Talking With Parents about the HPV Vaccine: Understanding & Addressing Parental Concerns

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Disclosures

• I am an investigator on investigator-initiated research projects funded by Merck
• I have served on an advisory panel for Merck
• I have served as an investigator on NIH-funded research related to HPV vaccination
• This webinar doesn’t contain any commercial conflict/bias or commercial support
Topics covered

- HPV vaccination rates and trends
- Reasons for non-vaccination
- What we know about reasons for non-vaccination
- A simple approach to HPV-vaccine communication
- Communicating with HPV-vaccine-hesitant parents
- Update on 9-valent HPV vaccine

HPV Vaccination in Illinois
2013 HPV Vaccination Rates for 13-17 year old girls*

1st Dose

3 Doses

U.S.  Illinois  Chicago  Rhode Island

*Elam-Evans. MMWR 2013.

2013 HPV Vaccination Rates for 13-17 year old boys*

1st Dose

3 Doses

U.S.  Illinois  Chicago  Rhode Island

*Elam-Evans. MMWR 2013.
Illinois: Trends in HPV Vaccination Rates for 13-17 year old girls & boys*

*CDC. National Immunization Surveys. MMWR 2009-2014

Understanding Non-Vaccination for HPV
Resistance to vaccination has always been present

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*

- Side effect concerns
- Safety concerns
- No doctor rec
- No recent Dr. visit
- Fears of disinhibition
- Doubts about efficacy
- No coverage

*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*

- No Doctor Rec
- Didn't know for males
- Side-effects
- Dangerous
- Disinhibition

Other reasons for non-vaccination*

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

*Donahue et al. Vaccine 2014

*Holman et al. JAMA Pediatrics – in press
What do we know regarding these reasons for non-vaccination?

- Vaccines are too new
- Safety concerns
- Child too young or 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 for nearly 9 years, after many years of research and testing
- MCV4 vaccine was licensed just one year before HPV4
- The HPV2 vaccine has been licensed and recommended for girls and young women for over 5 years, after many years of research and testing
- HPV4 has been licensed for boys and young men for over 5 years
- Many millions of doses have been administered in the U.S. and world wide
Are HPV vaccines too new?

No

Is HPV vaccination unsafe?

• No
• Concerns 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 is the mechanism of action?
  • What does the research show when large numbers of people are carefully studied?
Media Distortion: Miscommunication of VAERS data

• “Emily’s story is only one of 1,637 complaints involving Gardasil, filed as of May to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance database sponsored by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) in the United States.”

From Maclean’s Magazine, August, 2007

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.
What Does the Research Show?

• Study in Denmark & Sweden: Examined autoimmune, neurological, & other adverse events*
  • 997,585 girls 10-17 years old
    • 296,826 received 696,420 doses of HPV4 vaccine
    • 700,759 girls received no vaccine
  • No increased severe adverse events of any kind in the vaccinated vs. unvaccinated group
  
  *Arnheim-Dahlström et al. BMJ 2013

What Does the Research Show?

• Another study in Denmark & Sweden*
• Nearly 4 million females
  • Nearly 800,000 received HPV vaccine
  • Remainder were unvaccinated
• No increase in multiple sclerosis or other demyelinating diseases in the vaccinated vs. unvaccinated group

*Scheller et al. JAMA 2015
Is HPV vaccination unsafe?

- No, HPV vaccine is quite safe
- Probably the safest vaccine we have
- There are risks of common vaccine side-effects
  - Tenderness and swelling at the injection site
  - Mild fever
  - Fainting
- Also, no vaccine is 100% safe. Nothing we do or have our children do is 100% safe.

Child too young/not at risk?

- The point of a preventive vaccine, like HPV 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
- Vaccine protection lasts at least 10 years, probably much longer

Child too young/not at risk?

No
There’s no reason to delay vaccination

Is HPV vaccination ineffective?

*Clinical Trials indicate otherwise:*

- Both 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 ineffective?

- Studies in Australia and Denmark show that successful implementation of HPV vaccination programs led to:
  - Marked decreases in cases of genital warts*
  - Even among non-vaccinated males (indication of herd protection)**
  - Decreases in cervical abnormalities***


Is HPV vaccination ineffective?

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

Is HPV vaccination ineffective?

• No evidence of waning effectiveness over 8+ years after vaccination*
• Good evidence that the vaccines can be boosted, if needed**


Is HPV vaccination ineffective?

No, It is very effective
Leads 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.
Leads to sexual disinhibition?

No

(and not a reason to withhold vaccination)

Not recommended by provider

• This is a 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 HPV & vaccine

*Malo et al. Mat Child Health Journal 2013
Not recommended by provider

• 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


Not recommended by provider

• Multiple studies show that adolescents/parents who received a recommendation for HPV vaccine had a much, much greater odds of getting vaccinated*

Donahue et al. (unpublished data).
Not recommended by provider

Probably the primary reason for our relatively high non-vaccination rates

Talking with Parents:

Start simple
Make it routine!

