Promoting the HPV Vaccine

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Disclosures

• I have no relevant financial relationships with the manufacturers of any commercial products and/or providers of commercial services discussed in this presentation.

• I do not intend to discuss an unapproved/investigative use of a commercial product/device in the presentation.
Objective of this presentation

1. Understand challenges in HPV series completion and suggestions for improvement
2. Understand the better coverage potential with the new HPV-9 vaccine.
3. Understand more about adolescent vaccinations

Presentation outline

I. Adolescent vaccines
II. HPV vaccine
III. Your role to improve vaccination rates and reduce missed opportunities
Adolescents need vaccines too!!

Adolescent Vaccine Recommendations

– Tdap booster
– MCV4 (two doses)
– HPV (three doses)
– Influenza (annual)
Pertussis Vaccine
Recommendations - Tdap

• Tdap – Booster
  • Boostrix® (GSK): 10 years of age and older
  • Adacel® (sanofipasteur): 11-64 years of age
    – Recommended: 11 to 12 years
    – Catch-up: 13 to 18 years if not received at 11-12 years
    – Children 7 to 10 years of age not fully vaccinated with DTaP

Meningococcal – MCV4

• Routine vaccination of adolescents, preferably at age 11 or 12 years

• A booster dose at age 16 years
  – Potential decrease in immunity 5 years after initial dose
HPV VACCINE

HPV Infection

• 4 out of 5 people will be infected with 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
  – 9th graders: 1/3
  – 12th graders: 2/3; 1/4 have had 4 or more partners


Acquisition of HPV after Sexual Debut

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

Women (N=20,413)

- Cervix: 55% (n=11,279)
- Vulva: 15% (n=3,039)
- Oropharynx: 11% (n=2,317)
- Anus: 15% (n=3,084)
- Vagina: 4% (n=694)

Men (N=12,002)

- Oropharynx: 78% (n=9,312)
- Penis: 8% (n=1,003)
- Anus: 14% (n=1,687)


Cervical Cancer

- Cervical cancer is the most common HPV-associated cancer among women
  - In 2011, > 12,000 new cases and 4,000 attributable deaths occurred in the U.S.
  - Nearly two thirds of cervical cancers occur in women younger than 55 years of age
    - 14% between 20 and 34
    - 26% between 35 and 44
    - 24% between 45 and 54

<table>
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<th>Race</th>
<th>Ethnicity</th>
<th>Age-adjusted rate per 100,000 females</th>
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<td>Hispanic</td>
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Preventing HPV Disease
HPV Vaccines

• **Bivalent Vaccine** *(Cervarix®)*
  – HPV 16 and 18
    • HPV related cervical pre-cancers and cancer in women

• **Quadrivalent Vaccine** *(Gardasil®)*
  – HPV 6, 11, 16 and 18
    • HPV related cervical, vulvar, vaginal pre-cancers and cancer in women
    • Anal pre-cancers and cancer in women and men
    • Genital warts in women and men

• **Nanovalent Vaccine** *(Gardasil 9®)*
  – HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58
    • HPV related cervical, vulvar, vaginal pre-cancers and cancers in women
    • Genital warts in men and women
    • Anal pre-cancers and cancer in women and men

**Type Attribution by Cancer Site, US**

- **HPV 16/18**
- **HPV 31/33/45/52/58**
- **Other HPV**
- **HPV Negative**

**Females:** HPV4 recommended at 11-12 yrs or 13-26 yrs if not previously vaccinated

**HPV2 recommended at 11-12 yrs or 13-26 yrs if not previously vaccinated (females)**

**HPV4 permissively recommended 9-26 yrs (males)**

**Females: HPV4 recommended at 11-12 yrs or 13-26 yrs if not previously vaccinated**

**Males:** HPV4 recommended at 11-12 yrs or 13-21 yrs if not previously vaccinated; at 22-26 yrs for high risk

- **2006**
- **2009**
- **2012**

6/24/2015
Females: HPV2 and HPV4 recommended at 11-12 yrs or 13-26 yrs if not previously vaccinated

