Spring 2019 HPV Vaccination Update: Supporting Your Office Efforts

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American Academy of Pediatrics
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  – Slides and Q&A will be emailed ~2 weeks
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  – Directions to claim credit are on 70 & 71.
• 850+ people have registered for this webinar!
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- **CNE Course Advisor**: Jocelyn Guggenheim, RN, MS, CPNP
- **Lead Nurse Planner**: Cammie Townsend, DNP, MS/MBA, RN

No speaker, planner nor independent reviewer has any relevant financial relationships to disclose.

Faculty members do not plan on discussing unlabeled/investigational uses of a commercial product.
Objectives

• Describe the latest data on HPV cancers, HPV immunization rates, HPV vaccine effectiveness and safety

• Identify effective HPV communication strategies that all office staff can use to promote HPV vaccination

• Describe office-based strategies to improve HPV vaccination rates

• Explain the most current information about the HPV vaccination of mid-adults
Every year in the US, 43,000 people are diagnosed with a cancer caused by HPV

More than 1 case every 20 minutes

Source: https://www.cdc.gov/cancer/hpv/statistics/cases.htm
Breakdown of the US 43,000 new cancers likely caused by HPV

Women: n=24,391
- Cervix: 49%
- Vulva: 16%
- Anus: 18%
- Oropharynx: 3%
- Vagina: 14%

Men: n=18,280
- Oropharynx: 78%
- Anus: 16%
- Penis: 6%

Oropharyngeal Cancer: A New Epidemic

- 18,000 cases annually, 15,000 in men
- More common than cervical cancer
- HPV-related cancers increased by 225% in the past 20 years
- Rise in incidence and changing patient demographics due to HPV
  - Younger
  - Non-smokers
  - Non-drinkers
- No screening test
  - No endpoint in clinical trials
  - Late stage diagnosis
Incidence of Diseases Preventable by Adolescent Vaccine Series, US

<table>
<thead>
<tr>
<th>Disease</th>
<th>Annual Incidence (per 100,000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meningococcal Disease (all serogroups)</td>
<td>0.12</td>
</tr>
<tr>
<td>Meningococcal Disease Serogroup B</td>
<td>0.04</td>
</tr>
<tr>
<td>Pertussis</td>
<td>5.6</td>
</tr>
<tr>
<td>Oropharyngeal Cancer (HPV-associated)</td>
<td>4.8</td>
</tr>
<tr>
<td>Cervical Cancer (HPV-associated)</td>
<td>7.2</td>
</tr>
</tbody>
</table>

9-valent vaccine is estimated to prevent:
85% of cervical, 70% of oropharyngeal, 80% of anal, and 60% of penile cancers
HPV Vaccination Eliminates HPV Infection and the Downstream Consequences

Source: Schiffman M et al., 2013
Vaccine Type-HPV Infections, US Females

Pre-Vaccine Era, Early Vaccine Era and Later Vaccine Era

- Pre-vaccine era 2003-2006
- Early vaccine era 2007-2010
- Later vaccine era 2011-2014

Study also found vaccine type-HPV decreased 89% for vaccinated girls, 34% for unvaccinated girls: herd immunity

Decline in Pre-cancer
Now Impacting Women Ages 20-30

From the Victorian Cervical Cytology Report, 2015
Early Data: Vaccination Protects Against Invasive HPV-associated Cancers

*Data from the Finnish Cancer Registry, Helsinki, Finland*

<table>
<thead>
<tr>
<th>Malignancy</th>
<th>HPV Vaccinated women (65,565 person-years)</th>
<th>Non-vaccinated women (124,245 person-years)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Rate (95% CI)</td>
</tr>
<tr>
<td>Cervix</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Vulva</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Oropharyngeal</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>All HPV associated cancers</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Breast</td>
<td>2</td>
<td>3. (0.8,12)</td>
</tr>
<tr>
<td>Thyroid</td>
<td>1</td>
<td>1.5 (0.2, 11)</td>
</tr>
<tr>
<td>Melanoma</td>
<td>3</td>
<td>4.6 (1.5, 14)</td>
</tr>
<tr>
<td>Non-melanoma skin cancer</td>
<td>2</td>
<td>3.0 (0.8, 12)</td>
</tr>
</tbody>
</table>

