Cutting Edge Technology to Prevent Cancer - The HPV Vaccine

July 2017

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Disclosure

- We have no relevant financial relationships with the manufacturers(s) of any commercial products(s) and/or provider of commercial services discussed in this CME activity.
- We do not intend to discuss an unapproved/investigative use of a commercial product/device in my presentation.

Objectives

- Realize how common HPV is and know the virulent & less virulent strains of HPV.
- Be able to educate parents on HPV prevalence.
- Know more about the available HPV vaccines, recommendations for delivery, and the very few contraindications to administration.
- Understand the importance of a strong provider recommendation and how to use this.
- Be armed with messages to overcome vaccine hesitancy in your practice.
What a difference a vaccine makes

U.S. Deaths per year
- Pertussis - 20
- Meningococcal - 100
- Total = 120

U.S. Deaths per year
- Cervical Cancer - 4000
- Vaginal & Vulvar Cancer - 1900
- Anal Cancer - 1000
- HPV associated oropharyngeal cancer - 1700
- Total = 8,600

Vaccination Works!!

Let’s do the math!
- Annual number of new HPV infections
  - 10x higher than rate of chlamydia
  - 42x higher than rate of gonorrhea
  - 800x higher than rate of syphilis
Human Papillomaviruses

Highly Transmissible

Mucous Membranes

Keratinized Skin

High Risk

Low Risk

9 HPV Strains

6
11
16
18
31
33
45
52
58

How common is HPV?

- Human papillomavirus (HPV) is the most common sexually transmitted virus in the United States.
- Almost every sexually active person will acquire HPV at some point in their lives.
human papillomavirus — cervicovaginal prevalence of types 6, 11, 16 and 18 among women aged 14-34 years by age group and time period, national health and nutrition examination survey, 2003-2006 and 2009-2012

NOTE: error bars indicate 95% confidence interval.

source: markowitz le, liu g, hariri s, et al. prevalence of hpv after introduction of the vaccination program in the united states. pediatrics 2016;137(3):e20151968.

the cancer-preventing vaccine!
Timeline of HPV vaccination

- **2006**
  - FDA approves Gardasil 4 (girls), ACIP recommends

- **2009**
  - Cervarix FDA Approved (girls), Gardasil 4 FDA approved Boys

- **2014**
  - FDA approves Gardasil 9

- **2015**
  - ACIP approves Gardasil 9 as 2 dose series (9-14 yrs) (Oct); ACIP recommends same (Dec)

<table>
<thead>
<tr>
<th>Year</th>
<th>Vaccine Type</th>
<th>Manufacturer</th>
<th>Contraindications</th>
<th>Year Licensed</th>
<th>Coverage</th>
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<tbody>
<tr>
<td>2003</td>
<td>Vaccine Trial</td>
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<tr>
<td>2007</td>
<td>AL Nati Vaccine Program</td>
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<td></td>
<td>Oct 2009 Females</td>
<td></td>
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<tr>
<td>2011</td>
<td>HPV vaccine for boys</td>
<td></td>
<td></td>
<td>June 2006 females, Oct 2009 males</td>
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<tr>
<td>2015</td>
<td>HPV vaccine for routine vaccination in boys and girls</td>
<td></td>
<td></td>
<td>Dec 2014 Males and Females</td>
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</tbody>
</table>

**Estimated type contribution for HPV Malignancies & Vaccine Coverage**

- Bivalent Cervarix
  - HPV 16, 18
  - Manufacturer: GlaxoSmithKline
  - Contraindications: Hypersensitivity to latex

- Quadrivalent 4vHPV
  - HPV 6, 11, 16, 18
  - Manufacturer: Merck
  - Contraindications: Hypersensitivity to yeast

- 9-valent 9vHPV
  - HPV 6, 11, 16, 18, 31, 33, 45, 52, 58
  - Manufacturer: Merck
  - Contraindications: Hypersensitivity to yeast

[CDC](http://www.cdc.gov/hpv/hcp/need-to-know.pdf)
When to vaccinate

- ROUTINE vaccination for all kids 11-12 years
- Safe and FDA approved at age 9 yrs
- Catch up for females 13-26 yrs
- Catch up males 13-21 yrs (or up to 26 yrs for MSM, immunocompromised/HIV); may vaccinate 22-26 yo also
- Take home: Safe between 9-21 years, better immunity if < 15 years

October 2016 Update

- 11-12 yr olds, 2 doses ≥ 6 months apart
- If the series is initiated late, after age 15 yrs, 3 doses are still required (Today, 2mos, 6 mos)

DOES IT WORK?
10 years later
2006-2016
What do we know?

Does it really prevent Cancer?

Exposure
Infection
Latency
Disease
Warts
CIN
Early
Late
Cancer

Garland CID 2016

Has the program been successful?

Research studies have shown that the HPV vaccine reduces the risk of cervical cancer.
- HPV vaccine can prevent cervical cancer in women and men.
- HPV vaccine can prevent genital warts in women and men.

