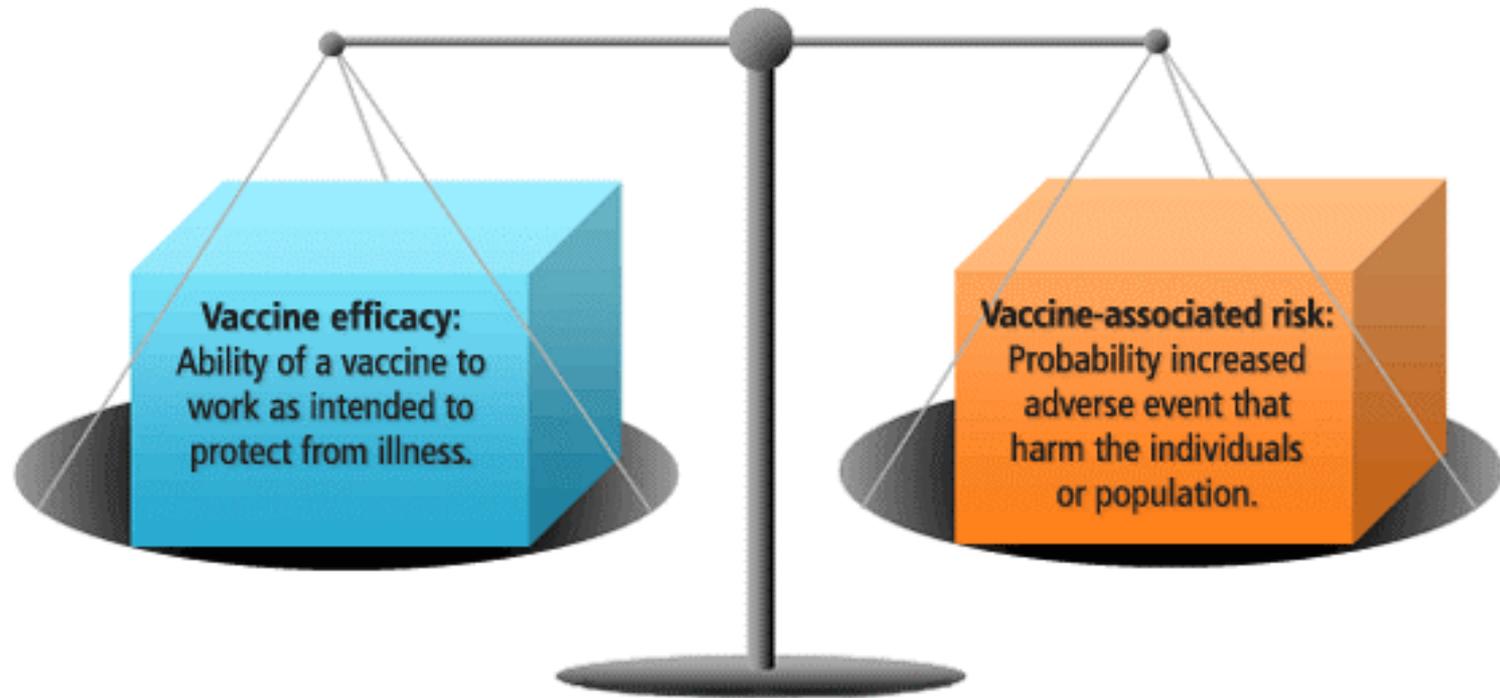
- ▶ Benefits of HPV vaccination far outweigh any potential risks
- ▶ Safety studies findings for HPV vaccination similar to safety reviews of MCV4 and Tdap vaccination

▶ 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



HPV VACCINE SAFETY

The Journey of Your Child's Vaccine

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).

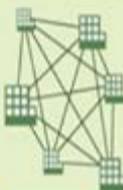


Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

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).

