Melinda Krakow, PhD MPH

Disclosure of Commercial Interest

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There will not be any off-label and/or investigational use of products discussed within the content at any of the presentations at this conference.

Why Parents Say ‘No’ to the HPV Vaccine

Dr. Anne Rositch & Dr. Melinda Krakow have indicated she has no relevant financial relationships within the past 12 months.
Why Parents Say ‘No’ to the HPV Vaccine

Shifting the focus from gender and sexuality to necessity and safety

Anne F. Rositch, PhD, MSPH
Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
Sidney Kimmel Comprehensive Cancer Center
HPV and cervical cancer

- More than 100 genotypes identified which infect human epithelium, ~50 which specifically infect the anogenital tract

- Approximately 14-18 are high risk or oncogenic.
  - HPV 16, 18, 26, 31, 33, 35, 39, 45, 51, 52, 53, 56, 58, 59, 66, 68, 73, and 82
  - HR-HPV infection is necessary, but not sufficient for development of invasive cervical cancer

- Remaining HPV types are not associated with cancer risk (low risk or non-oncogenic), but can cause low grade cervical abnormalities or benign proliferative warts (esp. HPV 6 and 11)
Incremental Contributions of HPV Types

% of Cancers

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# HPV vaccines

<table>
<thead>
<tr>
<th></th>
<th>Gardisil</th>
<th>Cervarix</th>
<th>Gardisil-9</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Year FDA approved</strong></td>
<td>2006</td>
<td>2009</td>
<td>2014</td>
</tr>
<tr>
<td><strong>HPV types covered</strong></td>
<td>6, 11</td>
<td>6, 11</td>
<td>6, 11, 16, 18</td>
</tr>
<tr>
<td></td>
<td>16, 18</td>
<td>16, 18</td>
<td>16, 18, 31, 33, 45, 52, 58</td>
</tr>
<tr>
<td><strong>Protection against cervical cancer</strong></td>
<td>70%</td>
<td>70%</td>
<td>90%</td>
</tr>
<tr>
<td><strong>Protection against genital warts</strong></td>
<td>90%</td>
<td>0%</td>
<td>90%</td>
</tr>
</tbody>
</table>
HPV Vaccine History

First FDA approval for use in females 9-26yo
- 2006

FDA approved for use in males 9-26yo
- 2007

ACIP recommends as routine vaccination for males
- 2009

ACOG recommends vaccinating males
ACIP permits use
- 2010

FDA approves Gardasil 9 vaccine
- 2011

President Obama states low HPV vaccine rates are a “serious but correctable threat to progress against cancer”
- 2014

FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old
- 2016

ACIP recommends 2-dose vaccine schedule
- 2018

* CDC Advisory Committee of Immunization Practices

www.cdc.gov/vaccines/who/teens/ vaccination-coverage.html

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### Current ACIP Vaccine Recommendations: Females

<table>
<thead>
<tr>
<th>Initiation after 15th birthday or Immunocompromised</th>
<th>Initiation before 15th birthday</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 doses 9vHPV At 0, 1, and 6 months</td>
<td>2 doses 9vHPV 6-12 months apart</td>
</tr>
<tr>
<td>With 11-12 year vaccines Ages 9-26</td>
<td>With 11-12 year vaccines</td>
</tr>
</tbody>
</table>
## Current ACIP Vaccine Recommendations: Males

<table>
<thead>
<tr>
<th>Initiation after 15\textsuperscript{th} birthday OR Immunocompromised</th>
<th>Initiation before 15\textsuperscript{th} birthday</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 doses 9vHPV 0, 1, and 6 months apart</td>
<td>2 doses 9vHPV 6-12 months apart</td>
</tr>
</tbody>
</table>

With 11-12yo vaccines

Ages 9-21yo unless: MSM Transgender
U.S. Vaccine Initiation Rates

Percentage


Females Males

Walker, MMWR, 2017
Vaccine initiation and completion in 2016

<table>
<thead>
<tr>
<th></th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initiation</td>
<td>65</td>
<td>56</td>
</tr>
<tr>
<td>Completion</td>
<td>49</td>
<td>38</td>
</tr>
</tbody>
</table>

Healthy people 2020 goal

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The impact of provider recommendation

Prevalence Ratios for HPV Vaccine Initiation

<table>
<thead>
<tr>
<th>Provider Recommendation</th>
<th>All Teens (weighted n = 18,948)</th>
<th>Females (weighted n = 9386)</th>
<th>Males (weighted n = 9562)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Crude PR</td>
<td>Adjusted PR</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>Ref 2.7 (CI: 2.4, 2.9)</td>
<td>Ref 1.9 (CI: 1.7, 2.2)</td>
<td>Ref 3.3 (CI: 2.9, 3.8)</td>
</tr>
<tr>
<td>Yes</td>
<td>2.7 (CI: 2.4, 2.9)</td>
<td>1.9 (CI: 1.7, 2.2)</td>
<td>3.3 (CI: 2.9, 3.8)</td>
</tr>
</tbody>
</table>

Vaccination by recommendation status

Girls

- Yes Rec: 69.2%
- No Rec: 35.80%

Boys

- Yes Rec: 63.4%
- No Rec: 19.20%
Who gets a provider recommendation?

