

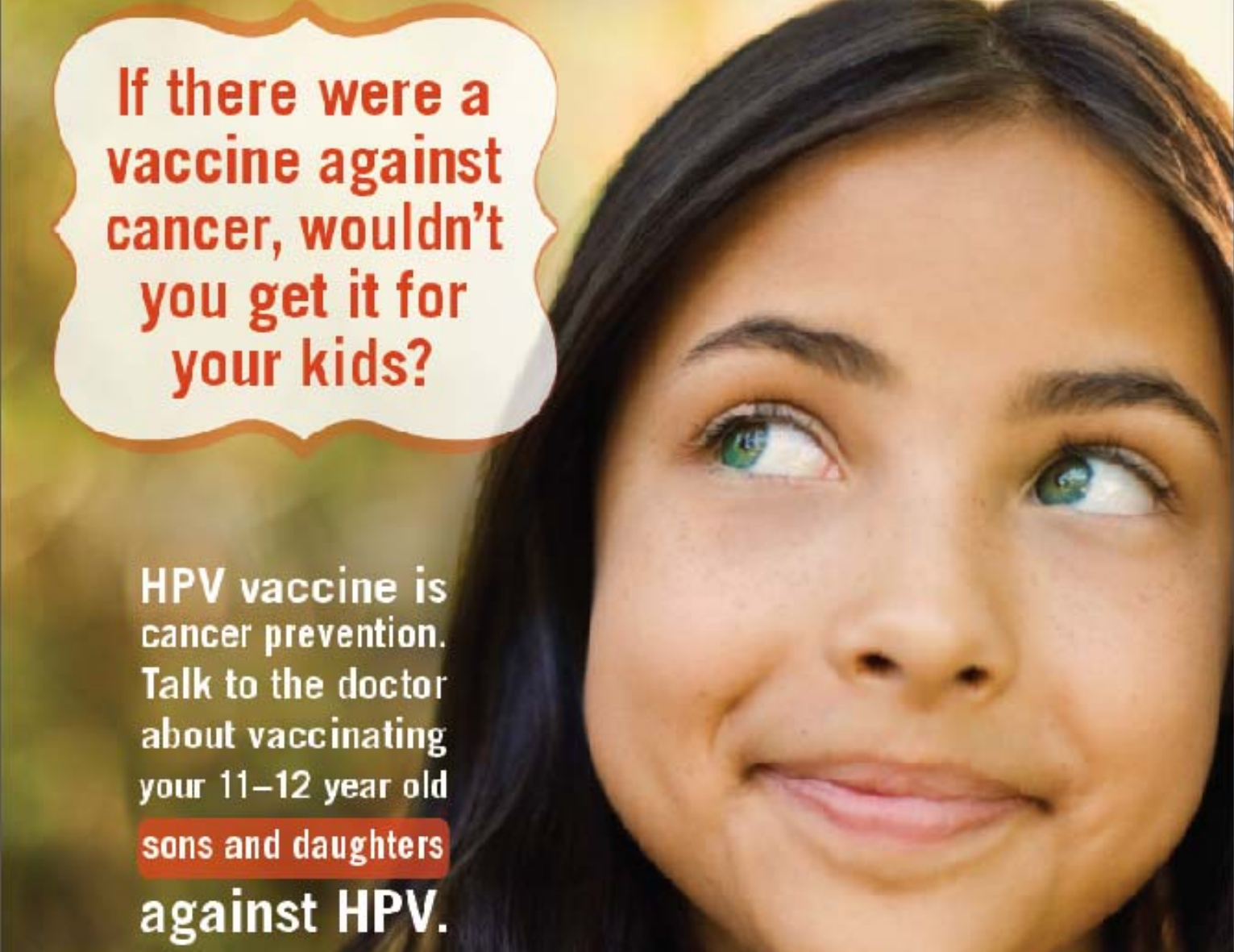
Objectives

1. Describe trends in adolescent immunization coverage in the United States during the period 2006-2014.
2. Identify which groups are currently recommended by ACIP to routinely receive HPV vaccination.
3. Identify at least one strategy which could be implemented in your practice or work setting to improve HPV vaccine coverage.

Disclosure

- No financial interests**
- No discussion of investigational products**

HPV vaccine: why we must and how we can do better



**If there were a
vaccine against
cancer, wouldn't
you get it for
your kids?**

**HPV vaccine is
cancer prevention.
Talk to the doctor
about vaccinating
your 11–12 year old
sons and daughters
against HPV.**

First, the facts.

1. HPV infection is common.

**An estimated 79 million Americans
are currently infected**

**14 million new infections each year
in the United States**

Intercourse not necessary for transmission

2. HPV causes cancer.

U.S. Cancers Attributed to HPV

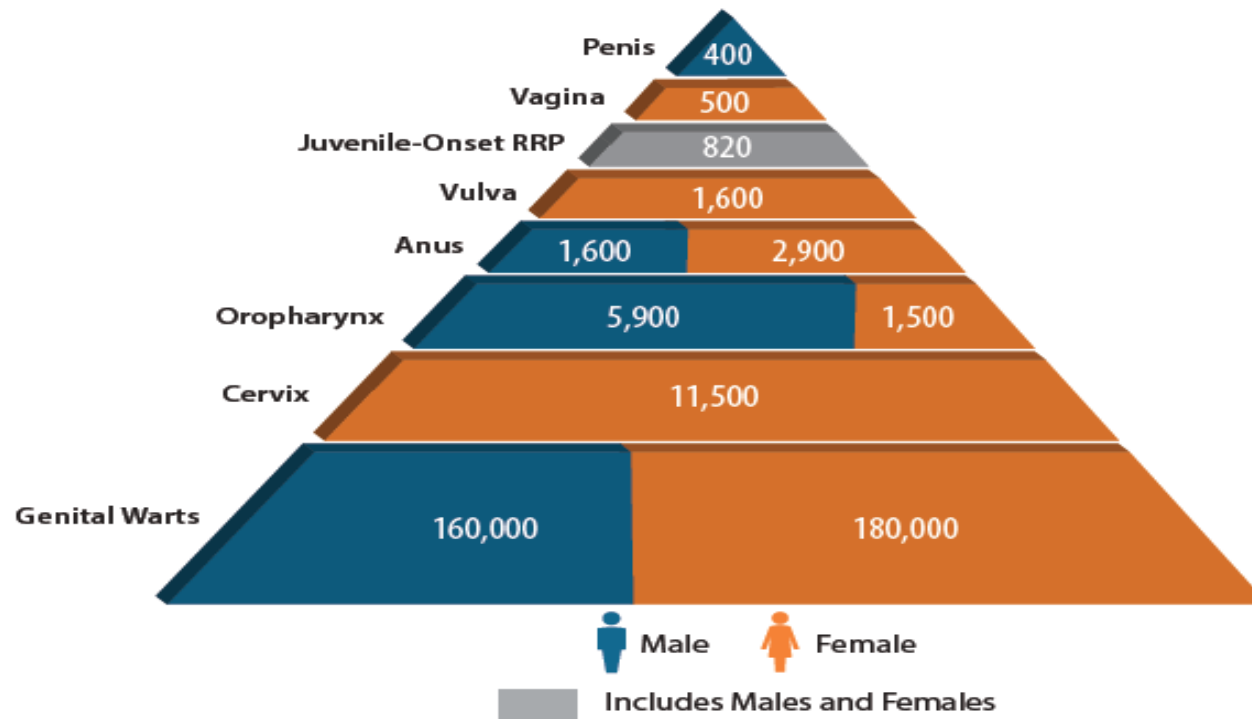
Cancer Site	Average # Cancers Per Year at Site (a)	Percent Probably Caused by HPV (a)	Number Probably Caused by HPV (a)	Percent HPV Cancers Probably Caused by HPV16 or 18 (b)	Number of Cancers Per Year Probably Caused by HPV16 or 18
Anus	4,767	93	4,500	93	4,200
Cervix	11,967	96	11,500	76	8,700
Oropharynx	11,726	63	7,400	95	7,000
Penis	1,046	36	400	87	300
Vagina	729	64	500	88	400
Vulva	3,136	51	1,600	86	1,400
TOTAL	33,371		25,900		22,000

CDC. Human papillomavirus-associated cancers – United States, 2004-2008. MMWR 2012 Apr 20;61(15):258-61

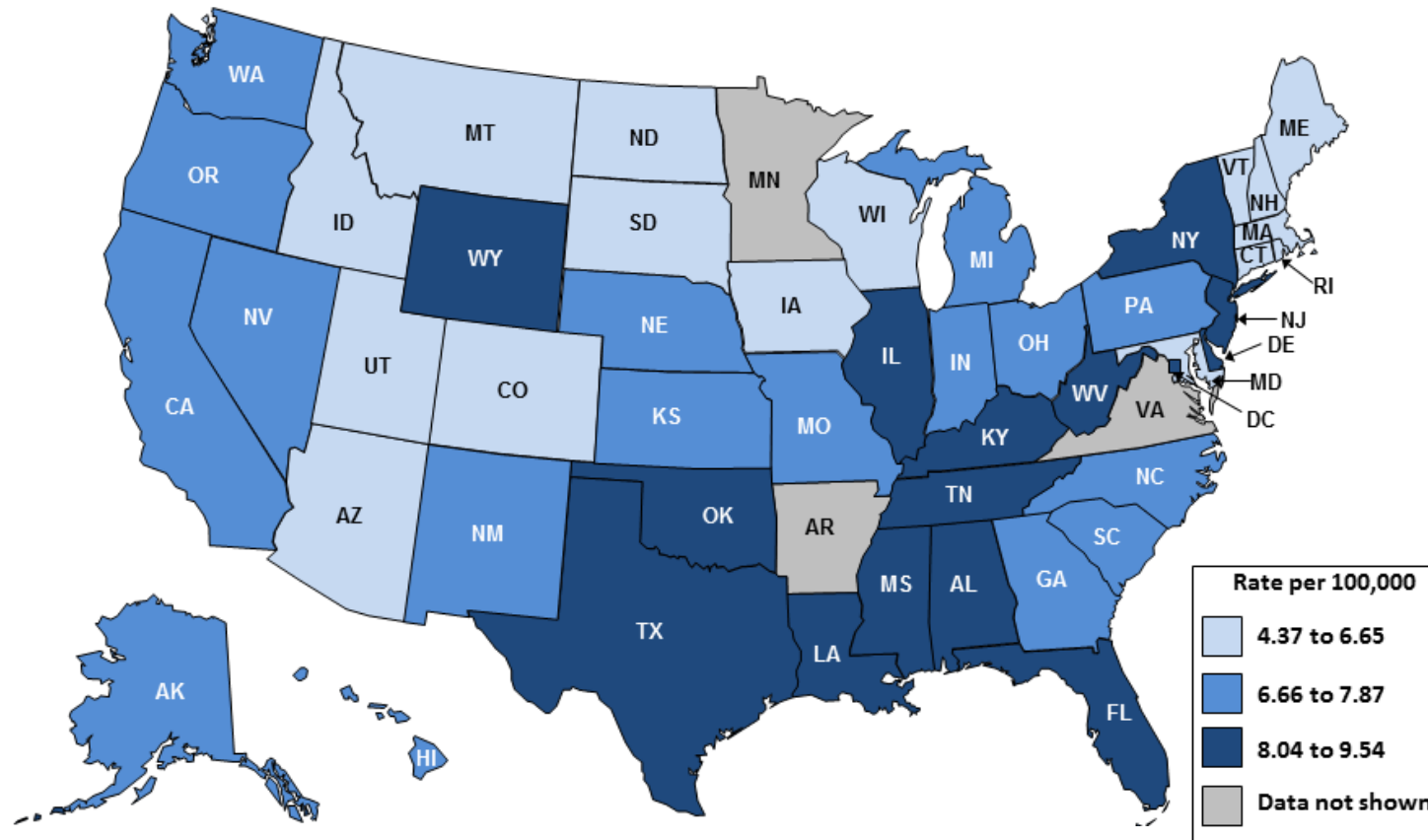
Gillison ML et al. HPV prophylactic vaccines and the potential prevention of noncervical cancers in both men and women. Cancer 2008;113(10 Suppl):3036-46