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

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

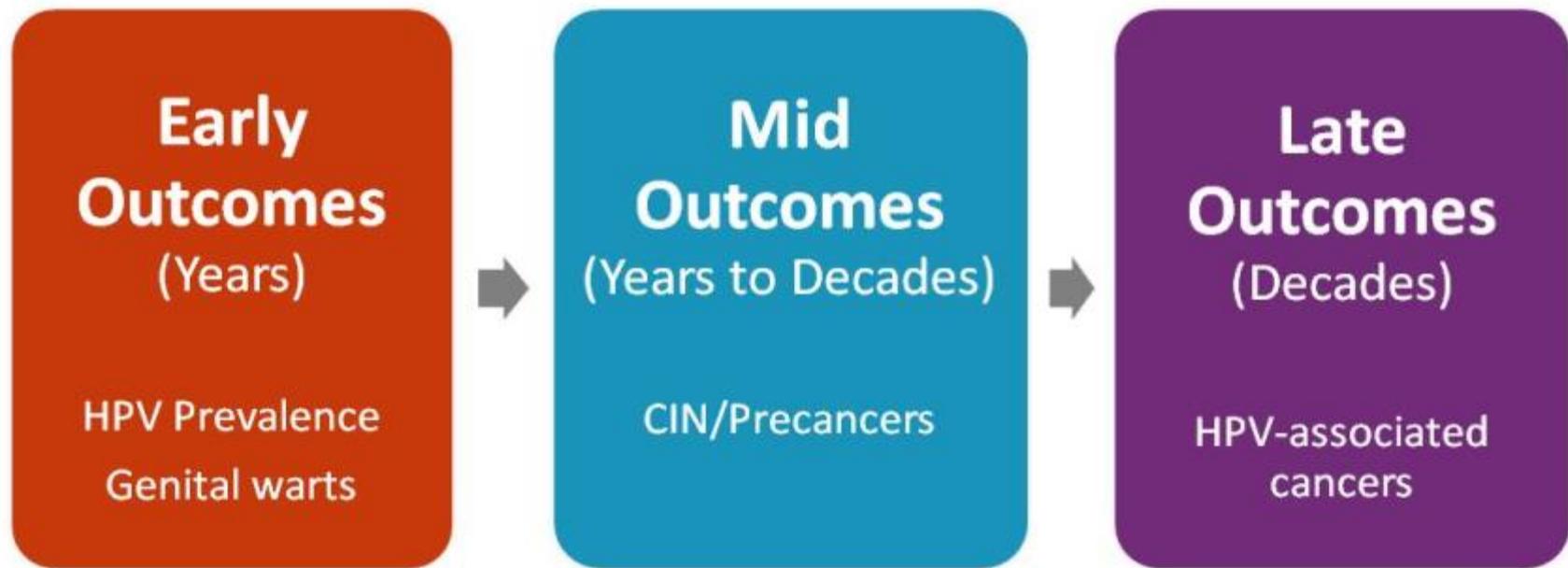
³Klein NP, et al.. Arch Pediatr Adolesc Med. 2012 Dec; 166(12):1140-8.

