

HPV Vaccination: The US Story and Challenges

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Disclosures

- Advised or participated in educational speaking activities, but do not receive an honorarium from any companies.
- In specific cases, my prior hospital, Montefiore Medical Center and current employer, Rutgers, has received payment for my time spent for these activities from Merck, GSK, Roche, Hologic, Photocure, Papivax, Natera, and PDS Biotechnologies.
 - If travel required for meetings with industry, the company pays for Dr. Einstein's travel expenses
- Montefiore and Rutgers has received grant funding for research-related costs of clinical trials that I have been the Overall or Montefiore PI within the past 12 months from Astra Zeneca, Roche, Photocure, Inovio, PDS Biotechnologies, and Becton-Dickinson.
- Rutgers receives payment for Dr. Einstein's time from: PDS, Natera, Papivax, and Photocure



Objectives

- Describe current US Recommendations
- Describe US data regarding uptake and effects
- Elaborate on messages for US providers to increase HPV vaccination



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

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: 2-Dose Series

CDC routinely recommends two doses of HPV vaccine for 11 and 12 year olds to prevent HPV cancers.

- ➡ The first dose is routinely recommended at 11-12 years old.
- ➡ The second dose of the vaccine should be administered 6 to 12 months after the first dose.
- ➡ Vaccination can be started at age 9.

Safety?

- 90 million doses delivered in US, 200 million worldwide
- As safe as other routinely recommended vaccines like meningococcus and Tdap



IOM Review: Syncope & Anaphylaxis

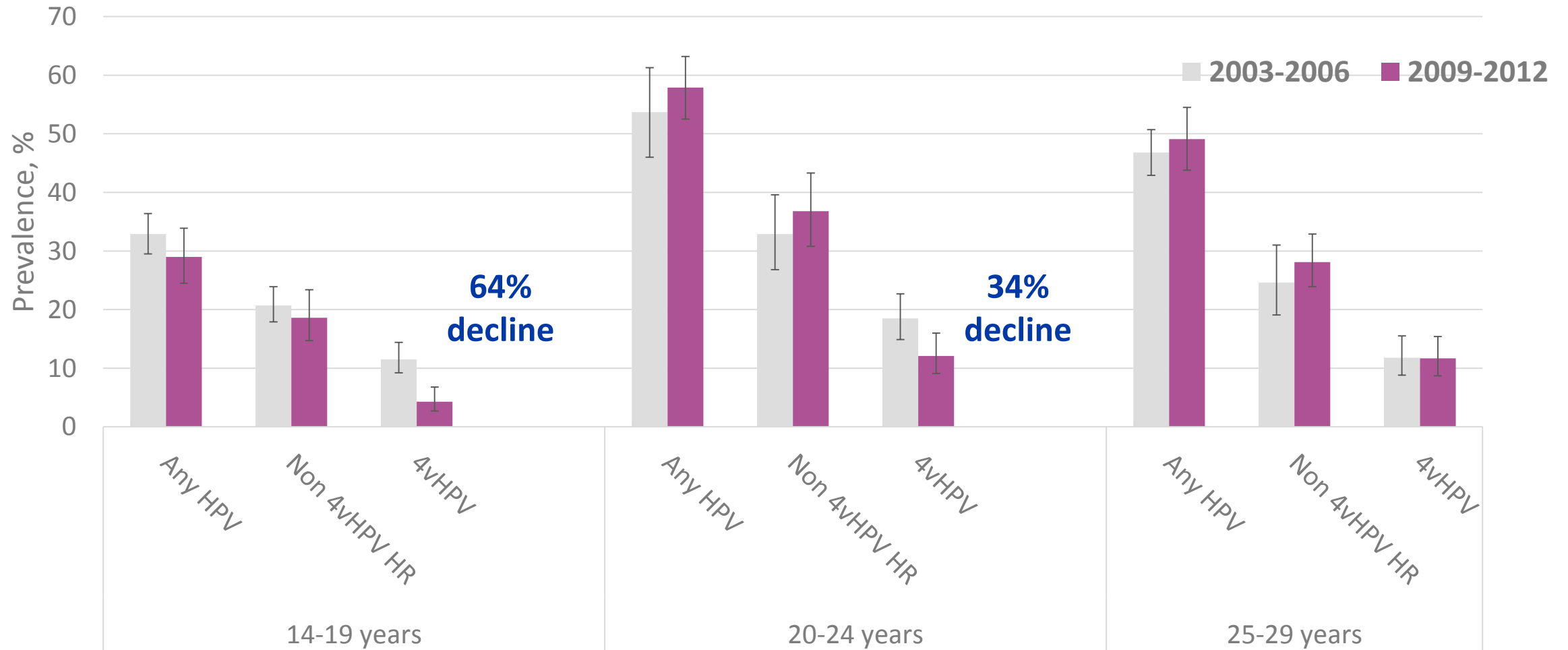
- ▶ IOM reviewed possible associations between 8 vaccines and adverse health events. Key findings:
 - ▶ Evidence “favors acceptance” of a causal relationship between HPV vaccine and anaphylaxis (rare)
 - ▶ Evidence “convincingly supports” a causal relationship between the injection of a vaccine and syncope
- ▶ Inadequate evidence was found for causal relationships between HPV vaccination and 12 other specific health events studied