President's Cancer Panel Annual Report 2012-2013

Numbers of U.S. Cancers and Genital Warts Attributed to HPV Infections

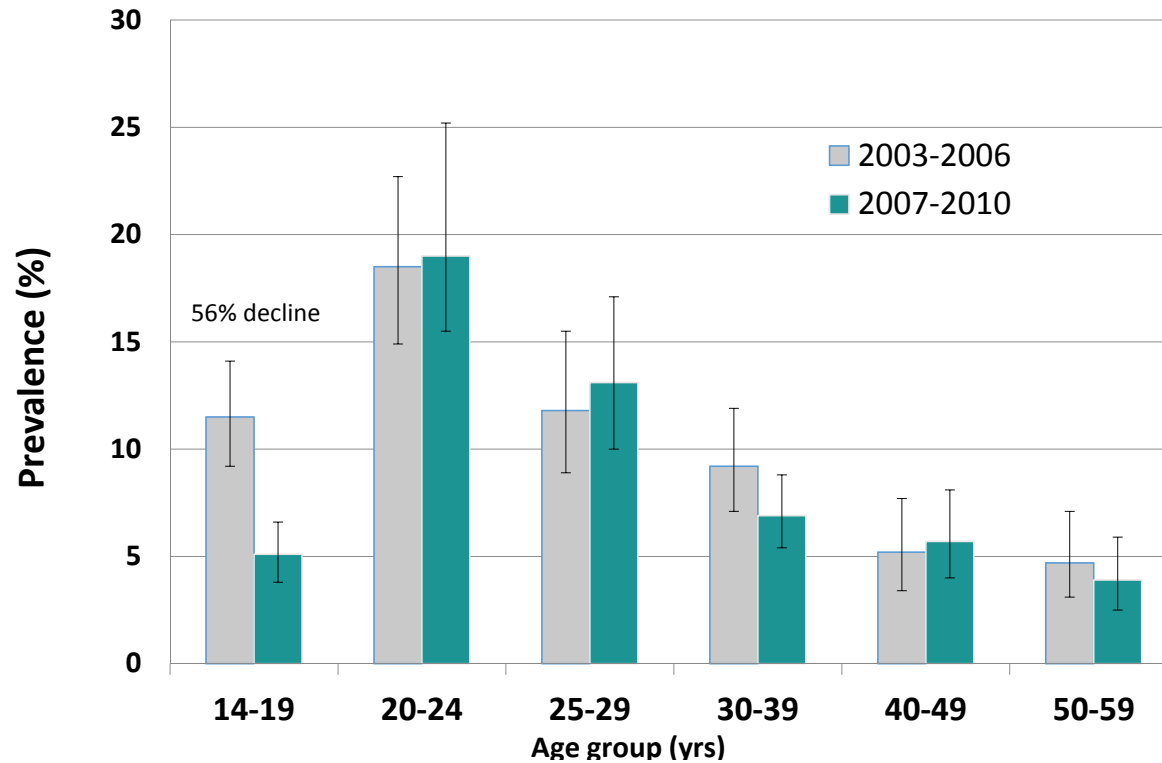


HPV-Associated Cervical Cancer Incidence Rates by State, United States, 2006-2010



3. HPV vaccine is effective.

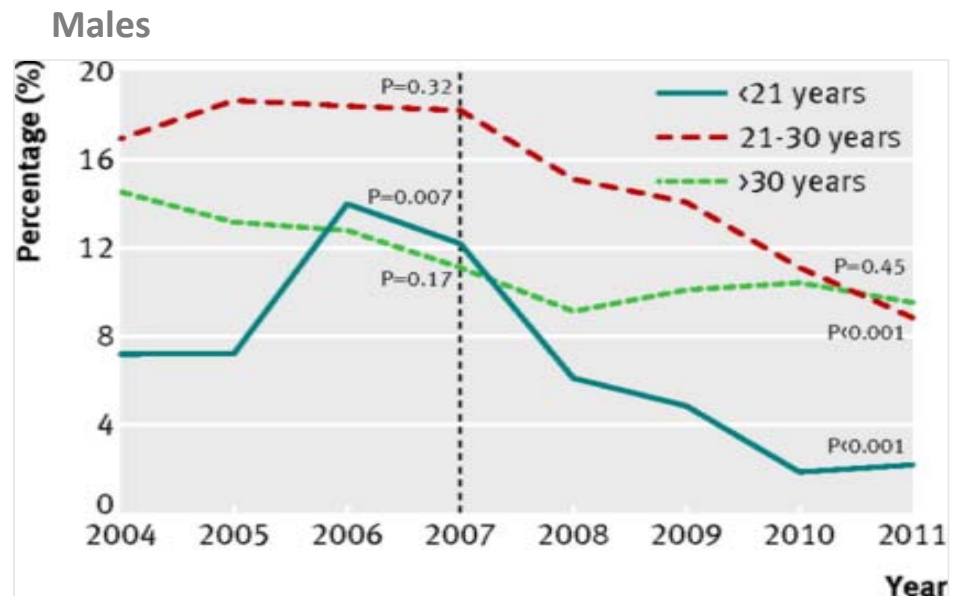
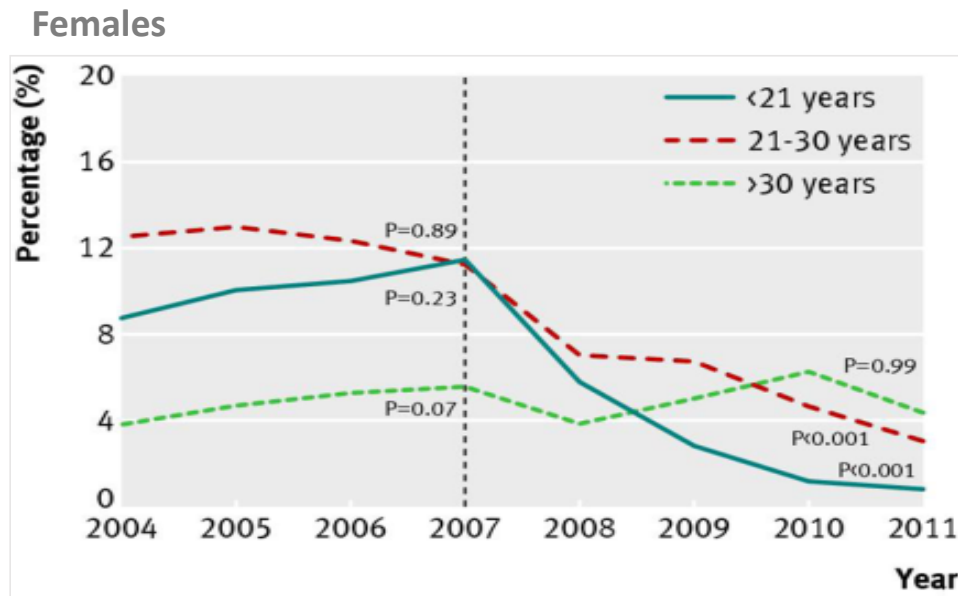
Prevalence of HPV 6, 11,16, 18* in Cervicovaginal Swabs, by Age Group , NHANES, 2003-2006 and 2007-2010