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

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



Monitoring Impact of HPV Vaccine Programs on HPV-Associated Outcomes

HPV VACCINE IMPACT

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

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%***



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

HPV Vaccine Three-Dose Coverage

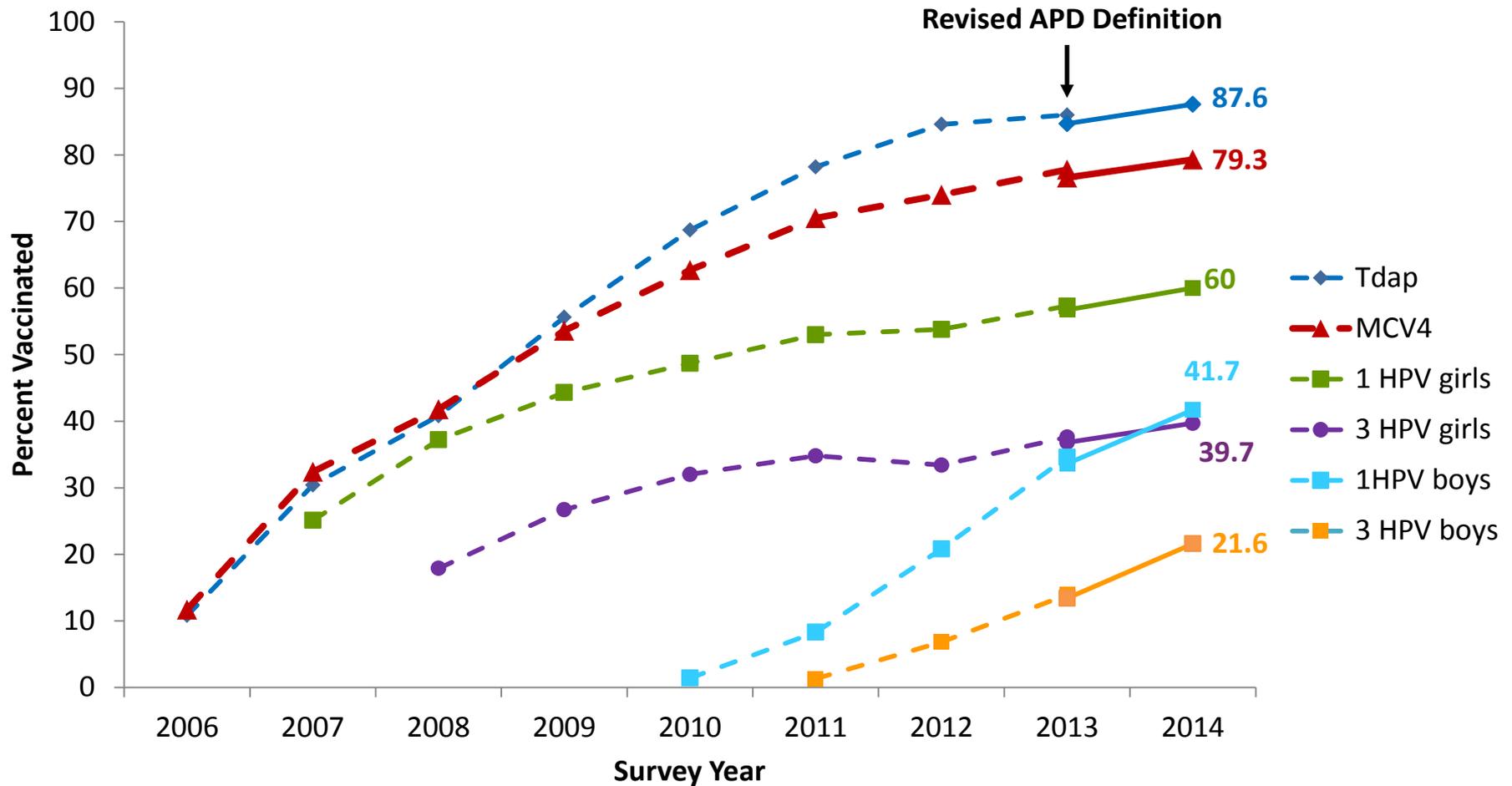


Among Girls in High-Income Countries

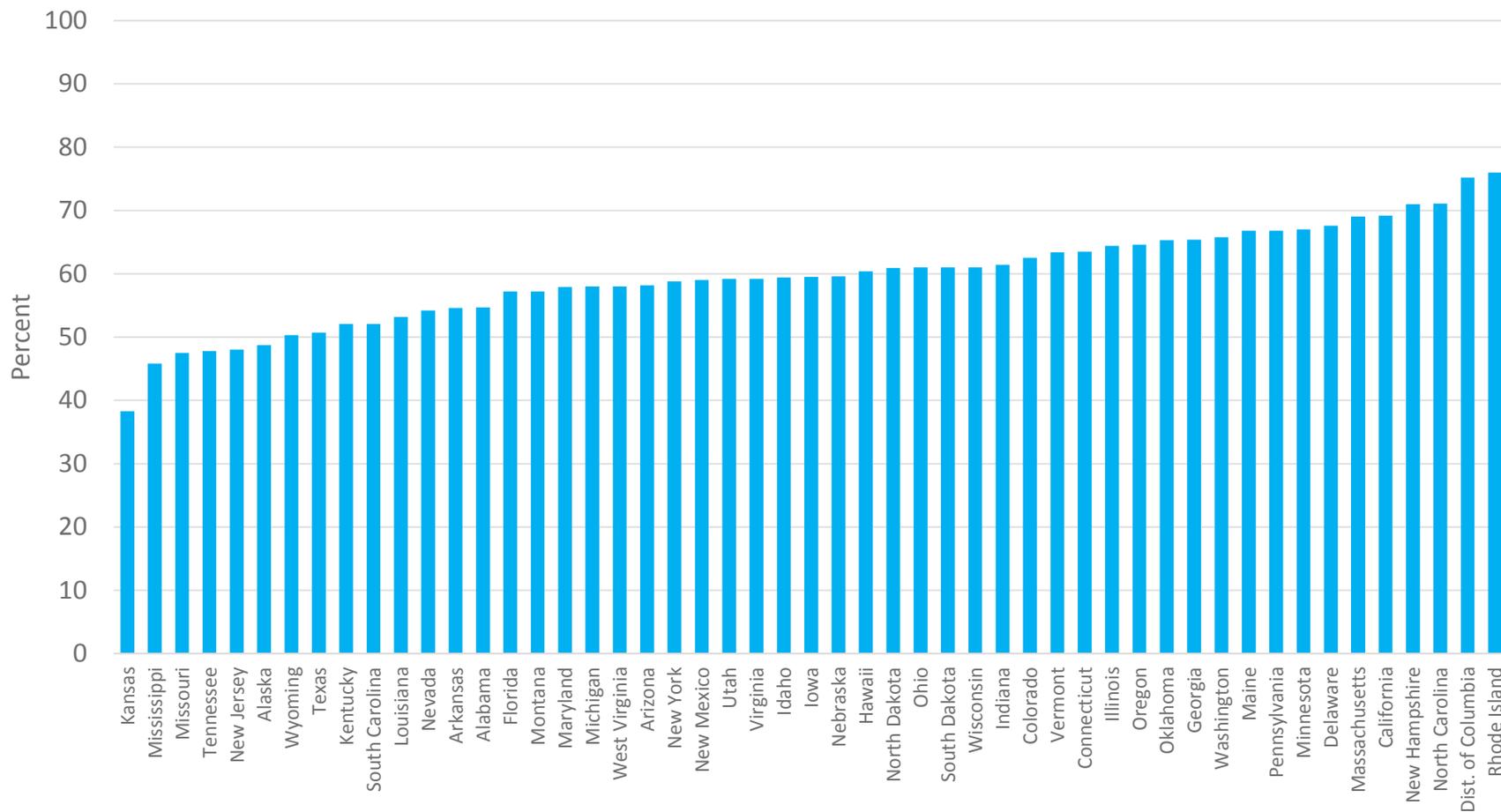
United States

HPV VACCINE COVERAGE

Adolescent Vaccination Coverage United States, 2006-2014



HPV Vaccine Series Initiation among Girls Aged 13-17 years, by State, NIS-Teen, 2014



