You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease, the Importance of the HPV Vaccine Recommendation, and Communicating about HPV Vaccination

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Faculty Disclosure

*Has in the past spoken on behalf of Merck Vaccines (more than one year ago); has no other conflicts*

*Lance Chilton, MD*

Objectives

Participants will be able to:
1. Describe the burden of HPV disease.
2. Define the importance of HPV vaccination for cancer prevention.
3. Explain the rationale for vaccinating youth at ages 11 or 12.
4. List the recommendations for HPV vaccine for girls and for boys.
5. Provide useful and compelling information about HPV vaccine to parents to aid in making the decision to vaccinate.
6. Locate resources relevant to current immunization practice.

In New Mexico, we’re doing pretty well with Tdap, but...

Understanding the Burden

HPV INFECTION & DISEASE
So, let’s talk about HPV vaccine and its promotion.

Ms. Aurelia Sánchez
- 38 y.o. mother of
  - Sara, age 7
  - Saúl, age 9
  - Linda, age 11
- Generally healthy
- Highly intelligent, well-educated

Dr. Harrison Yazzie
- 47 y.o. physician
- Married, father of
  - Emerson, age 15
  - Martha, age 18
- Highly intelligent, well-educated
- Committed to prevention of disease

HPV Types Differ in their Disease Associations

- ~40 Types
  - Mucosal sites of infection
  - Cutaneous sites of infection
  - ~ 80 Types
  - High risk (oncogenic) HPV 16, 18 most common
  - Low risk (non-oncogenic) HPV 6, 11 most common

HPV Infection

- Most females and males will be infected with at least one type of mucosal 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

New Cancers Caused by HPV per Year
United States 2006-2010

- Women (n = 17,600)
  - Cervix n=10,400 59%
  - Vagina n=400 3%
  - Vagina n=400 3%
  - Oropharynx n=3,800 21%
- Men (n = 9,300)
  - Cervix n=2,600 15%
  - Oropharynx n=7,200 77%
  - Anus n=1,400 15%
  - Anus n=1,400 15%


CDC, United States Cancer Statistics (USCS), 2006-2010

Every year in the United States 27,000 people are diagnosed with a cancer caused by HPV.

That’s 1 case every 20 minutes.

A little play

~80 Types

"Common" Hand and Foot Warts

Low Grade Cervical Disease

Laryngeal Papillomas

Genital Warts

Oropharyngeal Cancer

Anogenital Cancers

Cervical Cancer

HPV 6, 11 most common

HPV 16, 18 most common

Low risk (non-oncogenic)

High risk (oncogenic)
**HPV-Associated Cervical Cancer Incidence Rates by State, United States, 2006-2010**

10,000+ Cases and 4,000+ Deaths Every Year

**Cervical Cancer in New Mexico**

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Age-adjusted rate</th>
<th>Average number of new cases</th>
<th>Age-adjusted death rate</th>
<th>Average number of cancer deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>NM, Non-Hispanic White</td>
<td>6.5</td>
<td>32</td>
<td>1.7</td>
<td>10</td>
</tr>
<tr>
<td>NM, Hispanic</td>
<td>9.0</td>
<td>35</td>
<td>3.1</td>
<td>12</td>
</tr>
<tr>
<td>NM, American Indian</td>
<td>6.5</td>
<td>6</td>
<td>3.5</td>
<td>3</td>
</tr>
<tr>
<td>NM, Black</td>
<td>5.2</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NM, All Races Combined</td>
<td>*</td>
<td>76</td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>US, All Races Combined</td>
<td>7.4</td>
<td>11,070</td>
<td>2.4</td>
<td>3,870</td>
</tr>
</tbody>
</table>

*New Mexico Tumor Registry, 2006-2010 data*

**Without vaccination, annual burden of genital HPV-related disease in U.S. females:**

- 4,000 cervical cancer deaths
- 10,846 new cases of cervical cancer
- 330,000 new cases of HSIL: CIN2/3 (High grade cervical dysplasia)
- 1 million new cases of genital warts
- 1.4 million new cases of LSIL: CIN1 (Low grade cervical dysplasia)