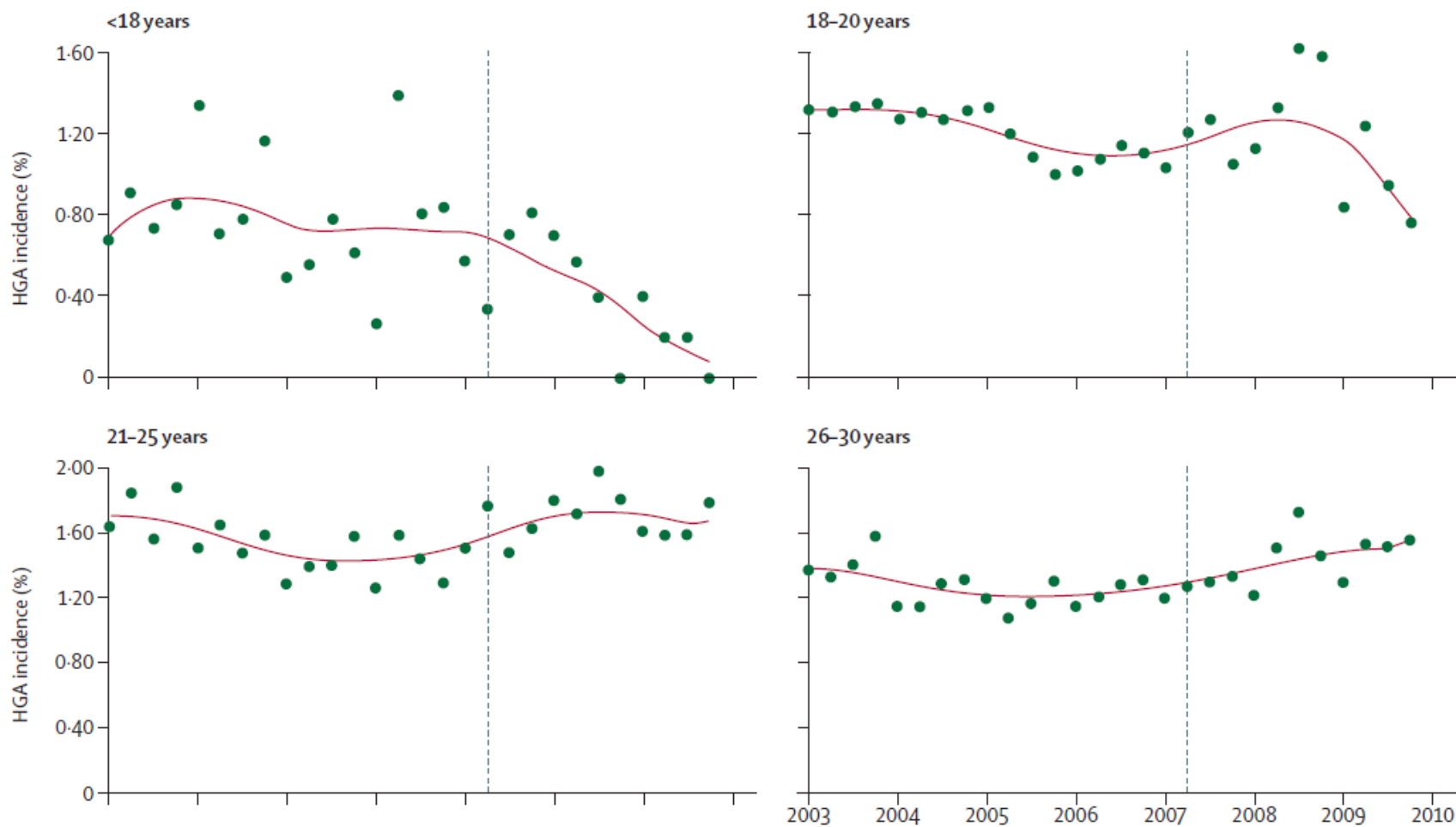
Markowitz, et al. Reduction in human papillomavirus (HPV) prevalence among young women following HPV vaccine introduction in the United States, National Health and Nutrition Examination Surveys, 2003-2010. *J Infect Dis* 2103 *weighted prevalence

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



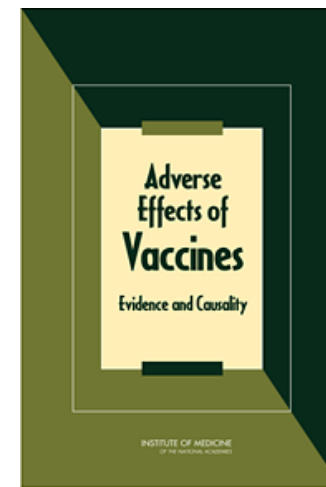
Incidence of high-grade cervical abnormalities, by age group



4. HPV vaccine is safe.

2011 Institute of Medicine (IOM) Report on Adverse Effects of Vaccines

- Syncope
 - IOM concluded that, *“the injection of a vaccine was a contributing cause of syncope.”*
- Anaphylaxis
 - IOM concluded that, *“the evidence favors acceptance of a causal relationship between HPV vaccine and anaphylaxis.”*



Adverse Effects of Vaccines: Evidence and Causality, Institute of Medicine, Aug 2011
<http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx>

Recent Concerns in HPV Vaccine Safety

- ❑ **Primary Ovarian Insufficiency (POI)**
 - Case reports in the media led to public concern
 - No safety findings in VAERS¹
- ❑ **Complex Regional Pain Syndrome (CRPS)**
 - Case reports in Japan of pain following HPV vaccination led to suspension of their HPV vaccine recommendation
 - Review and adjudication of case reports found no evidence for causal association observed between 2vHPV and CRPS²
 - No safety findings in VAERS
- ❑ **Postural Orthostatic Tachycardia Syndrome (POTS)**
 - Concerns in Europe led to European Medicines Agency (EMA) review of POTS (and CRPS) following vaccination³
 - Review did not find evidence to support that HPV vaccine caused POTS or CRPS

¹<http://www.cdc.gov/vaccinesafety/vaccines/hpv/hpv-safety-faqs.html>; ²Huygen et al. Investigating Reports of Complex Regional Pain Syndrome: An Analysis of HPV-16/18-Adjuvanted Vaccine Post-Licensure Data. EBioMedicine. 2015.; ³http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2015/07/WC500189481.pdf



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 November 2015
EMA/714950/2015

Review concludes evidence does not support that HPV vaccines cause CRPS or POTS

Reports of CRPS and POTS after HPV vaccination are consistent with what would be expected in this age group

HPV Vaccines Are Safe For Your Child

09/09/2015 CS256663B

HPV vaccines are very safe. CDC has carefully studied the risks of HPV vaccination. The benefits of HPV vaccination, such as prevention of cancer, far outweigh the risks of possible side effects.

HPV vaccines are safe and recommended for girls and boys at age 11 or 12

Human papillomavirus (HPV) is a common virus that can cause cancer in men and women. HPV can cause cancer of the cervix, vagina, and vulva in women and cancer of the penis, anus, and throat in men.

Like any vaccine or medicine, HPV vaccines can cause side effects

Some people have mild side effects after getting the HPV vaccine. Common side effects include:

- Pain, swelling, or redness in the arm where the shot was given.
- Fever

HPV Vaccine is Safe – (Gardasil)

09/09/2015 CS256663A

What are HPV Vaccines?

HPV vaccines protect against certain cancers caused by human papillomavirus (HPV) infection. HPV infection can cause cervical, vaginal, and vulvar cancers in women and penile cancer in men. HPV can also cause anal cancer, throat (oropharyngeal) cancer, and genital warts in both men and women. There are currently three HPV vaccines available for use in the United States. This fact sheet summarizes what we know about the safety of Gardasil, one of the available HPV vaccines.

Understanding HPV Vaccine Safety Studies and Monitoring

It is important to understand the following when reading about HPV vaccine safety studies:

Anyone can report side effects and adverse events.

CDC and FDA maintain a vaccine safety monitoring system called the [Vaccine Adverse Event Reporting System \(VAERS\)](#). VAERS accepts reports from anyone, including doctors, patients, and parents. While VAERS provides useful information on

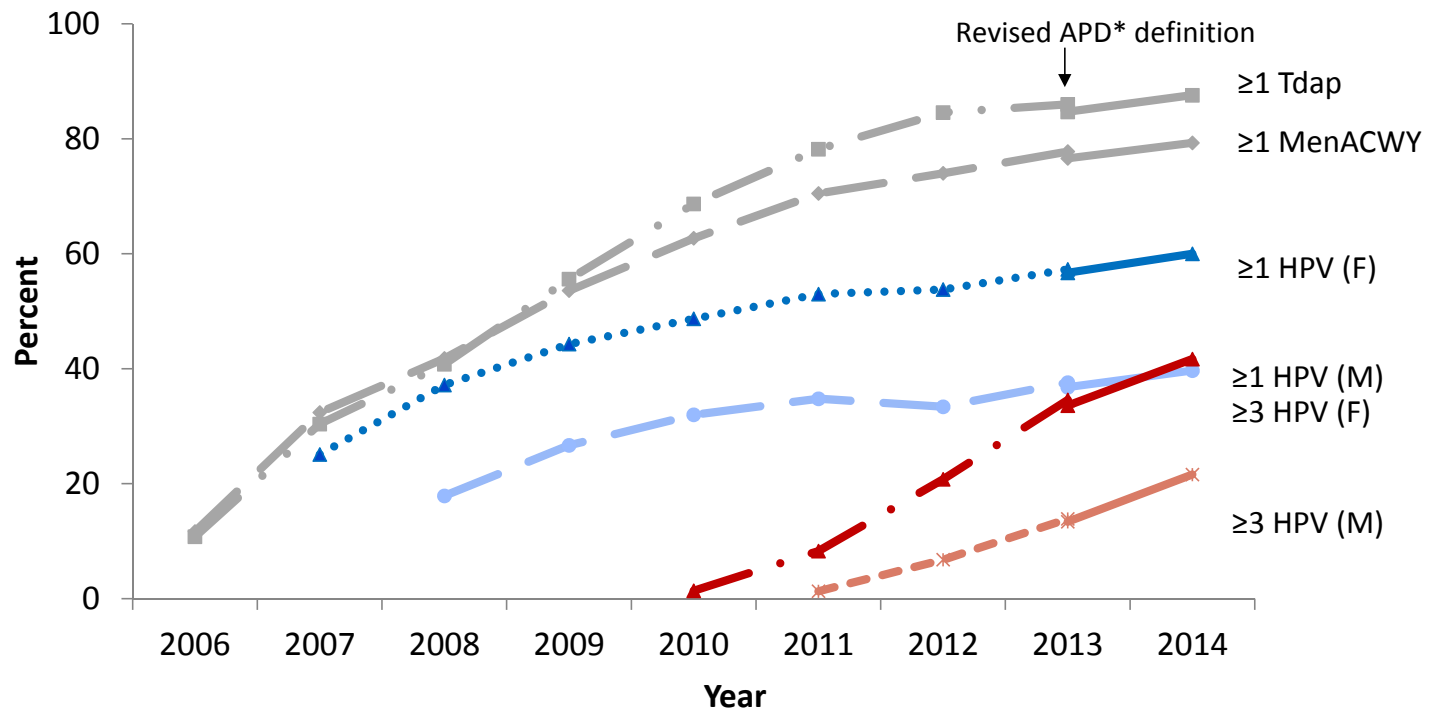
<http://www.cdc.gov/hpv/hcp/provide-parents.html>

“...allegations of harm from vaccination based on weak evidence can lead to real harm when, as a result, safe and effective vaccines cease to be used.”