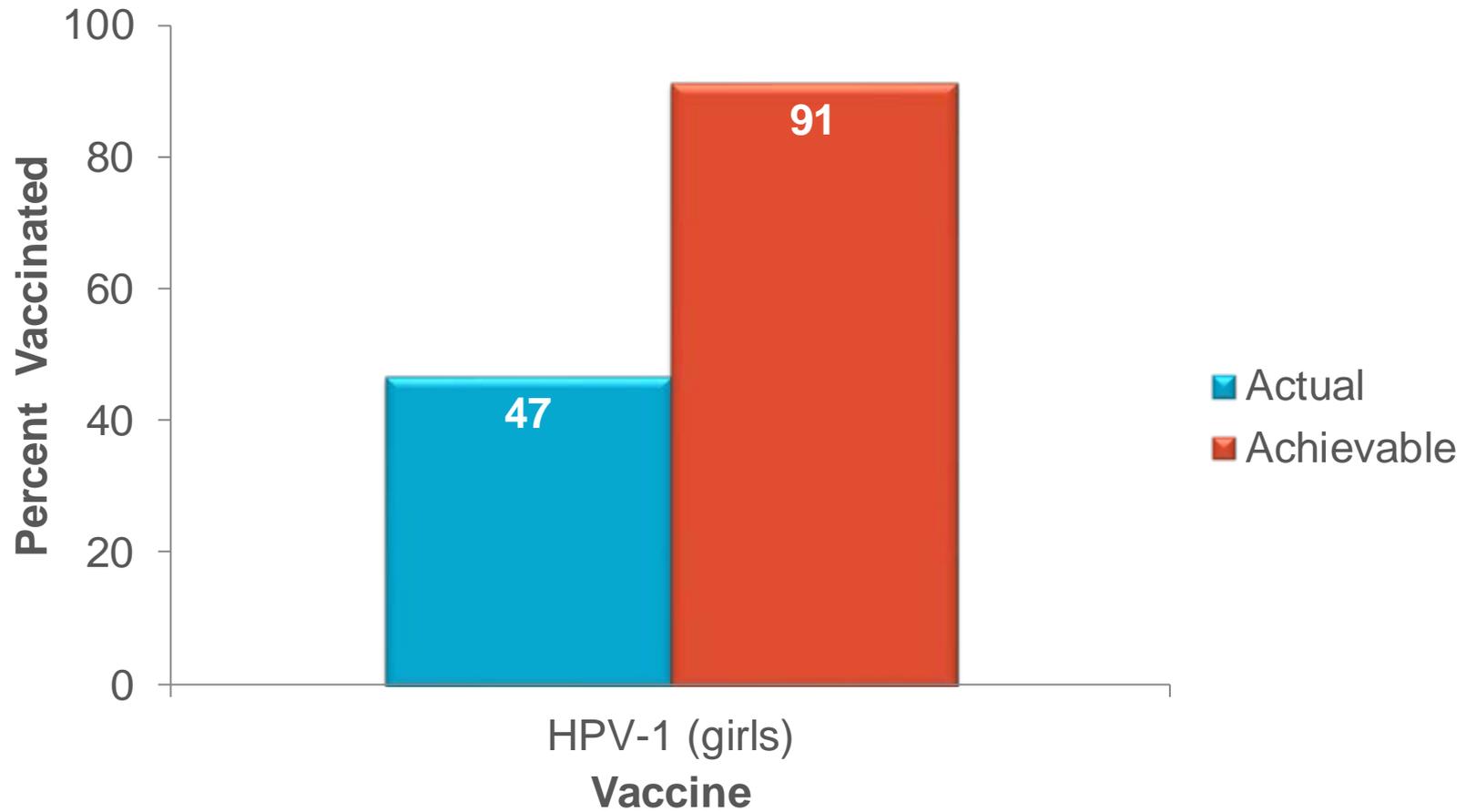
Abbreviations: HPV = Human papillomavirus; NIS-Teen = National Immunization Survey-Teen