Males: HPV4 recommended at 11-12 yrs or 13-21 yrs if not previously vaccinated; at 22-26 yrs for high risk

9-Valent HPV Vaccine

- Licensed by FDA in December, 2014
  - 9-26 year old females
  - 9-15 year old males
- ACIP discussed in February, 2016
  - Age & gender recommendations the same as for quadrivalent vaccine
  - Finish the series with whatever vaccine is available
  - No determination yet on what recommendations to make for those already fully vaccinated with the bivalent or quadrivalent vaccines
Nine Years Later
What do we know now?

EFFECTIVENESS

SAFETY

HPV Infections Decreased, US, 2007-10

- In 14-19 year olds, vaccine-type HPV prevalence decreased from 11.5 percent (2003-6) to 5.1 percent (2007-10)
  - 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

- National Health and Nutrition Examination Survey (NHANES) data

Genital Warts, Females by Age Group, US, 2003-2010

Genital Warts among Females < 26 years, Australia, 2004-2010
The HPV vaccine is safe

• 60 million doses distributed in US since 2006
• Nearly 175 million doses distributed worldwide
• Most common adverse events were mild
• For serious adverse events monitored by VAERS, no unusual patterns were found that would suggest the events were caused by the HPV vaccine
• Findings similar to the safety of MCV4 and Tdap

HPV Vaccine Coverage Report Card
Most Recent Coverage Data

- Information from the 2013 NIS:
- Females n=8264, Males n=9554 – all 13-17 year olds

<table>
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<th>Female 1 dose</th>
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<th>Female 3 doses</th>
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<td>38.6%</td>
<td>50%</td>
<td>29.1%</td>
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<td>41.1%</td>
<td>32.6%</td>
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Vaccine Coverage Levels among 13-17 years olds, US, NIS-Teen, 2006-2012

Source: MMWR. 2013;62:685-93

Understanding Non-Vaccination for HPV
Parents of girls*:

- 501 mothers of 14-17 year old girls surveyed in 2010
- U.S. national sample
  - 50% reported non-vaccination of daughter
- These parents were asked to indicate reasons for non-vaccination

*Kester et al. Mat Child Health Journal 2013

Parental reasons for non-vaccination of daughters*

*Kester et al. Mat Child Health Journal 2013
Parents of boys*:

- 779 parents of 11-17 year old boys surveyed in 2012
- U.S. national sample
  - 71% (n=555) reported non-vaccination of son
- These parents were asked to indicate reasons for non-vaccination

*Donahue et al. Vaccine 2014

Parental reasons for non-vaccination of sons*

*Donahue et al. Vaccine 2014
Other reasons for non-vaccination*

• My child is too young
• My child is not at risk
• Vaccine is too new
• Question whether vaccination works

*Holman et al. JAMA Pediatrics – in press

What do we know regarding these reasons for non-vaccination?

• “HPV vaccines are too new”
• Safety concerns
• “My child is too young or is not at risk”
• Doubts about vaccine effectiveness
• Could lead to early initiation of sexual behavior and unsafe sex
• No or weak recommendation by HCP
Are HPV vaccines too new?

- The HPV4 vaccine has been licensed and recommended for girls and young women since 2006
- MCV4 (meningococcal) vaccine was licensed just one year before HPV4
- Many millions of doses have been administered in the U.S. and worldwide (>100 countries)

Are HPV vaccines too new?

No
Is HPV vaccination unsafe?

• No
• Concerns are based on individual stories, which may be tragic, but do not implicate HPV vaccine
• One or even several stories by themselves cannot address vaccine safety
• Questions that should be asked:
  – What does the research show when large numbers of people are carefully studied?

What Does the Research Show?