**WHO's Global Advisory Committee on
Vaccine Safety
March 12, 2014**

5. More young people need to get HPV vaccine to protect them from cancer.

Estimated HPV Vaccination Coverage among Adolescents Aged 13-17 Years, NIS-Teen, United States, 2006-2014



MMWR 64(29);784-792 * APD = Adequate provider data

26 million:

number of girls under 13 years of age in the United States

168,400:

number who will develop cervical cancer if none are vaccinated

54,100:

number will die from cervical cancer if none are vaccinated

For each year we stay at 30% coverage instead of achieving 80%,

4,400:

number of future cervical cancer cases we will not prevent

1,400:

number of cervical cancer deaths we will not prevent

6. Health care providers should recommend HPV vaccine the same way they do other preteen vaccines.

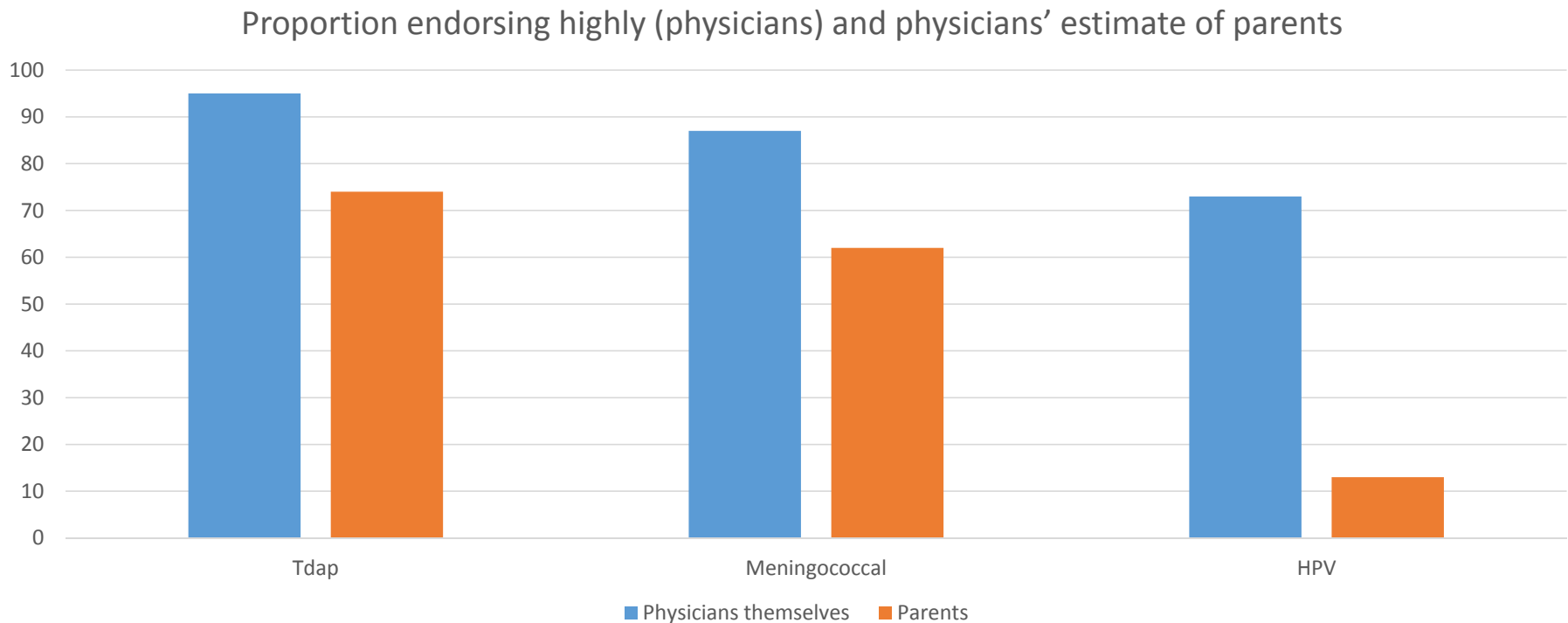
Reasons for Not Vaccinating Adolescents with HPV Vaccine, Unvaccinated Adolescents* Aged 13-17 Years, NIS-Teen, United States, 2014

Parents of Girls		Parents of Boys	
	% (95% CI)		% (95% CI)
Not needed/necessary	18.3 (15.8-21.1)	Not needed/necessary	18.9 (16.8-21.1)
Safety concerns/ side effects	16.2 (13.6-19.2)	Not recommended	18.0 (16.0-20.3)
Lack of knowledge	12.9 (9.9-16.7)	Lack of knowledge	13.7 (11.8-15.8)
Not recommended	9.8 (7.9-12.0)	Not sexually active	9.9 (8.2-12.0)
Not sexually active	8.8 (7.0-11.0)	Safety concerns/ side effects	7.3 (5.6-9.4)

* Analysis limited to adolescents with zero HPV vaccine doses, whose parents reported that they were not likely to seek HPV vaccination for their adolescent in the next 12 months

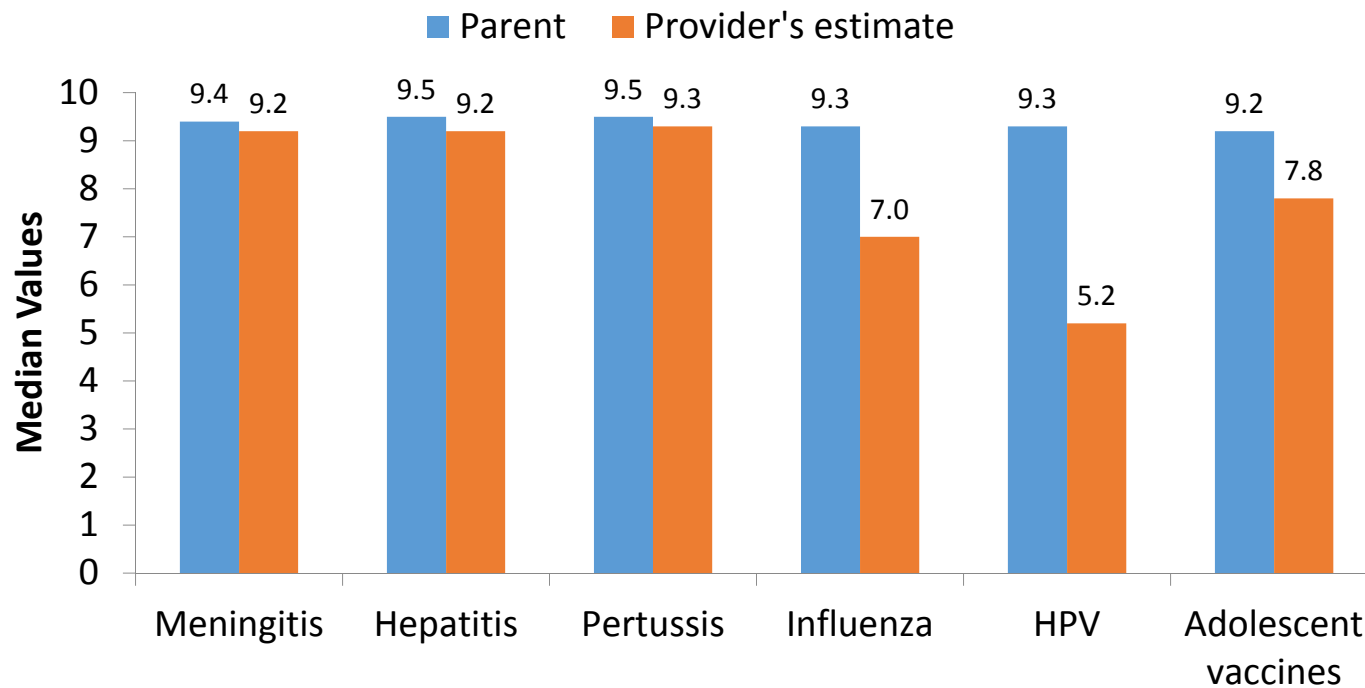
Unpublished NIS-Teen 2014 data

Physicians' Perceptions of Adolescent Vaccine Endorsement for Patients Ages 11-12, 2014



Gilkey MB et al, Preventive Medicine 2015;77:181-185

Parent opinions on the importance of vaccines and provider estimates of parental responses



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

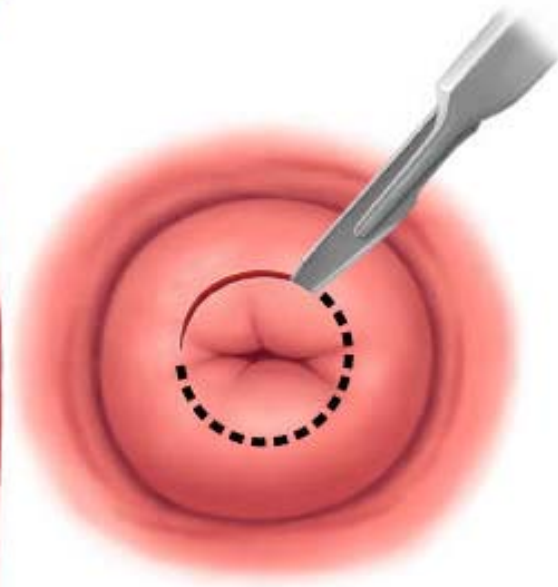
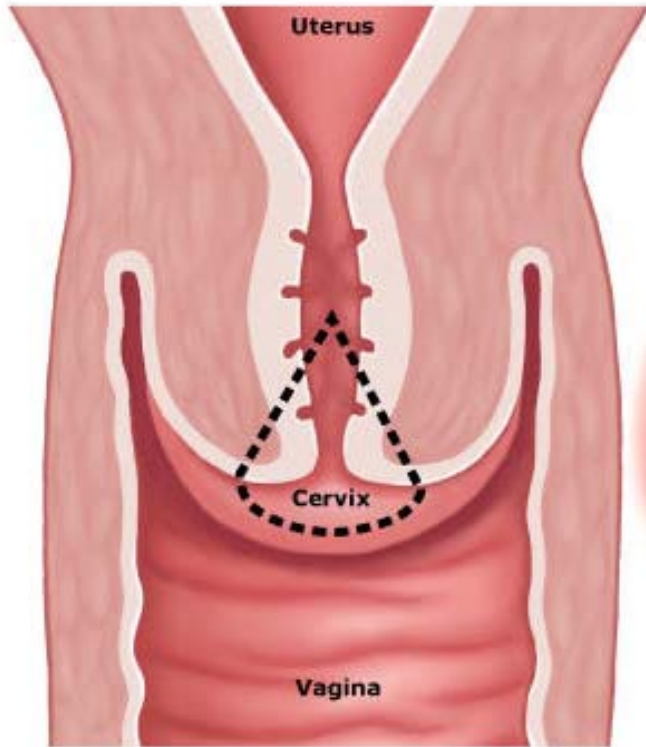
“optional”

“new vaccine”

“not at risk”

“you can wait”

**7. Preventing cancer is better than
treating it.**



8. HPV vaccine will save lives.

26 million:

number of girls under 13 years of age in the United States

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For each year we stay at 30% coverage instead of achieving 80%,

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What's the problem?