What progress can we see?

- First impact noticed on genital warts
- Shortest incubation period from exposure
- Cervical lesions
  - Now being documented especially in Australia
- Cancer will take longer
  - Decades after exposure to HPV

HPV 6/11/16/18 Prevalence

- Australian Women 18-24 years
  - 86% after 3 doses
  - 76% after 1 dose
- US SA Females 14-24 years
  - 89% after 1 dose
- Evidence of herd immunity!

WARTS!

- Marked reductions in countries with high vaccine uptake (Australia and Denmark)
  - Reductions were greatest in youngest vaccine groups
  - Yearly reduction of 50% in multiple studies
  - Up to 92% reduction 4 years after vaccination (Australia)
- Herd Immunity!
Vaccine Recommendations and Goals

- Healthy People 2020 targets teens 13-15
  - 80% receiving 3 doses (baseline 16.6% in 2008)
  - No state met this in 2012-13
- HPV is the most common STI; 15-24 yo account for 50% of new infections yearly
- 42 states met the target for Tdap, 18 for MCV, 11 for VZV
Components

- Made from 1 protein of the HPV virus
- Virus like particles (VLPs)
- Will not cause HPV
- Non-oncogenic
- Immune response 10-100X stronger than natural immunity

Background for Specific Safety Questions

HPV vaccine induces T-helper and memory B cell responses
Possibly results in wide cross-protective immunity

Immunity from the vaccine is **better** than immunity from the disease.
Adverse Effects

- Most are local, site-related (increase with each dose, 20-90%)
- Temperature of 100 degrees for 2 weeks (similar in placebo group)
- Nausea, dizziness, myalgia and malaise (equal in placebo group)
- Syncope following adolescent vaccines - seated during vaccine, observation
- No serious adverse reactions (monitored by CDC and FDA)

CDC’s Immunization Safety Office conducts four primary vaccine safety activities:

VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

An early warning system that helps CDC and FDA monitor problems following vaccination. Anyone can report suspected vaccine reactions and locates to NIOSH.

CLINICAL IMMUNIZATION SAFETY ASSESSMENT (CISA) PROJECT

A partnership between CDC and several medical centers that conduct clinical research on vaccine-associated health risks in select groups of people.

VACCINE SAFETY DATALINK (VSD)

A collaboration between CDC and several health-care organizations that allows ongoing monitoring and proactive searches of vaccine-related data.

EMERGENCY PREPAREDNESS FOR VACCINE SAFETY

In the event of a disease outbreak or threat to public health, vaccines may be needed. CDC activates emergency preparedness activities to ensure that vaccines remain safe.

Safe! Effective! Recommend!

- HPV significant disease burden
- Vaccine is safe and effective
- Time to talk to patients!!!!
Strong Provider Recommendation

- Provider recommendation is strongly correlated with vaccination
  - Over 70% of adolescents who receive recommendation get vaccinated against HPV

Give a Strong Recommendation to Receive HPV Vaccine at Ages 11 or 12

- 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

CDC 2015
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.

**Same day:** Recommend HPV vaccine *today*. Recommend HPV vaccination the *same day* you recommend Tdap & meningococcal vaccines.

Unpublished CDC data, 2013.

Vaccination Message

**Your recommendation matters!**

- Recommend all routine vaccines together
  - Do not separate “required” from “recommended”
  - Use recall/reminder systems to help ensure complete vaccination
- Vaccinate at ALL appointments (not just well checks)
- Educate parents on vaccine-preventable diseases
- Use standing orders to vaccinate

Some Parents Need Reassurance

**Many parents simply accept this bundled recommendation**

- Some parents may be interested in vaccinating, yet still have questions. Interpret a question as they need additional reassurance from YOU, the clinician they trust with their child’s health care
- Ask parents about their main concern (be sure you are addressing their real concern)

Unpublished CDC data, 2013.
Audience Participation

- What questions have you received?

**What is the HPV vaccine?**

**Why VACCINATE SO YOUNG?**

**Are you giving it to your kids?**

**My child isn’t having sex so why do they need it?**

Take Home

- Almost everyone will get HPV at some point.
- HPV is the leading cause of oropharyngeal CA in males and cervical CA in females.
- Vaccination protects against the most oncogenic strains (16, 18) and 7 other virulent strains.
- Routine vaccination is recommended at 11-12 years for all kids.
- Vaccination is safe and effective.
- Your recommendation is crucial in vaccine uptake!

Thank You!

Healthy Kids
References

10. Garland SM. Safety and immunogenicity of a 9-valent HPV vaccine in females 12-26 years of age who previously received the quadrivalent HPV vaccine. Vaccine 2015; 33(6855-6864).
23. WHO. INFORMATION SHEET OBSERVED RATE OF VACCINE REACTIONS HUMAN PAPILLOMA VIRUS VACCINE, 2012.