HPV vaccine series initiation: receipt of ≥ 1 HPV vaccine dose

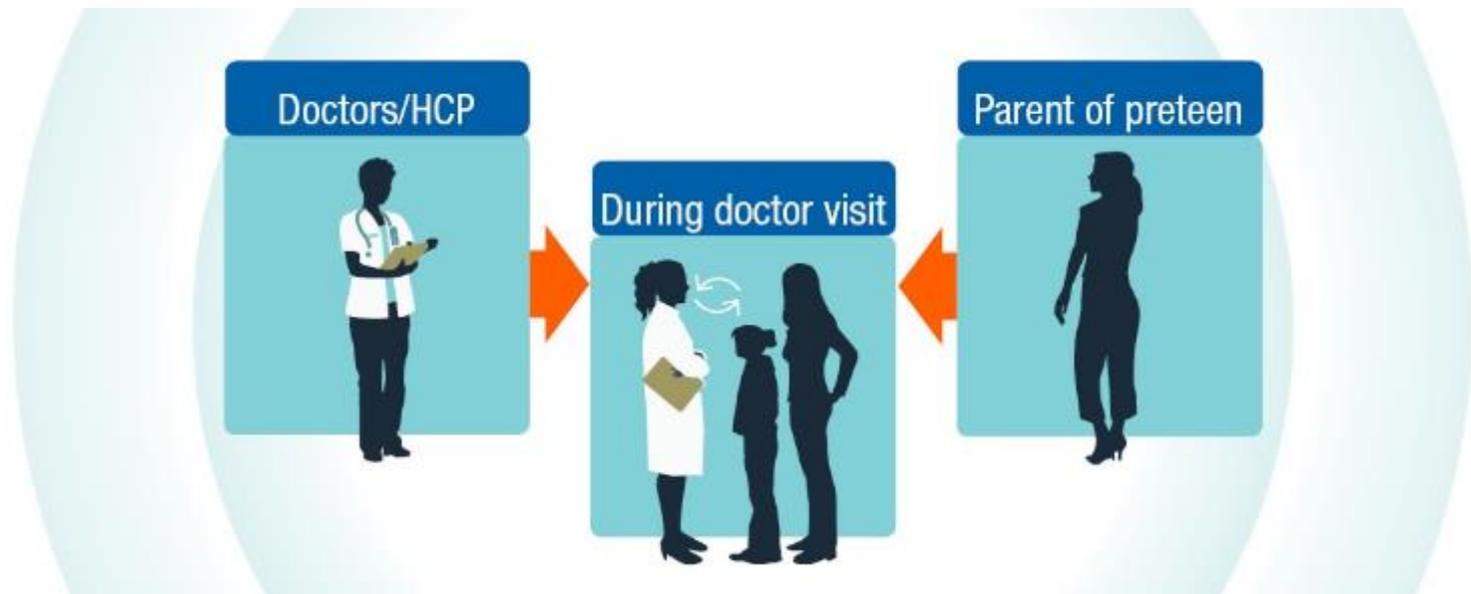
Source: MMWR 64(29);784-792



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