HPV Vaccination Coverage, Adolescents 13-17 Years by State, NIS-Teen 2017

Legend (%)
- 46.9 - 59.3
- 59.4 - 65.0
- 65.1 - 69.1
- 69.2 - 73.0
- 73.1 - 91.9
- NA

Top Reasons for Not Starting HPV Vaccine Series From Parents of Unvaccinated Boys & Girls, 2016

- Safety concern/side effects
- Not needed
- Not sexually active
- Lack of knowledge
- Not recommended

Objectives

- Describe the latest data on HPV cancers, HPV immunization rates, HPV vaccine effectiveness and safety
- Identify effective HPV communication strategies that all office staff can use to promote HPV vaccination
- Describe office-based strategies to improve HPV vaccination rates
- Explain the most current information about the HPV vaccination of mid-adults
HPV Vaccination Coverage in Males 13-17 Years by Parental Report of Provider Recommendation

- Weighted Sample Prevalence of Provider Recommendation: 65.5%
- HPV Vaccination coverage with provider recommendation: 68.8%
- HPV Vaccination coverage without provider recommendation: 35.4%

Vaccination Initiation Rates Depend on a High Quality Recommendation

- If no recommendation or presented as options: 20-30%
- If low-quality recommendation: 50%
- If high-quality recommendation (same way, same day): 70-90%

Optional Versus **High Quality** Recommendation

- **Optional**: "Have you thought about what shots you’d like to get today?"
  - May unintentionally imply shot is not important or few people do it
  - 20-30% vaccination rate in studies of both childhood and adolescent vaccines

- **High quality**: "We have some shots to do today"
  - Implies shot is important and most people get it
  - 70-90% vaccination rate in studies of both childhood and adolescent vaccines
Putting High Quality Recommendations into Practice: Same Way, Same Day

“Your child needs 3 vaccines today- Tdap, HPV and meningococcal”

If starting before age 11, you can say:

“Today, your child needs the HPV vaccine to protect him against cancers and other diseases caused by HPV.”
The Opener by the Nurse/MA

• Encourage convenient same-day vaccination
  “Today, Pat should have 3 vaccines. They’re designed to protect him from the infections that cause meningitis, HPV cancers, and pertussis. Do you have any questions for me?”

• If a parents hesitates, the MA/nurse should say
  “Our practice is so dedicated to cancer prevention that I’m sure the doctor will want to talk with you about your concerns.”
HPV Vaccine: Same Way Same Day Mobile App

• A brief 15-minute, interactive, role-play simulation

• Learn how to:
  – avoid common conversation pitfalls and improve communication skills during HPV vaccine conversations.

• Download this complimentary App today from the Apple iTunes Store or Google Play Store.
Clinical Challenge #1

You are seeing an 11-year old patient who has received all recommended vaccines up to today.

- When the nursing staff said, “Today we will have three vaccines for Emma – Tdap, HPV, and meningitis vaccines,”
- the mother replied, “I don’t think she should have the HPV one.”
Motivational Interviewing: 4 Steps

Step 1: Ask the parent to share concern(s)

– “So you seem to have questions about the HPV vaccine. I want to make sure I answer all your questions, so let’s talk about it. Would you mind sharing what your particular concerns are?” (Note: non-threatening)

– Mom: “Well, I’ve heard that it’s a vaccine to prevent a disease that’s transmitted by having sex, and she is a looooong way from having sex.”
Motivational Interviewing: 4 Steps

Step 2: Ask permission to share information

– The provider reflects back what the parent is saying to be sure he/she understands (empathy), summarizes, asks permission to share their own perspective, and then advises the parent to vaccinate today.

– Example: “So I can hear that you’re concerned that she’s too young for the HPV vaccine because HPV is transmitted by sexual activity. Well, I completely get that – she is only 11 after all. I’ve thought a lot about this. Is it okay if I go over how I’ve come to think about this vaccine?”
Step 3: Provide info to change a parent’s perspective

1) “I used to think of this vaccine as something to prevent a sexually transmitted disease, but realized it’s really about preventing cancer.”

2) “We recommend it at this age because younger kids have a better immune response. That’s why they need only 2 doses instead of 3.”

This avoids arguing as you have not contradicted the parent’s point.
Avoid Countering Emotion with Data

What NOT to say: “Well data shows that many adolescents will be having sex by middle school, and if you’re worried about her having sex, studies have shown that it won’t increase the likelihood of her having sex.”