Does this work?

- Large clinical trials and over 10 years of follow-up
- Data tracking across the globe



Prevalence of HPV before & after introduction of HPV vaccination in the United States



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 year 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

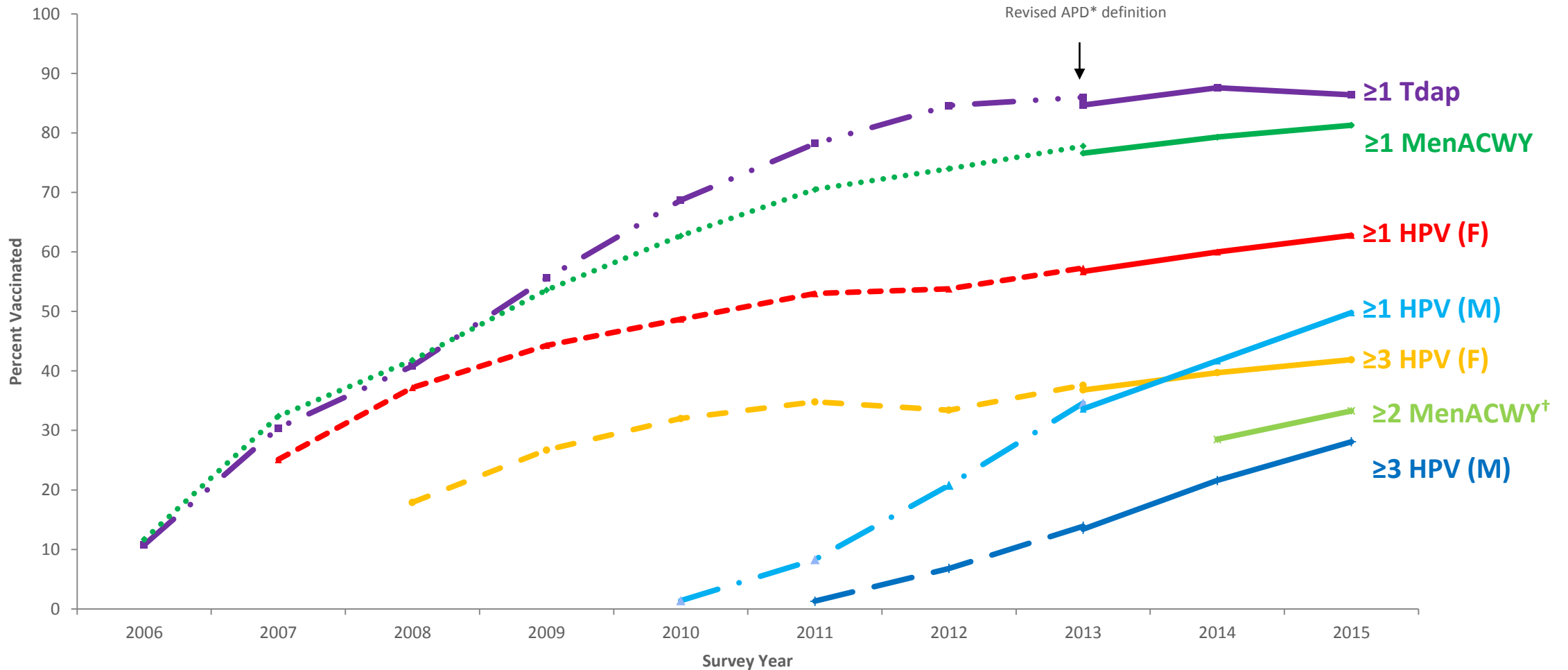
More US issues...