More likely if . . .
- Income > $75,000 (PR: 1.13)
- “Other” insurance (1.09)
- Mom is a college grad (1.14)
- HepB & Tdap shots (1.22; 1.44)

Less likely if . . .
- Male (PR: 0.73)
- Midwest or South (0.95; 0.89)
- 1+ years since doctor’s visit (1.15-1.28)

Girls: 74.3%
Boys: 53.7%
Disparities in receipt of high-quality recommendation

[Bar chart showing disparities in high-quality HPV vaccine recommendation based on child's age and sex.]
Differences in vaccination even if recommended

*Among teens with a recommendation...*

**Less likely to vaccinate if:**
- Male (PR: 0.91)
- 1+ years since last doctor’s visit (0.70-0.89)

**More likely to vaccinate if:**
- Older (PR: 1.12-1.24)
- Hispanic (1.13) or Multi-racial (1.09)
- Hepatitis B & Tdap vaccines (1.34; 2.17)
HPV vaccination initiation

**Shown to be lower** in adolescents who:

- Lack a provider recommendation
- Are above the poverty level
- Live in rural areas
- Male
- White race

→ So, we have a good sense of who isn’t vaccinating but not *why*!
Study Objectives

1. To evaluate parental reasons for not intending to vaccinate their child

2. Identify changes in reasons for lack of initiation of HPV vaccination from 2010 to 2016

3. To examine differences between reasons reported for girls vs. boys
Data: National Immunization Survey-Teen

Annual, random digit-dialing survey conducted by the U.S. CDC

• Tracks national vaccination rates
• ~35,000 parents surveyed annually

We focused on:

• Provider-verified data
• Teens ages 13-17
• Data from years 2010-2016

→ If child hadn’t initiated and parent didn’t intend to vaccinate, asked: why?
Assessing reasons for lack of HPV vaccination

- Prevalence of each parent reported reason for lack of initiation
  - Calculated using survey-weighted methods

- Evaluate trends over time and compared girls vs. boys
  - Log-binomial regression

* p<0.001

Reason for Lack of HPV Vaccine Initiation
Girls: 2010 vs 2016

PERCENTAGE

Not a school requirement  Need More Info  Anti-vaccination sentiment  Religious Reasons  Concern for Increased Sexual Activity  Cost  Efficacy Concern

* *  * *  *

p<0.001

2010  2016
Reason for Lack of HPV Vaccine Initiation
Boys: 2010 vs 2016

* p<0.001
Reason for Lack of HPV Vaccine Initiation
Boys: 2010 vs 2016

* p<0.001
Reason for Lack of HPV Vaccine Initiation 2016: Girls vs Boys

- Not recommended
- Lack of knowledge
- Safety/side effect concerns
- Not sexually active yet
- Not needed

* p<0.001
AHA! THE SURE SIGN OF PROMISCUITY!!

CHRISTIAN RIGHT

HPV VACCINE
Summary of key findings

1) Perceived lack of necessity and lack of knowledge have decreased slightly in males, but they remain the most common reasons for lack of vaccine initiation for both genders.

2) Safety concerns still persist but differed by gender, reported by 22% of parents of females and just 14% of parents of males in 2016.

3) Child not being sexually active was only reported by 10% of parents in 2016, which may reflect growing understanding of the need to vaccinate before sexual debut.

4) Increase their child’s sexual activity was reported as a concern by less than 1% of parents.
HPV vaccine safety

TEXAS: 14-YEAR OLD VIRGIN FALLS PREGNANT AFTER FLU SHOT

HPV vaccine cited in infertility case
Wis. sisters say drug led to ovarian failure by age 16

San Angelo, TX | A 14-year-old schoolgirl

ANOTHER MOTHER WANTS YOU TO SEE WHAT AN HPV VACCINE INJURY LOOKS LIKE

ARJUN WALIA × APRIL 24, 2017

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Quadrivalent HPV Vaccination and the Risk of Adverse Pregnancy Outcomes

Nikolai M. Scheller, M.D., Björn Pasternak, M.D., Ph.D.,
Ditte Mølgaard-Nielsen, M.Sc., Henrik Svanström, Ph.D.,
and Anders Hviid, Dr.Med.Sci.
HPV vaccine safety

<table>
<thead>
<tr>
<th>Condition</th>
<th>Risk per one million doses</th>
<th>Risk increased?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaphylaxis</td>
<td>1.7</td>
<td>No</td>
</tr>
<tr>
<td>Guillan-Barre Syndrome</td>
<td>&lt;1.4</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition</th>
<th>Relative risk (95% CI)</th>
<th>Risk increased?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seizures/epilepsy</td>
<td>0.66 (0.54-0.80)</td>
<td>No</td>
</tr>
<tr>
<td>VTE</td>
<td>0.92 (0.54-1.57)</td>
<td>No</td>
</tr>
<tr>
<td>Auto-immune disorders</td>
<td>0.9 (0.5-1.5)</td>
<td>No</td>
</tr>
</tbody>
</table>

Over 10 years of unpublished and published data worldwide, showing that the HPV vaccine is safe, and the side effects are **NOT** different from other vaccines.

*But, in the case of HPV vaccination, there is a noticeable gap between the science supporting vaccine safety and the perception of millions of parents of adolescents in need of cancer protection.*
Conclusions

HPV vaccine messages should

• Reflect the current trends and focus on *persistent* concerns about knowledge, safety, and necessity

• Recognize that concerns regarding sexual activity are low and decreasing and should not be a barrier to discussing the vaccine

• Recognize differences in reasons for lack of vaccination for girls vs. boys
THANK YOU!
Feel free to contact me with questions: arositch@jhu.edu

Co-author acknowledgements:

Krakow M, Beavis A, Cosides O, Rositch AF.
Characteristics of Adolescents Lacking Provider-Recommended Human Papillomavirus Vaccination.

Beavis A, Krakow M, Levinson K, Rositch AF.
Reasons for Lack of HPV Vaccine Initiation in NIS-Teen Over Time: Shifting the Focus From Gender and Sexuality to Necessity and Safety.

Rositch AF, Krakow M.
Invited Commentary: Moving From Evidence to Impact for Human Papillomavirus Vaccination-The Critical Role of Translation and Communication in Epidemiology.