Statistics do not work in an emotional argument.
Motivational Interviewing: 4 Steps

Step 4: Make a personalized recommendation

– Parent, “I’ve heard about some bad side effects from the HPV vaccine.”

– Provider: “I’ve also seen things on social media, and I’m very happy to say that none of those things have been true when they’ve been investigated. In my practice, I’ve been giving the vaccine to my patients for more than 10 years now. I haven’t seen any serious side effects, and it is preventing precancers. Having said that, this is a decision that only you and your daughter can make. What do you think?”
Elicit Positive Talk (Change Talk)

- Use a 1-10 scale
  Provider: “On a scale of 1 to 10, where 10 is the most important, where does HPV vaccine fall for you? Parent: “2 or 3.” Provider: “Why is it a 3 and not a 1?”

  – Ask open-ended questions
    “You’ve mentioned side effects as a concern. What do you see as some possible side effects of not getting the HPV vaccine?”

  – Reflect parent’s positive & negative, then focus on positive
    “You see HPV cancer as frightening, but you’re worried about the vaccine’s safety. Tell me more about your perspective on HPV cancers.”
If a Parent Declines the HPV Vaccine

• Declination is not final
  – Many parents who decline at first will vaccinate later
  – The conversation can be revisited
• Offer reading material
• Don’t over-remember this
• Relax. You have done your best for this child.
Is the HPV vaccine safe?

Yes!

Photo Credit: http://bit.ly/2Ewabb4
Coincidence or Cause?
Coincidence or Cause?
Coincidence or Cause?

Images from https://www.kisspng.com/free/violet-beauregarde.html
Coincidence or Cause?
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Coincidence or Cause?
Coincidence or Cause?
<table>
<thead>
<tr>
<th>System</th>
<th>Collaborators</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine Adverse Event Reporting System (VAERS)</td>
<td>CDC and FDA</td>
<td>Frontline, spontaneous reporting system to detect potential vaccine safety issues</td>
</tr>
<tr>
<td>Vaccine Safety Datalink (VSD)</td>
<td>CDC and 8 integrated health care systems</td>
<td>Large-linked database system used for active surveillance and research ~9.4 million members (~3% of US pop)</td>
</tr>
<tr>
<td>Clinical Immunization Safety Assessment (CISA) Project</td>
<td>CDC and 7 academic centers</td>
<td>Expert collaboration that conducts individual clinical vaccine safety assessments and clinical research</td>
</tr>
<tr>
<td>Post-Licensure Rapid Immunization Safety Monitoring Program (PRISM)</td>
<td>FDA and 6 partner organizations</td>
<td>Large distributed database system used for active surveillance and research ~170 million individuals (~53 of US pop)</td>
</tr>
</tbody>
</table>
VAERS
Vaccine Safety Datalink, Clinical Immunization Safety Assessment, Post-Licensure Rapid Immunization Safety Monitoring Program
HPV Vaccine Long-term Safety Data

• No increase of
  – 2011- anaphylaxis, GBS, stroke, blood clots, appendicitis, or seizures (than unvaccinated or who received other vaccines)
  – 2013 – Blood clots or adverse events related to the immune system & central nervous system (almost 1 million girls)
  – 2014 – Venous thromboembolism or blood clots (>1 million women)
  – 2012 & 2014 – Autoimmune disorders
  – 2015 – Multiple sclerosis or other demyelinating diseases
  – 2018- Primary ovarian insufficiency, rheumatologic conditions

• And over 60 other conditions

Gee et al., 2016; Cameron et al, 2016; Chao et al., 2011; Suragh et al., 2018; Wise et al, 2018
Over 10 Years of HPV Vaccine Safety Data

• Reactions after vaccination may include:
  ▪ Injection site reactions: pain, redness, and/or swelling in the arm where the shot was given
  ▪ Systemic: fever, headaches
• HPV vaccines should not be given to anyone who has had a previous allergic reaction to the HPV vaccine or who has an allergy to yeast
• Brief fainting spells (syncope) and related symptoms (such as jerking movements) can happen soon after any injection, including HPV vaccine
• Patients should be seated (or lying down) during vaccination and remain in that position for 15 minutes

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3 Steps to Increase Adolescent Immunization Rates at the Practice Level