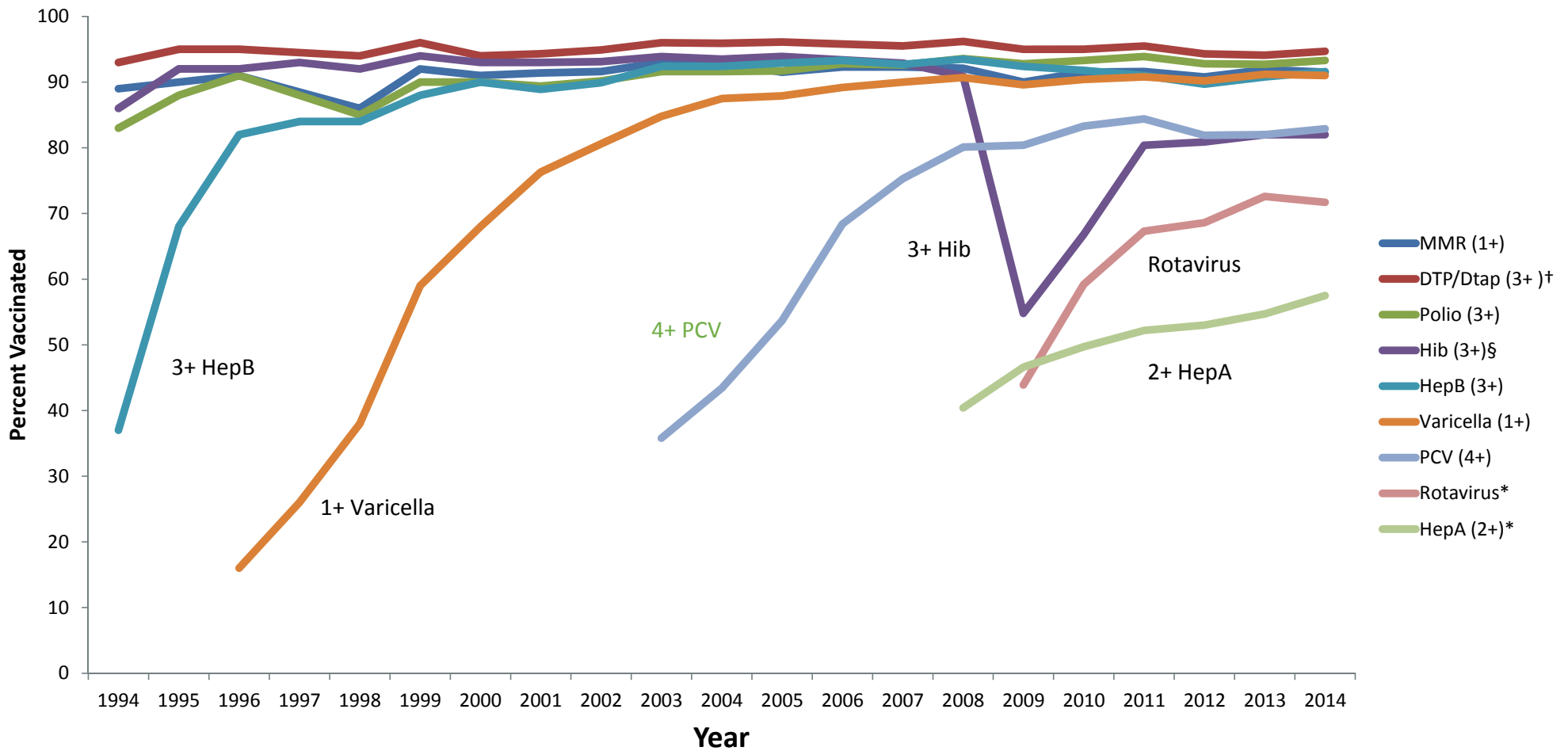
ACIP Recommendations

- ❑ 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 who have sex with men and immunocompromised men (including persons HIV-infected) through age 26
- ❑ Vaccination of females is recommended with 2vHPV, 4vHPV (as long as this formulation is available), or 9vHPV
- ❑ Vaccination of males is recommended with 4vHPV (as long as this formulation is available) or 9vHPV

*vaccination series can be started at 9 years of age

[MMWR 2015;64:300-4](#)

Vaccine Coverage among Children 19-35 Months, National Immunization Survey, United States, 1994-2014

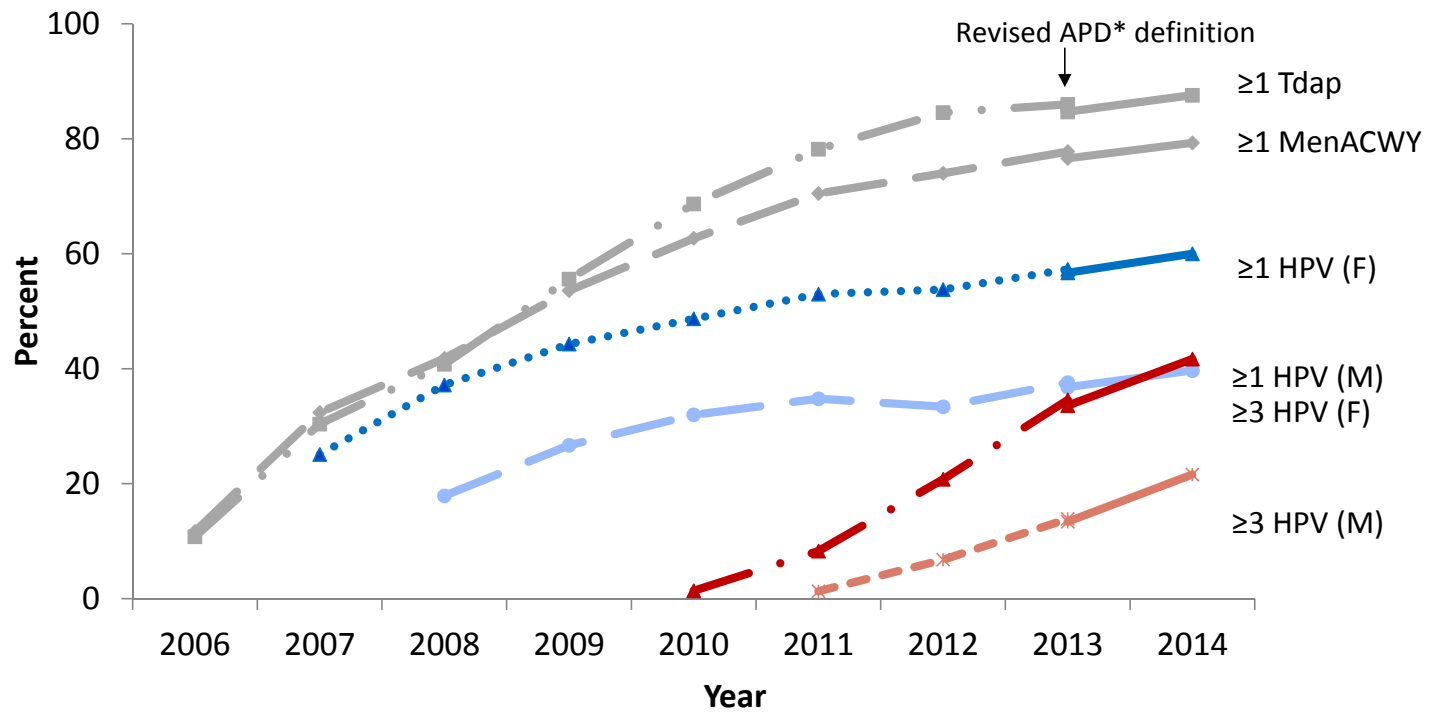


**Provider motivation
and skill**

Parental acceptance

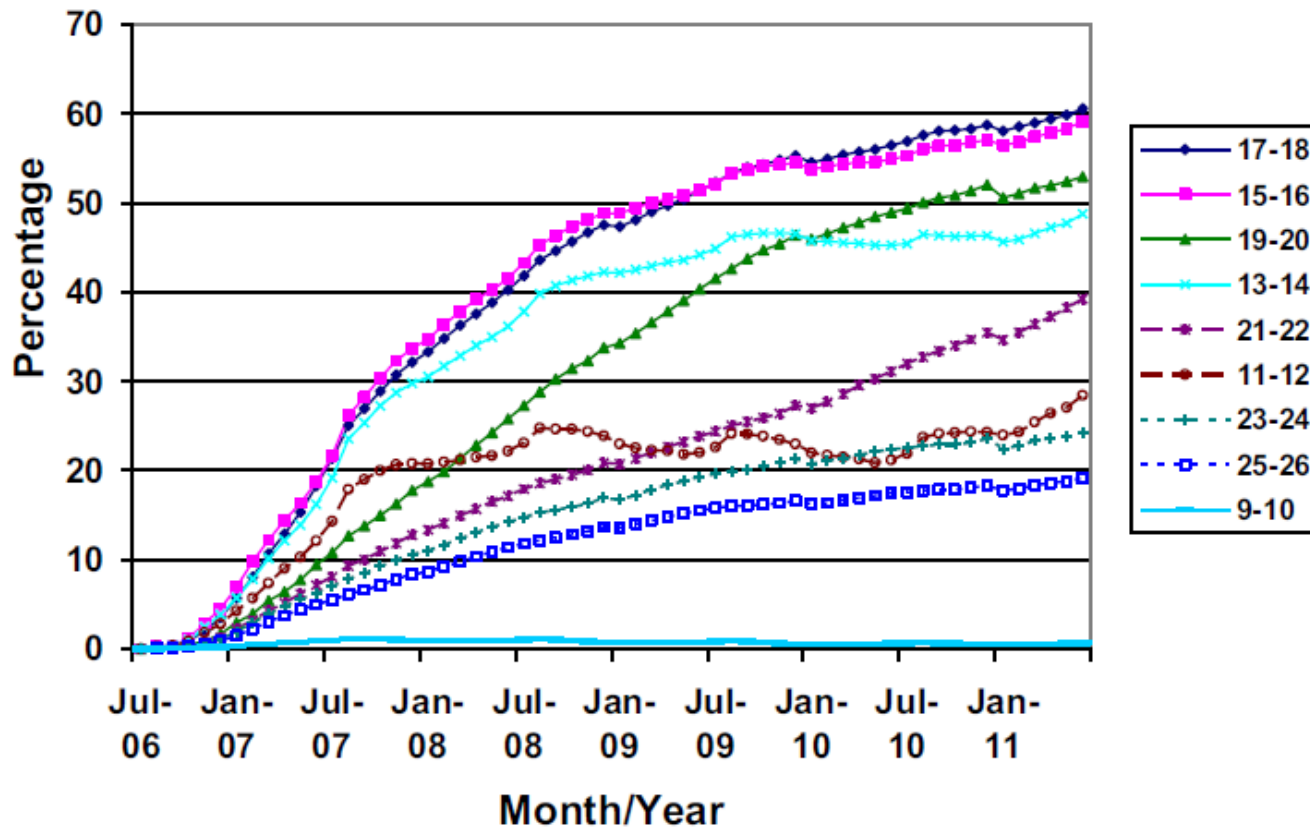
Systems support

Estimated HPV Vaccination Coverage among Adolescents Aged 13-17 Years, NIS-Teen, United States, 2006-2014