 Nearly 3 million cases and $7 billion


**Evidence-Based HPV Disease Prevention**

HPV VACCINE

**HPV Vaccine Comparison**

<table>
<thead>
<tr>
<th>HPV Types Included in Vaccine</th>
<th>6</th>
<th>11</th>
<th>16</th>
<th>18</th>
<th>31</th>
<th>33</th>
<th>45</th>
<th>52</th>
<th>58</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV Vaccine</td>
<td>Bivalent</td>
<td>Quadrivalent</td>
<td>9-valent</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

These HPV Types Cause:
- Genital warts
- ~66% of Cervical Cancers
- ~15% of Cervical Cancers

Gardasil9

**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
HPV Vaccination is Routinely Recommended

- HPV vaccination is recommended for both females and males ages 11-12 years
- HPV vaccine series should be completed before the 13th birthday

Routine immunization for 11- and 12-year-olds includes HPV vaccination. Clinicians should recommend HPV vaccine on the same day and in the same way as the other vaccines for preteens.

Updated ACIP Recommendations: Interchangeability

If vaccination providers do not know, or do not have available the HPV vaccine product previously administered, or are in settings transitioning to 9vHPV:

For protection against HPV 16 and 18,
- Females: Any HPV vaccine product may be used to continue or complete the series
- Males: 4vHPV or 9vHPV may be used to continue or complete the series
- For all with complete 2vHPV or 4vHPV series, additional 9vHPV not recommended

ACIP Recommendations: Timing of the Series

- 2vHPV, 4vHPV and 9vHPV are each administered in a 3-dose schedule
  - Interval between doses 1 → 2: ~6 weeks (1-2 months)
  - Interval between doses 1 → 3: 6 months
- If the vaccine schedule is interrupted, the series does not need to be restarted

Prediction

- Coming in October:
  - Two-dose recommendation for younger patients
  - Spacing ~6-12 months apart

Parents Want to Know: HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

- HPV Vaccine is SAFE
  - Benefits of HPV vaccination far outweigh any potential risks
  - Safety studies findings for HPV vaccination similar to safety reviews of MCV4 and Tdap vaccination
- HPV Vaccine WORKS
  - Population impact against early and mid outcomes have been reported in multiple countries
- HPV Vaccine LASTS
  - Studies suggest that vaccine protection is long-lasting
  - No evidence of waning protection

VAERS: HPV Vaccine Safety Monitoring

- Ongoing safety monitoring has shown most reports are non-serious
- Among the 7.6% of reports coded as “serious,” most frequently cited possible side effects are headache, nausea, vomiting, and fever
- Syncope (fainting) continues to be reported following vaccination among adolescents
- Adherence to a 15-minute observation period after vaccination is encouraged

Non-CDC HPV Vaccine Safety Activities

- Post-licensure commitments from manufacturers
  - Vaccine in pregnancy registries
  - Long term follow-up in Nordic countries
- Official reviews
  - WHO’s Global Advisory Committee on Vaccine Safety
  - Institute of Medicine’s report on adverse effects and vaccines, 2011
  - Yes to anaphylaxis (rare), maybe to syncope no to anything else

9vHPV Vaccine Safety

- Seven pre-licensure studies including 15,000 males and females
- Generally well tolerated
  - Adverse event profile similar to that of 4vHPV across age, gender, race, and ethnicity
  - More injection-site reactions expected among those who receive 9vHPV

HPV vaccine impact monitoring

- Post licence evaluations are important to evaluate real world effectiveness of vaccines
- Population impact against early and mid outcomes have been reported:
  - Genital warts
    - Australia, New Zealand, Denmark, Sweden, Germany, Quebec, US
  - HPV prevalence
    - Australia, Norway, Denmark, Sweden, UK, US
  - Cervical lesions
    - Australia, British Columbia, Denmark, Sweden, US

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 yr 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

Published by Oxford University Press on behalf of the Infectious Diseases Society of America 2013.

Genital Warts – An Even Better Selling Point?