- Policies requiring parental consent
- Access issues
- School mandates are very limited- but not the complete solution anyways
- Missed opportunities
- Poorly presented- often presented as optional, providers poorly equipped to engage the conversation with parent's questions



Adolescent Vaccination Coverage

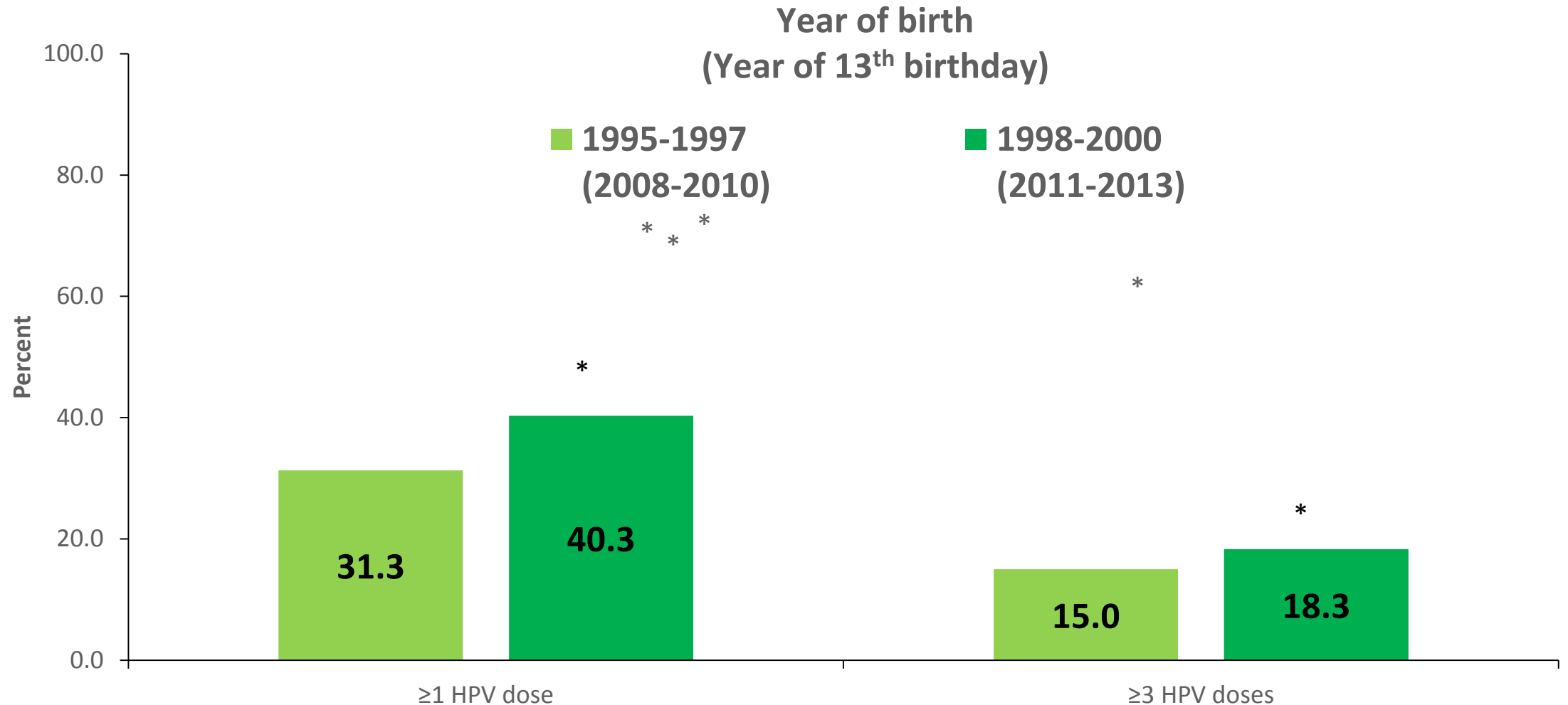
United States, 2006-2015



Reagan-Steiner, et al. MMWR; August 26, 2016 / 65(33);850–858

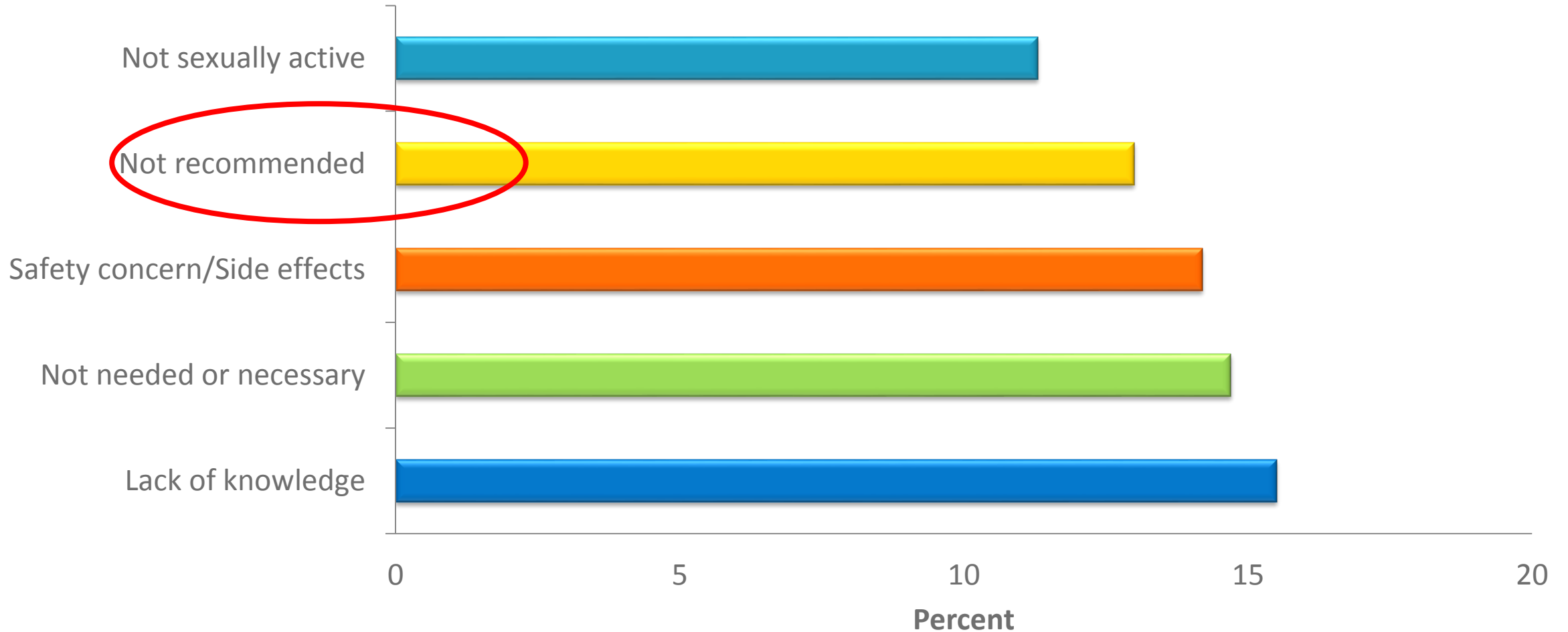
* APD = Adequate provider data †≥2 doses MenACWY among adolescents aged 17 years

HPV Vaccination Coverage in Girls by age 13, by Combined 3-year Birth Year Cohorts