• Motivate yourself and your staff

• Use reminder or recall messages to bring adolescents in

• “GRASP” your opportunity to vaccinate
  – Grow: Cultivate a pro-immunization culture
  – Routines: Have specific routines & specific roles
  – Agreed-upon office vaccination policies
  – Standing orders
  – Provider Prompts
Step 1: Motivate Yourself & Your Staff

• Staff need to **understand the diseases** they are preventing
  – IAC’s Unprotected People Reports
    ▪ [www.immunize.org/reports](http://www.immunize.org/reports)
  – Personal Testimonies
    ▪ [www.vaccineinformation.org/personal-testimonies](http://www.vaccineinformation.org/personal-testimonies)
  – American Cancer Society Survivor Stories
    ▪ [https://www.youtube.com/watch?v=MOO5NgWSbNA](https://www.youtube.com/watch?v=MOO5NgWSbNA)

• Know your office’s immunization rates
  – Most providers overestimate their rates
Step 2: Use Reminders or Recall Messages

• Use reminder or recall messages to bring adolescents in for well care
• Electronic Medical Records (EMR) and state Immunization Information Systems (IIS) can support this
• Many media: phone calls, letters, postcards, e-mail, text messages, or patient portals, automated calling services
Step 3: “GRASP” your opportunity to vaccinate

Photo credit: https://commons.wikimedia.org/wiki/File:Menadue_chase_down_tackle_(cropped).jpg
Grow a Pro-immunization Culture

- **Every staff member** should
  - Be ready to explain HPV vaccine’s importance to families
  - Use the “same way, same day” approach
  - If the parent has concerns, leave the door open for discussion with the provider
  - Be fully immunized themselves

- Designate a **vaccine champion** to
  - Oversee the office’s immunization program
  - Be a key resource for technical vaccination information
  - Assess and disseminate immunization rates regularly
Tasks are less likely to be forgotten if it is clear

• **What** are the immunization-related tasks that need to be accomplished

• **When** in your office work flow are they expected (routine)

• **Who** is taking responsibility for each task (role)
Have Agreed-upon Office Vaccination Policies

Policy examples

– All providers use the same vaccination schedule
– Vaccinate at every visit type
– Give all indicated vaccines at a single visit
Use **Standing Orders (SO)**

- Enable vaccination of patients without
  - the need for a provider examination or
  - a direct order from the provider at the time of the interaction

- Authorize appropriately trained healthcare personnel
  - as allowed by state law – to:
    - Assess a patient’s immunization status and
    - Administer vaccinations according to a protocol approved by a physician or other authorized practitioner

- IAC offers templates for standing orders
  - [www.immunize.org/standing-orders](http://www.immunize.org/standing-orders)
Many offices have activated the vaccine prompts in their EHR.

It helps if the nursing staff also prompt the providers:
- It can be as simple as pulling the VIS for each vaccine that’s due and putting it on the provider’s keyboard.

Use of vaccine screening checklists can help identify patients with contraindications/precautions:
- www.immunize.org/handouts
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Expansion of HPV Vaccination to Age 45: Will This Prevent More Cancer?

Adapted From Webinar Given 10/29/18 With Debbie Saslow, PhD | Senior Director, HPV-related and Women’s Cancers, American Cancer Society & Vice Chair, National HPV Vaccination Roundtable
How Does Vaccination of Adult Men and Women Compare to Children?
Timeline

• October 5\textsuperscript{th}, 2018: FDA approved Gardasil 9 for men and women ages 27-45 years
  – Based on safety and efficacy in a clinical trial

• February 27-28, 2018: ACIP presentations on additional evidence and economic analysis, potential vote considering
  – Disease burden
  – Effectiveness (in a real world setting)
  – Cost-effectiveness
HPV Vaccine’s Effectiveness and Cost-Effectiveness

- 11 studies from 6 countries
- 2/3 of studies showed no effectiveness or cost-effectiveness for women over age 20
Burden of Disease

• Vaccinating through age 26
  – Estimated to prevent at least 25,000 HPV-related cancers annually

• Vaccinating through age 45
  – Estimated to prevent only 193 more cancers
People want to know

- Is it safe?
- Does it work for adults?
- Will my insurance pay for it?
HPV Vaccination is safe for all Ages

• Common side effects are a sore arm, and occasionally short-term fever or headache, similar to other vaccines

• No serious side effects have been reported caused by the vaccine for kids or adults

Source: Castellague et al Br J Cancer, 2011
PARENTS MAY ASK YOU:

• Will it work for my child?