HPV Vaccine
Duration of Immunity

- Studies suggest that vaccine protection is long-lasting; no evidence of waning immunity
- Available evidence indicates protection for at least 8-10 years
- Multiple cohort studies are in progress to monitor the duration of immunity

HPV Vaccine Three-Dose Coverage

Updated Prevalence of HPV Infection, 14-19 year olds

Markowitz et al., Pediatrics, Feb. 2015

Adolescent Vaccination Coverage
United States, 2006-2014
Impact of Eliminating Missed Opportunities by Age 13 Years in Girls Born in 2000

Missed opportunity: Healthcare encounter where some, but not all ACIP-recommended vaccines are given. HPV-1: Receipt of at least one dose of HPV. MMWR. 63(29);620-624.

HPV Vaccine Series Initiation
Girls 13-17 Years, by State, 2013

Clinicians Underestimate the Value Parents Place on HPV Vaccine

Give a Strong Recommendation to Receive HPV Vaccine at Ages 11 or 12
Reason parent gives for not wanting HPV
Not sexually active
Not recommended
Safety concern/side effects
Not needed or necessary
Lack of knowledge

A strong recommendation from you is the main reason parents decide to vaccinate
Many moms in focus groups stated that they trust their child’s doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

Talking to parents about HPV VACCINE

Make a Bundled Recommendation
Help them understand why the vaccine is needed at ages 11 or 12. Let them know that for girls who have not had sexual contact, they will not get the vaccines prescribed before exposure. Emphasize that any preventable harm is preventable with the vaccine.

Address Parents’ Questions
Help them understand why the vaccine is needed at ages 11 or 12. Let them know that for girls who have not had sexual contact, they will not get the vaccines prescribed before exposure. Emphasize the importance of the vaccine to help prevent HPV disease in their daughter. Let them know how many parents give HPV to the children in their lives.
**Make an Effective Recommendation**

- **Same way:** Effective recommendations group all of the adolescent vaccines
  Recommend HPV vaccination the same way you recommend Tdap & meningococcal vaccines. **Don’t apologize!**
- **Same day:** Recommend HPV vaccine **today**
  Recommend HPV vaccination the same day you recommend Tdap & meningococcal vaccines.

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

*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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If main concern is **“Why does my child need this vaccine”** try saying:

*HPV vaccine is very important because it prevents cancer.*

I know we’d like to protect Maureen from cancer and I’d feel better if she got her first dose of the HPV vaccine series today when it will work best.

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If main concern is **“My daughter will wait for marriage/won’t be exposed”,** try saying:

*HPV is so common that almost everyone will be infected at some time.*

When your daughter marries, she could catch HPV from her husband. He might have been infected before he ever met her.

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If main concern is **“why now, let’s wait until child is older,”** try saying:

*HPV vaccine produces a more robust immune response in preteens than in older teens which is why I recommend starting the HPV vaccine series today.*

Also, not all sexual contact is consensual

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If main concern is **“HPV vaccine will be a green light for sex,”** try saying:

*Studies (at least 4) have shown that getting the HPV vaccine doesn’t make kids more likely have sex, or to have sex at a younger age.*
If main concern is “would you give it to your child,” try saying:

Yes, I convinced my daughters to have it given to their children because I think preventing cancer is very important.

If main concern is “side effects,” try saying:

Vaccines, like any medication, can cause side effects. With HPV vaccine most are mild, primarily pain or redness in the arm. This should go away quickly.

HPV vaccine has not been linked with any serious or long-term side effects.

Before leaving the exam room, remind parents when to come back. Try saying:

To work, Robert needs the full HPV vaccine series, so ... Please make sure to make appointments for the next shot (1-2 months) on the way out, and put that appointment on your calendar before you leave the office today!

Increase the number of target patients who come in & leave vaccinated

1. Align office policy with mission – e.g., immunize at every opportunity at all ages
2. Align communication with mission
3. Standing orders
4. Prompt the person who is supposed to order the vaccine
   - Nursing personnel
   - EHR
   - Both

Factsheets for Parents in English & Spanish

cdc.gov/vaccines/YouAreTheKey

HPV PORTAL FOR PROVIDERS
HPV VACCINE IS CANCER PREVENTION
And YOU are the key!

Thank you, NMAFP! Lance Chilton

#WeCanStopHPV