MMWR 64(29);784-792 * APD = Adequate provider data

HPV Vaccine One Dose Coverage among Females by Age Vaccine Safety Datalink



Schmidt MA et al., J Adolesc Health 2013;53:637-641

**Lack of provider
motivation
and skill**

**Lack of
parental acceptance**

Barriers

Why Is HPV Vaccine Coverage So Low?

Parents

- Parents are not offered vaccination
- Parents perceive vaccine as optional or unnecessary at that time
- Parents perceive that their providers discouraged vaccination
- Parents want information about vaccine safety
- Parents do not understand the reason to vaccinate at 11 to 12 years of age

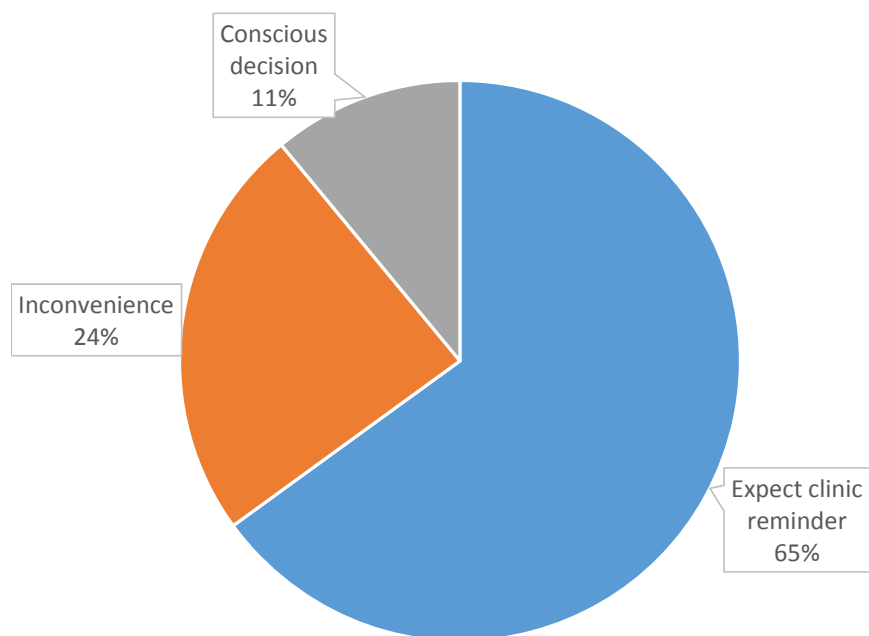
Providers

- Providers are reluctant to give multiple shots at one visit
- Providers introduce HPV vaccination at age 11 years but do not recommend it strongly
- Providers recommend vaccination based on their estimation of sexual activity
- Providers have limited experience with HPV and underestimate risk
- Providers perceive HPV as more emotionally charged than other vaccines
- Delaying vaccination leads to nonvaccination

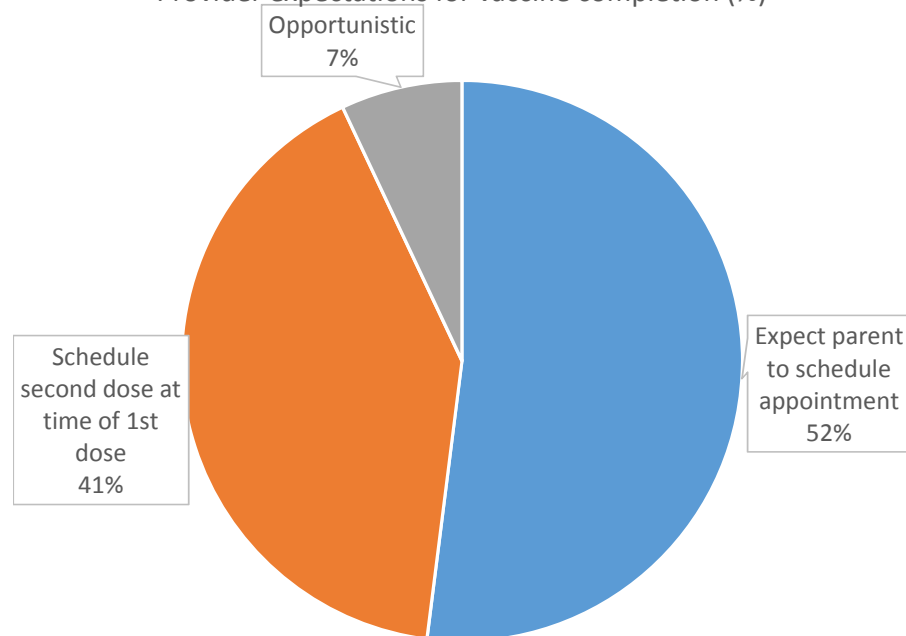
Both providers and parents know they are often unaware of the timing of sexual debut.

Why don't adolescents finish the HPV vaccine series?

Reasons given by parents for incomplete vaccination (%)



Provider expectations for vaccine completion (%)



What can we do about it?

Changing Clinical Practice

- Evidence-based practice standards, guidelines, or recommendations
- Clinical and staff knowledge and skill
- Professional norms and peer influence
- External pressure, incentives, and expectations for improvement
- Patient acceptance
- Evidence of deviations from recommended practices that are accepted by providers as valid and accurate
- Understanding of the etiology of deviations (causes/influences, barriers, facilitators)
- Feasible operational methods

States and Local Areas with Increases* in HPV Vaccination Coverage among Females Aged 13–17 Years, NIS-Teen, 2014

	≥ 1 HPV Dose		≥ 3 HPV Doses	
	Estimate (95% CI)	Percentage point increase	Estimate (95% CI)	Percentage point increase
Dist. of Columbia**	75.2(±9.4)	22.8	56.9(±10.9)†	28.6
Georgia**	--	--	47.1(±9.7)	14.5
Illinois††	64.4(±6.5)	13.2	47.7(±6.9)	15.4
Illinois-Chicago**	78.1(±8.1)	20.5	52.6(±10.7)†	16.1
Montana	57.2(±9.2)	13.8	42.9(±9.1)	16.0
North Carolina	71.1(±8.1)	13.9	54.0(±9.2)	22.3
Utah**	59.2(±8.3)	17.7	--	--

* Statistically significant difference from 2013 (Revised) estimates (p<0.05).

** Received 2013 Prevention and Public Health Fund (PPHF) awards to increase HPV vaccination coverage.

† Estimates with confidence interval (CI) half-widths >10 may not be reliable.

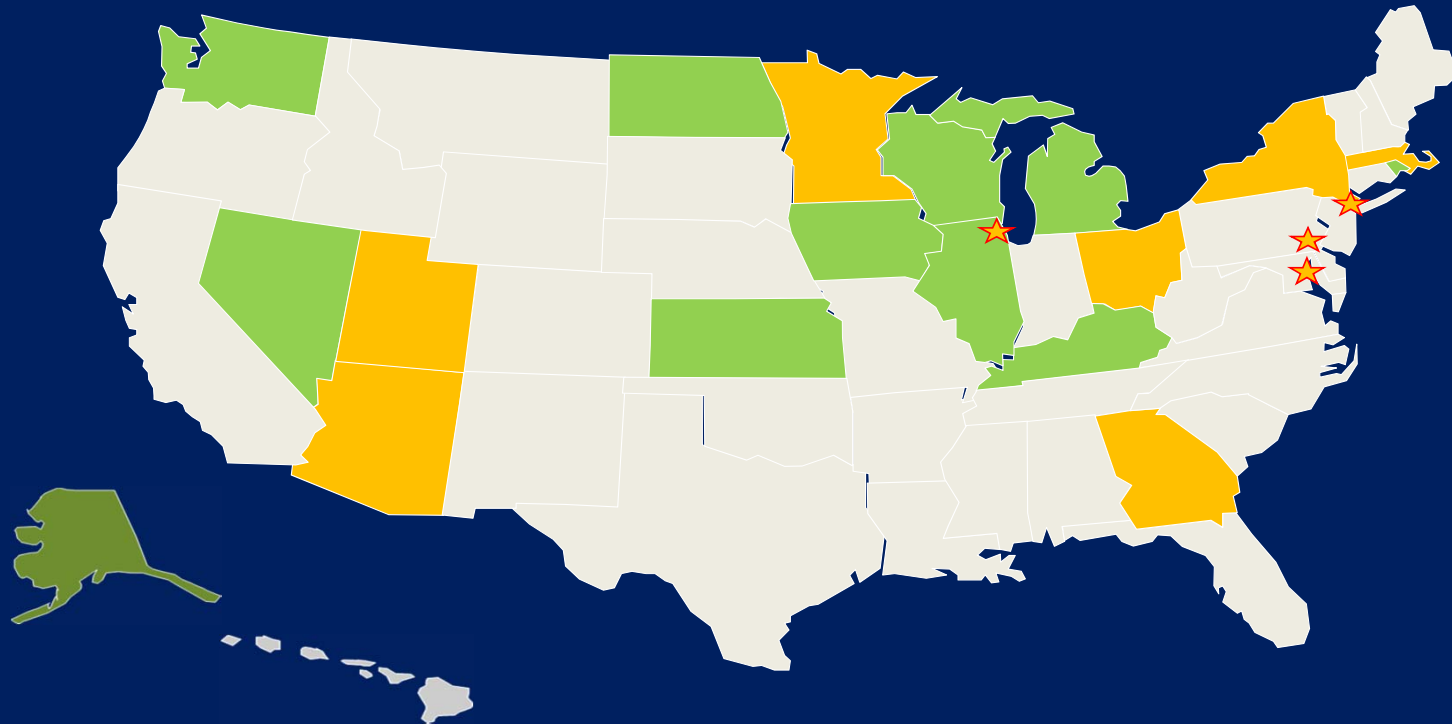
†† Received 2014 PPHF award to increase HPV vaccination coverage.