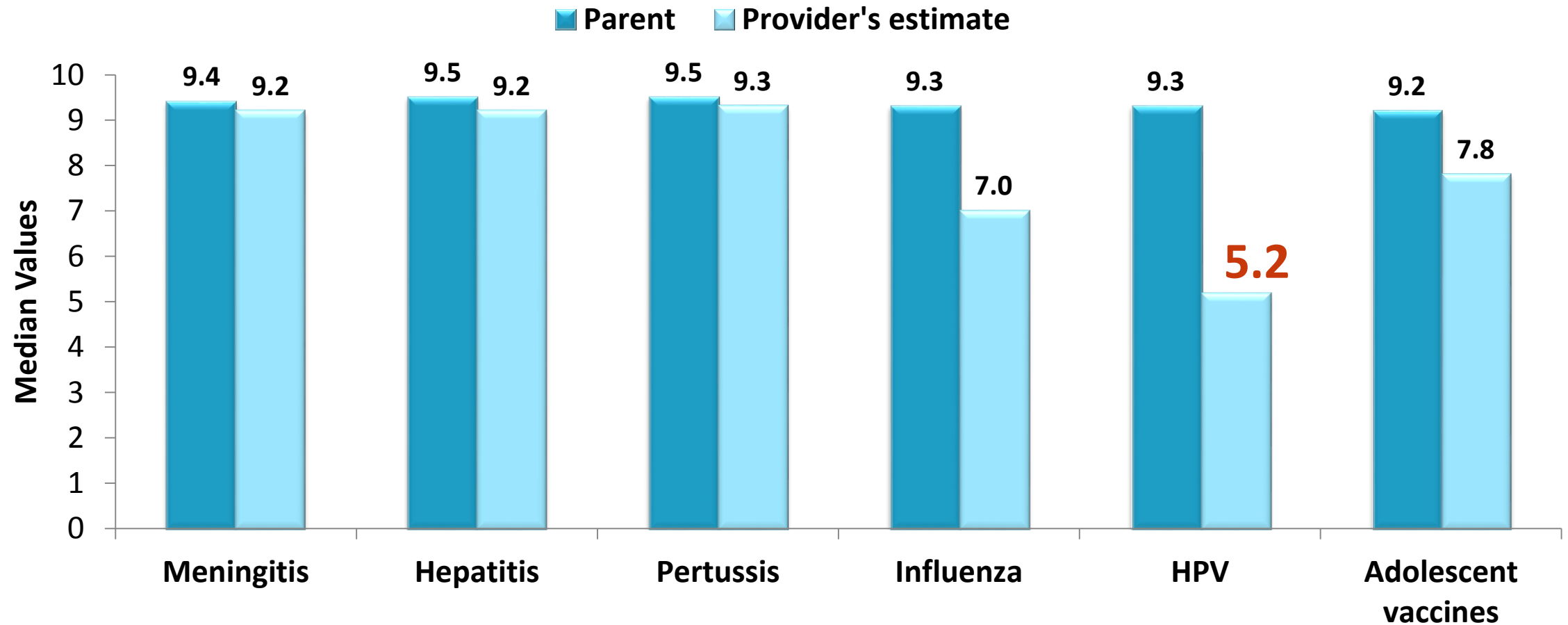


* Statistically different from 1995-1997 combined birth year cohort ($p < 0.05$).

Reasons parents won't initiate HPV vaccination for children



Clinicians underestimate the value parents place on HPV vaccine




The **perceived** and **real** concerns of
parents influence how the
provider **recommends** and
administers HPV vaccine.


So how do we discuss HPV vaccination with parents?

CLEAR and CONCISE messages INCREASE vaccination rates





*Your preteen
needs three vaccines **today**
to protect against
meningitis,
HPV cancers,
and pertussis.*