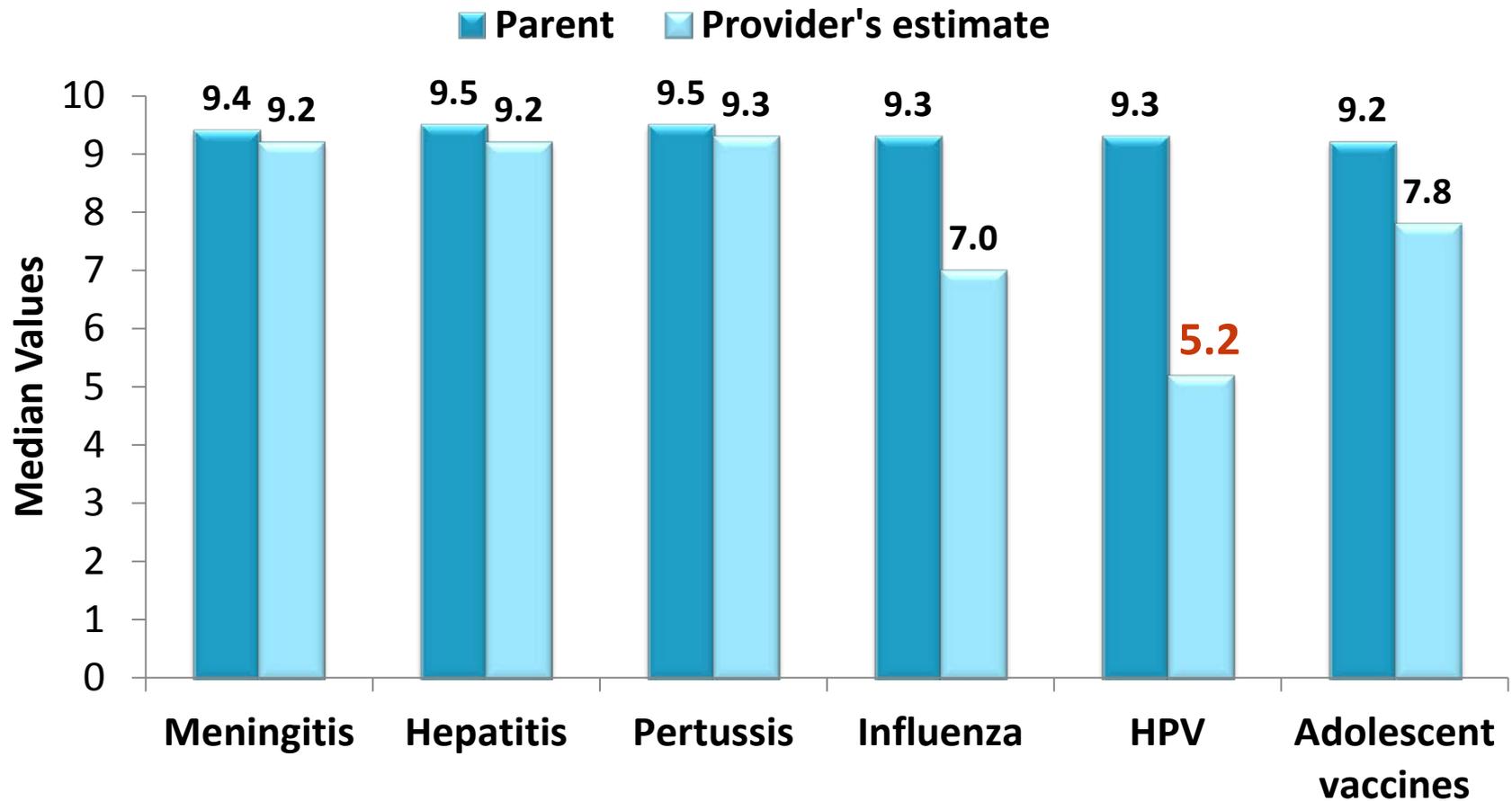
Missed opportunity: Healthcare encounter when some, but not all ACIP-recommended vaccines are given. HPV-1: Receipt of at least one dose of HPV. MMWR. 63(29);620-624.