• Safety continues to be closely monitored by several different systems*
• VAERS data to date show no significant concerns about safety**
• Study based on over 600,000 doses of vaccine found no increased risk for***:
  • Stroke
  • Seizures
  • Allergic reactions
  • Many other conditions

** Slade et al. JAMA 2009.
*** Gee et al. Vaccine 2011.
“My child is too young/not at risk”

- The point of a **preventive** vaccine is to vaccinate **before** exposure
- Vaccine-induced anti-HPV response stronger among younger vs. older teens*
- Most persons will eventually be infected with HPV, so nearly everyone is at some risk
- In some studies of unvaccinated adolescents, most were infected with HPV 16/18 within five years of sexual debut**
- Vaccine protection lasts at least 10 years, probably much longer

**Ermel et al, STI 2013

Child too young/not at risk?

There’s no reason or benefit to delaying vaccination
Is HPV vaccination effective?

Clinical Trials indicate so:

- Both previously licensed vaccines were significantly effective at preventing infection with vaccine HPV types
- HPV2 effective at prevention of cervical pre-cancers
- HPV4 effective at prevention of cervical, vulvar, vaginal, and anal pre-cancers
- HPV4 effective at prevention of genital warts

Is HPV vaccination effective?

- Studies in Australia and Denmark show that successful implementation of HPV vaccination programs led to:
  - Marked decreases in cases of genital warts*
  - Evidence of “herd protection”**
  - Decreases in cervical abnormalities***

Is HPV vaccination effective?

• Even with relatively low vaccination rates in the U.S., vaccine-type HPV prevalence decreased among 14-19 year old girls*


Is HPV vaccination effective?

• No evidence of waning effectiveness over 8+ years after vaccination*

• Good evidence that the vaccines can be boosted, if needed**

Is HPV vaccination effective?

Yes, It is very effective

Does vaccination lead to “sexual disinhibition”? 
• Over 15 studies published since 2012 show no evidence of sexual disinhibition*
• 3 of these studies looked at STI as well as behavioral outcomes**

** Cummings et al. Vaccine 2012.
    Jena et al. JAMA Internal Med (in press).

So, does it lead to sexual disinhibition?  

No  
(and not a reason to withhold vaccination)
The HPV vaccine was not recommended by provider

- This is the real problem
- HCPs generally support HPV vaccination
- But also report barriers*
  - Cost of stocking vaccine
  - Concerns about reimbursement
  - Questions about safety
  - Lack of knowledge about the HPV vaccine

*Malo et al. Mat Child Health Journal 2013

- Non-recommendation has been a particular problem with male vaccination*
- More comfort with vaccinating older vs. younger adolescents**
  - Suggests tendency to put off HPV vaccine until after the recommended ages of 11-12

**Weiss et al. J Adolesc Health 2010;
• Many studies show that when adolescents and parents received a strong recommendation from their HCP, the odds of being vaccinated were much higher*


No recommendation from provider

Probably the primary reason for our relatively high non-vaccination rates
What Can You Do?

• Give a STRONG recommendation
  – How often do you get a chance to prevent cancer?

• Start conversation early and focus on cancer prevention
  – Vaccination given well before sexual experimentation begins
  – Better antibody response in preteens

• Offer a personal story
  – Own children/grandchildren/c lose friends’ children
  – HPV-related cancer case

• Welcome questions from parents
  – Remind parents that the HPV vaccine is safe and not associated with increased sexual activity

• Screen immunization status at every visit
  – Adolescents rarely come to the doctor!

Strategies to approach HPV

• Reminder/recall system
  – Provider level (e.g., EMR prompts)
  – Parent/patient level (e.g., postcards, telephone calls, text messaging)

• Standing orders

• Provider assessment and feedback
  – Assessment of vaccination coverage levels within the practice and discussion of strategies to improve vaccine delivery

• Utilizing immunization information systems
What Can You Do??

• Educate
  – Teach your patients about the benefits of vaccination

• ADVOCATE
  – For timely and protective vaccinations

• BE AN EXAMPLE
  – Immunize yourself, your coworkers, and loved ones.

EDUCATE
ADVOCATE

BE AN EXAMPLE
Thank you for your time.