MMWR 64(29);784–792.

2013/2014 PPHF HPV Immunization Awardees

2014 Awardees

- Washington
- North Dakota
- Michigan
- Wisconsin
- Rhode Island
- Illinois
- Iowa
- Kentucky
- Kansas
- Nevada
- Alaska



2013 Awardees

- Minnesota
- Massachusetts
- New York
- New York City
- Philadelphia
- District of Columbia
- Ohio
- Chicago
- Georgia
- Utah
- Arizona

Abbreviations:

PPHF = Prevention and Public Health Fund;
HPV = Human papillomavirus

2013 and 2014 PPHF HPV Immunization Awardee Activities

- Developing a jurisdiction-wide joint initiative with immunization stakeholders;
- Implementing a comprehensive communication campaign targeted to the public;
- Implementing Immunization Information System (IIS)-based reminder / recall for adolescents aged 11–18 years;
- **Using assessment and feedback to evaluate and improve the performance of immunization providers in administering the 3-dose HPV vaccine series consistent with current ACIP recommendations;**
- Implementing strategies targeted to immunization providers to:
 - Increase knowledge regarding: HPV-related diseases (including cancers), and HPV vaccination safety and effectiveness;
 - Improve skills needed to deliver strong, effective HPV vaccination recommendations;
 - Decrease missed opportunities for timely HPV vaccination and series completion; and
 - Increase administration of HPV vaccine doses consistent with current ACIP recommendations.

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Assessment of the healthcare provider's vaccination coverage levels and immunization practices

Feedback of results to the provider along with recommended quality improvement strategies to improve processes, immunization practices, and coverage levels

Incentives to recognize and reward improved performance

Exchange of information with providers to follow up on their progress towards quality improvement in immunization services and improvement in immunization coverage levels

Changing Clinical Practice

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- Feasible operational methods

What can healthcare providers do?

- Make an effective recommendation for HPV vaccination as cancer prevention for every 11- or 12-year-old patient
- Assess HPV vaccine coverage for each provider in your practice and develop an office-wide strategy to improve it
- Implement systems strategies to improve HPV vaccine coverage
- Engage the entire practice – not just the healthcare providers – in committing to improve HPV vaccine coverage

HPV Vaccination: What Works

Parents

- Parents want to prevent cancer
- Parents trust their provider's recommendation
- Parents think benefits outweigh risks
- Parents want a strong recommendation

Providers

- Providers emphasize cancer prevention
- Providers normalize the HPV vaccine and coadminister with other vaccines
- Providers give a strong recommendation

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

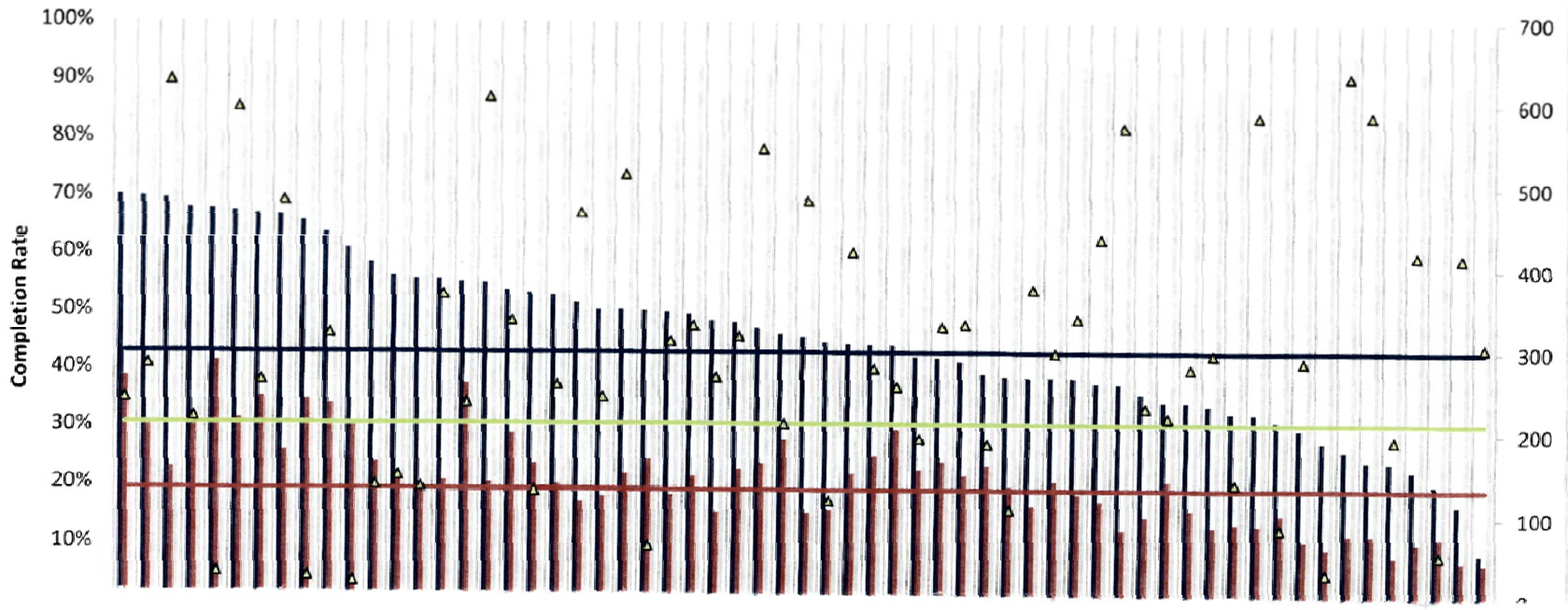
Sophia is due for three vaccines today. These will help protect her from meningitis, HPV cancers, and pertussis. We'll give those shots at the end of the visit.

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Vaccination Series Started and Completed Rates By Provider

Active Pediatric Providers, Patients Ages 13 - 17



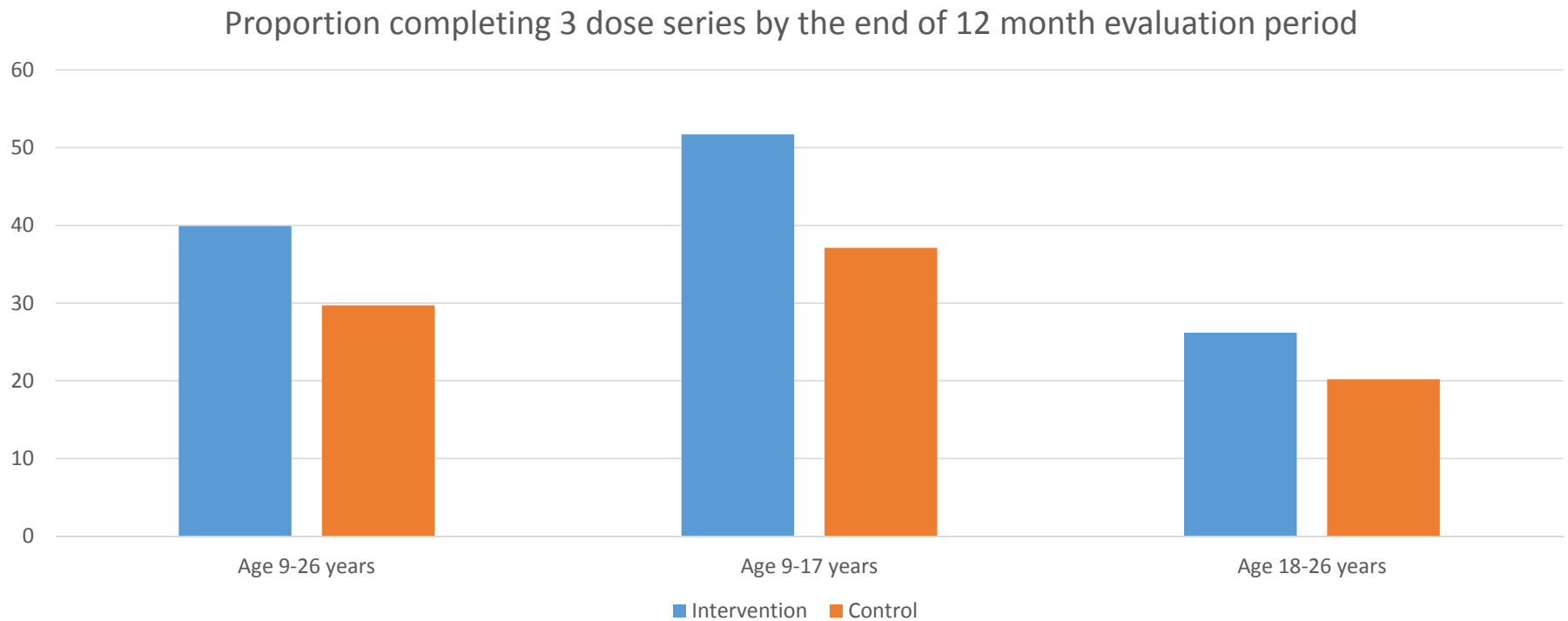
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Systems Strategies to Improve HPV Vaccine Coverage

- Establish standing orders for HPV vaccination beginning at age 11-12 years in your practice
- Conduct reminder/recall beginning at 11-12 years of age
- Assess HPV vaccine coverage at every visit and prompt clinical staff to give HPV vaccine at that visit
- Schedule return visit for next dose before the patient leaves the office
- Document each dose in the child's medical record and the state's immunization information system

Impact of a Mailed Reminder Letter on HPV Series Completion in Girls and Young Women



Chao C et al, Journal of Adolescent Health 2015;56:85-90

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MDH activities

- **HPV PPHF grant**

- Stakeholders
- **Reminder/recall**
- Public awareness
- Provider education
- Assess. & feedback

- **Adolescent PPHF grant**

- Assess. reports

- Evaluation

- Lessons Learned

Statewide reminder postcards

- Households with 11-12 year olds
- Addresses from Minnesota Immunization Information Connection (MIIC) with Westlaw updates

Dear Parent,

At ages 11 or 12, preteens need three vaccines: a Tdap booster against tetanus, diphtheria, and pertussis (whooping cough); a dose of meningococcal vaccine; and three doses of human papillomavirus (HPV) vaccine. If you are concerned about the cost of shots, free or low cost immunizations are available. Talk to your doctor or clinic.