• Will it work for me?
HPV Vaccination Works Well for Children...  
... But Less Well After Age 20

Extremely low risk of pre-cancer for kids vaccinated on time

3 year risk % of precancer (CIN3+) among women having colposcopy for low grade Pap abnormalities

- Unvaccinated
- Vaccinated <18
- Vaccinated 18-20
- Vaccinated 21-24

Source: Castle, Prev Med, 2018

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®
Not Much Cervical Pre-cancer Was Prevented by Vaccination in 27-45 Year Old Women

No change when they looked at the entire study population (including those with previous infection)

Lower risk in women without any infection

Source: Castellague et al. Br J Cancer, 2011

Number of cases:
- Per protocol: 1581 vaccine, 1584 placebo
- ITT: 1911 vaccine, 1908 placebo

Vaccine
Placebo
Who is Most Likely to Benefit?

• Children
• Adults whose HPV risk approximates those of 11-12 year olds
Should You Vaccinate the Whole Family?

Kids should all be Vaccinated. Clear evidence of benefit. Vaccine is safe.

Mom and dad can be vaccinated. Possible benefit by preventing HPV types they don’t have now but may be exposed to in the future. Vaccine is safe.

Photo credit: https://pixabay.com/en/photos/
Remind parents that HPV vaccination helps prevent certain **HPV-related cancers & diseases** later in life.

Discuss vaccination with parents of your **11- & 12-year-old** patients when they're in your office **today**.

Recommend the **same day & the same way** you recommend other adolescent vaccines.
QUESTIONS ANSWERED HERE EVEN THE SILLY ONES

Questions?

Photo credit: https://www.flickr.com/photos/travelinlibrarian/223839049
Thank You Presenters!

• Sharon Humiston, MD, MPH, FAAP is Professor of Pediatrics at Children’s Mercy in Kansas City, Missouri. She is a clinician and health services researcher; her research focuses on innovative and practical approaches to improve vaccine delivery. She works on HPV vaccination initiatives for both the Academic Pediatric Association and the American Academy of Pediatrics. She served on the Steering Committee of the American Cancer Society’s HPV Vaccination Roundtable and was the founding chair of the Roundtable’s Provider Training Task Group. Dr. Humiston is the Associate Director for Research for the Immunization Action Coalition and she previously worked in the Training and Education Branch of the CDC’s National Immunization Program (now the National Center for Immunization and Respiratory Diseases).

• Kristin Oliver, MD, MHS, FAAP is an Assistant Professor in the Departments of Pediatrics and Environmental Medicine and Public Health at the Icahn School of Medicine at Mount Sinai. Dr. Oliver has extensive experience working in public health and policy agencies. She served as a health care analyst for GAO in Washington DC, and has conducted research projects with the CDC, the New York City Department of Health, and UNICEF. Dr. Oliver’s research and scholarly interests include vaccine preventable diseases, school based health, and tobacco cessation. She is currently a member of the American Academy of Pediatrics’ HPV Expert Physician Panel. Dr Oliver’s clinical practice in Pediatrics is at Mount Sinai’s School Based Health Centers.

• Rebecca Perkins, MD, MSc, FACOG is an Associate Professor of Obstetrics and Gynecology at Boston University School of Medicine, and a practicing gynecologist at Boston Medical Center. Her career is dedicated to reducing health disparities in cervical cancer. Her current research focuses on improving utilization of HPV vaccination and cervical cancer screening guidelines. Dr. Perkins is currently working on national projects related to HPV vaccination and cervical cancer prevention with the American Cancer Society, American Academy of Pediatrics, and ASCCP.
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Contact Hours: 1.0 of which 1.0 are eligible for pharmacology credit.

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• Slide 5-6

• Slide 7

• Slide 8

• Slide 9

• Slide 10
References

- **Slide 11**

- **Slide 12**

- **Slide 13**

- **Slide 15**

- **Slide 16**

- **Slide 17**

- **Slide 18**
References

**Slide 22**

**Slide 24-29**

**Slide 39**

**Slide 42**
References

• Slide 43

• Slide 63

• Slide 61 & 65