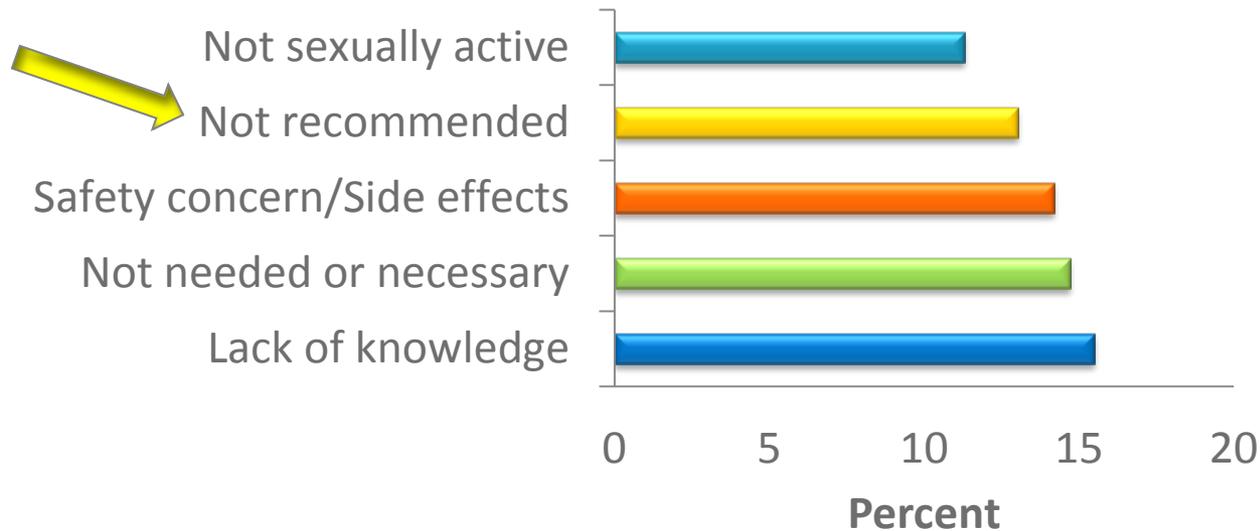
Talking about HPV vaccine

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

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.

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.

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> |

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)

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

Human Papillomavirus (HPV)



For Parents and Public



HPV is a very common virus; nearly 80 million people—about one in four—are currently infected in the United States. Learn how you can protect the children in your family from this cancer-causing virus.

- [What is HPV](#)
- [HPV and Cancer](#)
- [HPV Cancer Screening](#)
- [HPV Vaccine](#)

For Healthcare Professionals



Provided on this site are ready-to-use tools and resources for your practice to successfully communicate with parents about HPV vaccination.

Know the Facts: Continuing education on the burden of HPV cancer.

- [Continuing Education Courses](#)
- [Provider Fact Sheets and Schedules](#)
- [Schedules & Recommendation](#)

For Partners and Programs



CDC encourages partner organizations, state programs, and cancer leaders to promote adolescent vaccinations within their communities by increasing awareness about their importance.

Building a Partnership Strategy: Find information about how to collaborate on adolescent immunization communication campaigns or support your state programs.

www.cdc.gov/hpv/hcp/index.html

The screenshot shows the CDC HPV website for clinicians. On the left is a navigation menu with categories like 'HPV Home', 'For Parents & Public', 'For Clinicians', 'Know the Facts', 'Continuing Education', 'Provider Fact Sheets', 'Schedules & Recommendations', 'HPV Coverage Data', 'Commit to the Cause', 'Tools for Your Office', 'Information for Parents', 'Spanish Resources', 'Lead the Conversation', and 'Resources'. The 'For Clinicians' section is expanded. The main content area features a banner with a stethoscope and the text 'YOU ARE THE KEY TO CANCER PREVENTION'. Below the banner are three sections: 'KNOW THE FACTS', 'COMMIT TO THE CAUSE', and 'LEAD THE CONVERSATION', each with a brief description of the resources available.

CDC > HPV Home

For Clinicians

f t +

HPV YOU ARE THE KEY TO CANCER PREVENTION

KNOW THE FACTS
Get information on the burden of HPV cancers, the importance of HPV vaccination, and how to help parents overcome hesitancy about HPV vaccine.

COMMIT TO THE CAUSE
Find ways to help improve HPV vaccination rates by promoting vaccination in your offices. Get CDC resources to help raise awareness among parents about the importance of HPV vaccine for preventing cancer.

LEAD THE CONVERSATION
Learn how to successfully communicate about HPV vaccine with the parents of your preteen patients, as well as how to become an HPV



Continuing Education

www.cdc.gov/vaccines/ed/hpv/default.htm

Verification Code = **HPVKey**

CE Expires **February 26, 2016**



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

#WeCanStopHPV