- There are 3-4 recommended “adolescent platform” vaccines:
  - Tdap
  - HPV
  - Meningococcal
  - Influenza
- Don’t separate HPV from the others!

Put HPV in the middle

- HPV is typically mentioned last
- Instead, say, “Tdap, HPV vaccine, and Meningococcal vaccine”
- This approach will help to prevent provider hesitation before mentioning HPV
Recommend, don’t just offer

“I recommend 3 vaccines for this visit:

Tdap to prevent pertussis,
the first dose of HPV vaccine, which prevents cancers,
and meningococcal vaccine to prevent meningitis

I strongly recommend all three. What questions do you have?”

Two additional points:

• Make the same routine recommendation for both boys and girls, starting at ages 11-12 years … or before

• After administration make sure to emphasize importance of return for 2nd and 3rd doses
Talking with Parents:

For hesitant parents and those who want more information

Be prepared to answer questions about

- Safety
- Reasons for vaccination at 11-12
- Effectiveness
- Why boys need the cervical cancer vaccine
The parental protection instinct – in four acts…

Expression of anti-HPV vaccine sentiments or hesitancy…

• Can provoke frustration and anger in provider, which can lead to:
  • Rigid refusal to be “manipulated”
  • Overcompensating: “giving in” to patient’s demands
  • Avoidance of the patient or the vaccine
  • Awkwardness around recommendation
The following dialogues were adapted from:


Also see:
www2.aap.org/cisp/pediatricians/riskcommunicationvideos.html

An Unsuccessful Approach

- HCP: Your daughter is due for some vaccines today. There’s Tdap and meningococcal vaccines, and we also can give the HPV vaccine.
- Pt: That sounds like a lot. I’m not sure I’m comfortable with that many vaccines at one time.
- HCP: You have nothing to worry about. We know it’s safe.
- Pt: Well, I’ve heard that too many vaccines at once can overwhelm her immune system. I’ve seen research on the internet about this. Also, I’ve heard that HPV vaccine is too new and may not be safe.
- HCP: You can’t trust those websites. Good scientific research shows that vaccines are safe.
An Unsuccessful Approach

• Pt:  I still feel uncomfortable about these vaccines, especially HPV. I know my daughter is not having sex. We have raised her right.

• HCP: Well, but how would you feel if your daughter ended up getting cervical cancer?

• Pt:  I don’t think that’s the same thing.

• HCP: Your daughter just needs these vaccines today.

• Pt:  She’s my daughter. I’ll make that decision.

A More Successful Approach

• HCP: Your daughter is due for some vaccines today. She’ll be getting a total of three shots: Tdap, HPV, and meningococcal vaccines.

• Pt:  That sounds like a lot. I’m not sure I’m comfortable with that many vaccines at one time.

• HCP: What concerns do you have?

• Pt:  Well, I’ve heard that too many vaccines at once can overwhelm her immune system. I’ve seen research on the internet about this. Also, I’ve heard that HPV vaccine is too new and may not be safe.
A More Successful Approach

• HCP: I understand that you want to do what is best for your child; so do I. Many parents feel bombarded with conflicting information and do not know whom to believe.

• Pt: From what I’ve seen on TV, I’m not sure I can trust the ingredients in vaccines. Science isn’t always right.

A More Successful Approach

• HCP: I recognize that science does not provide answers to all the questions that concern you, but science is the best tool we have to get reliable answers to important questions. Let’s take some time to talk about your questions about vaccine ingredients. Then, if you would like, I can give you some trustworthy information sources about vaccines.
Parents want to talk to their HCPs:

• HCP is most used source of information about immunization and most trusted source
• But, parents report problems with*:
  • content of discussions
  • communication/interaction


Summary

• Majority of parents do not require intensive intervention around HPV vaccination
• For HPV vaccine-hesitant parents, it is important to develop a decision-making partnership
  • Being an informed decision-maker is important to many parents
  • Reflects shift from paternalistic model to shared model of decision-making
  • Helps empower parents to make informed decision
• No matter what, it’s important to know the facts about HPV vaccination
9-Valent HPV Vaccine

• Licensed by FDA in December, 2014
• ACIP discussed in February
  • Age & gender recommendations the same as for quadrivalent vaccine
  • Finish the series with whatever vaccine is available
  • No change yet in 3-dose schedule
  • No determination yet on what recommendations to make for those already fully vaccinated with the bivalent or quadrivalent vaccines

Questions that parents will have:

• Should I wait to vaccinate?
• It’s new, so do we know that it’s safe?
• My daughter just got her 3\textsuperscript{rd} shot of HPV vaccine, can she get re-vaccinated?
• My son got his first 2 shots with the old vaccine, can he finish with the new vaccine?
• Will insurance cover it?