- Looking for immunization records? For copies of your child's vaccination records, talk to your doctor or call the Minnesota Immunization Information Connection (MIIC) at 651-201-5503 or 1-800-657-3970.
- Be ready for school next year. While all three vaccines are recommended for preteens, Tdap and meningococcal vaccinations will be required for all students entering seventh grade in the fall of 2014, unless an exemption applies.
- For more immunization, please call 800-657-3970 or 651-201-5503 or go to www.health.state.mn.us/vax4teens.

Immunization Program
P.O. Box 64975
St. Paul, MN 55164-0975

Presorted
First-Class Mail
U.S. Postage
PAID
Permit No. 171

Missing the party because you're sick!

The **BIG** test!

Lunch with friends

Getting vaccinated

DIFFICULT

EASY

DO SOMETHING EASY TODAY

→ **Get vaccinated.** ←

Teens are at risk for diseases like meningitis, pertussis and HPV. If you're not up to date on vaccines, see your doctor. Getting over being sick is difficult for anyone. Getting vaccinated is easy.

For more information please visit www.health.state.mn.us/vax4teens

Adapted from the Colorado Department of Public Health and Environment

MDH

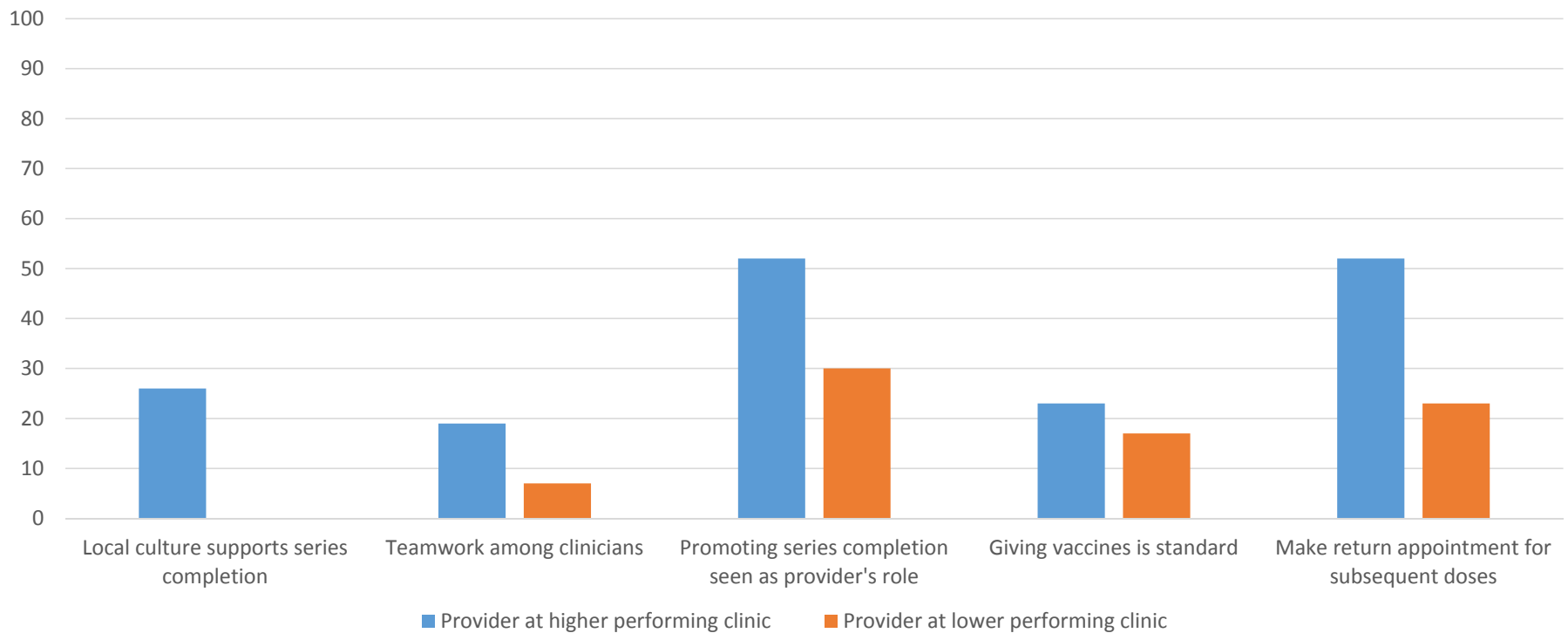
Results

- 121,717 sent
- 9,833 returned (8%)

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Factors that May Impact HPV Vaccine Series Completion in Clinics with Higher and Lower Series Completion: Pro-HPV Vaccination Culture



Hudson SM et al. Vaccine 2016

What can community- and state-level organizations do?

- Convene and commit to implementing effective strategies
- Immunization programs: AFIX focused on adolescent vaccination
- Provider organizations: help members develop the motivation and skills to make an effective recommendation for HPV vaccination
- Cancer programs: motivate immunization providers to prevent cancers caused by HPV in their patients
- Health care payers: use HPV vaccination coverage as a quality measure
- All organizations: increase public awareness and support for HPV vaccination as cancer prevention
- All organizations: promote or implement systems strategies to improve HPV vaccine coverage

messages from former patients

"I finally found a pediatrician
for my baby that I feel like I
can trust the way my mom and dad
always trusted you."

"I'm starting my internship in pediatrics in July. You probably never knew it, but you always were my role model."

"That new infant car seat that's
been in the news? I invented
it."

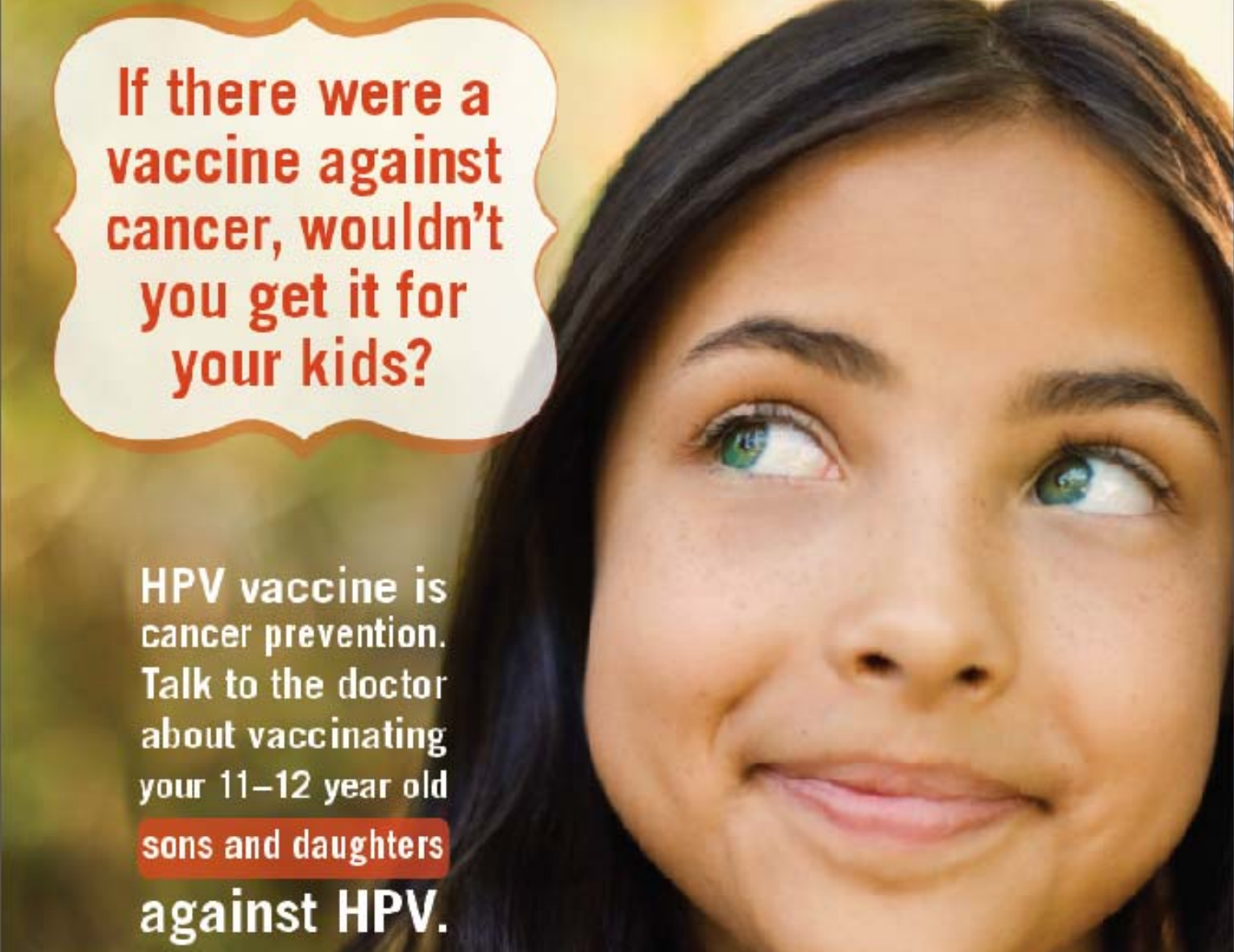
"My mom just told me how you
saved my life when I was little.
I didn't know."

"I just got diagnosed with
cervical cancer."

HPV vaccine prevents
cancer.

HPV vaccine prevents
cancer.

Vaccinate your patients.



**If there were a
vaccine against
cancer, wouldn't
you get it for
your kids?**

**HPV vaccine is
cancer prevention.
Talk to the doctor
about vaccinating
your 11–12 year old
sons and daughters
against HPV.**

Thank you

www.cdc.gov/vaccines

www.cdc.gov/hpv

www.cdc.gov/vaccinesafety