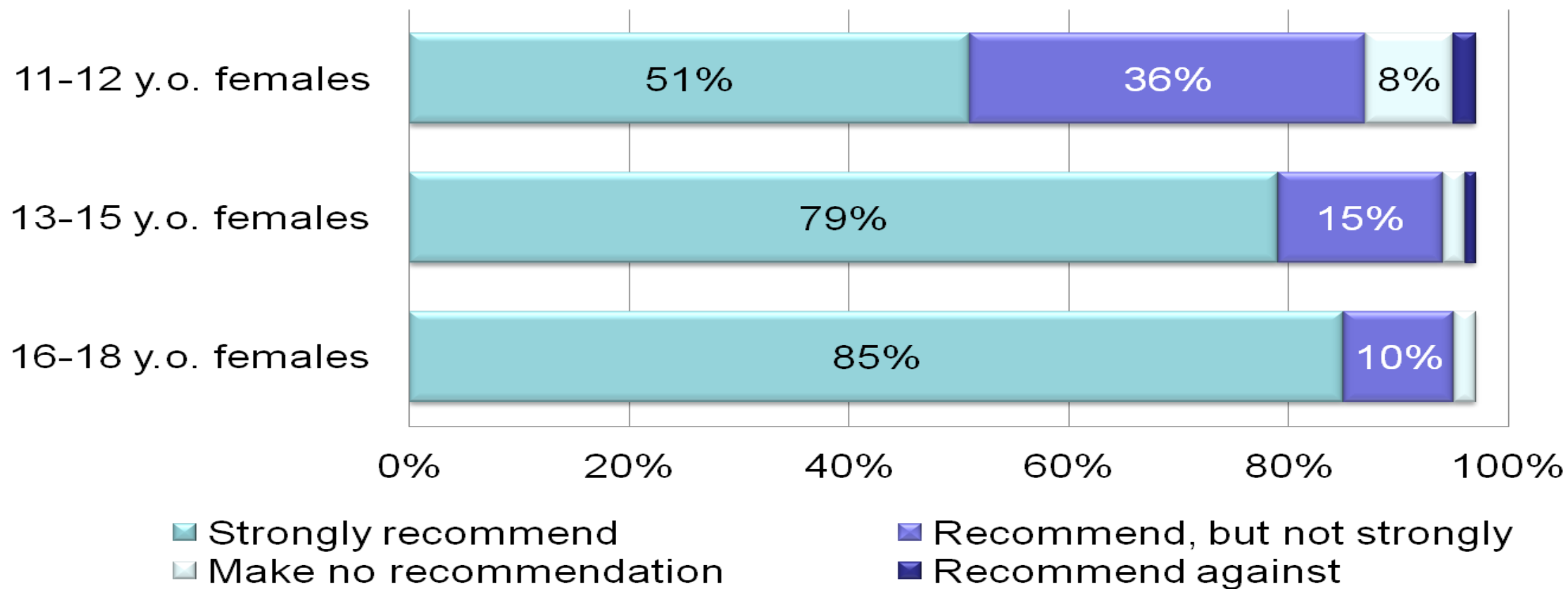


HPV vaccination is important because it
prevents cancer.

That's why I'm recommending that your child
start the HPV vaccine series today.



Most clinicians wait too long to make strong recommendations for HPV vaccine





As with all vaccine-preventable diseases, we want to protect your child early. If we start now, it's one less thing for you to worry about.

Also, your child will only need two shots of HPV vaccine at this age. If you wait until 15, your child will need three shots.

We'll give the first shot today and then you'll need to bring your child back in 6 to 12 months from now for the second shot.



I have some concerns about the safety of the vaccine—I keep reading things online that says HPV vaccination isn't safe.

Do you really know if it's safe?





It sounds like you are generally in support of vaccines, but you have concerns about the safety of HPV. Is that right?

So if you had information that convinced you the HPV vaccine was safe you might consider letting your daughter get it?

I'd like to share with you what I know about the safety of HPV vaccine...





I know there are stories in the media and online about vaccines,
and I can see how that could concern you.

However, I want you to know that HPV vaccine has been
carefully studied for many years by medical and scientific
experts.

Based on all of the data, I believe HPV vaccine is very safe.





Vaccines, like any medication, can cause side effects. With HPV vaccination this could include pain, swelling, and/or redness where the shot is given, or possibly headache. Sometimes kids faint when they get shots and they could be injured if they fall from fainting. We'll protect your child by having them stay seated after the shot.



*I'm just worried that my child will perceive this as a
green light to have S-E-X*





Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age. Starting the HPV vaccine series today will give your child the best protection possible for the future.



If a parent doesn't say yes...

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 & conflicting info 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: make sure you understand & are answering the question they actually care about.•Allow time to discuss the pros & cons of vaccines.•Be willing to discuss parents' ideas.•Offer written resources for parents.•Tailor your advice using this presentation.

If a parent declines...

- Declination is not final.
The conversation can be revisited.
- End the conversation with at least 1 action you both agree on.
- Because waiting to vaccinate is the risky choice, many pediatricians ask the parent to sign a *Declination Form*

Cost issues

- Shouldn't be- certainly not for kids
- Routine recommendation by ACIP
- Recommended by all scientific stakeholding organizations
- Payers, Vaccines For Children (VFC), ACA all covered
- Issue for older catch-up population and off labeled use (over age 26)



Resources

- American Cancer Society HPV Vaccine Roundtable:
<https://www.cancer.org/health-care-professionals/national-hpv-vaccination-roundtable.html>
- Center for Disease Control- 'You are the Key Slides' available at ACS Vaccine Roundtable Resources and CDC website
- American Academy of Pediatricians Champions Toolkit
- American College of Obstetricians and Gynecologists Immunizations for Women downloads
- American Academy of Family Physicians immunizations downloads
- Immunization Action Program (<http://www.immunize.org/hpv/>)

