Optimization of the Pharmacist’s Role within the Immunization Neighborhood with Emphasis on HPV
May 28, 2015 1-2:30 pm ET

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Development and Support
This activity was developed by the American Pharmacists Association and is supported by a contract provided by the National Vaccine Program Office (NVPO). The opinions expressed in this program do not represent the viewpoints of NVPO.

Attendance Code
HPV
To obtain CPE credit for this activity, you are required to actively participate in this session. The attendance code is needed to access the assessment and evaluation for this activity. Your CPE must be filed by June 29, 2015 in order to receive credit.
Accreditation Information

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity, Optimization of the Pharmacist’s Role within the Immunization Neighborhood with Emphasis on HPV, is approved for 1.5 hour of continuing pharmacy education credit (0.15 CEUs). The ACPE Universal Activity Number assigned by the accredited provider is: 0202‐0000‐15‐142‐L01‐P.

To obtain continuing pharmacy education credit for this activity, participants will be required to actively participate in the entire webinar and complete an assessment and evaluation located at www.pharmacist.com/live-activities by June 29, 2015.

Initial Release Date: May 28, 2015
Target Audience: Pharmacists
ACPE Activity Type: Knowledge-based
Learning Level: 2
Fee: There is no fee for this activity

Disclosures

- Adam Welch, PharmD declares he has served as a consultant and received honoraria from Pfizer.
- Kelly Goode, PharmD, Mark Sawyer, MD, Bruce Gellin, MD, MPH and APhA’s education staff declare no conflicts of interest or financial interests in any product or service mentioned in this activity, including grants, employment, gifts, stock holdings, and honoraria. For complete staff disclosures, please see the Education and Accreditation Information section at www.pharmacist.com/education.

Bruce Gellin, MD, MPH
Deputy Assistant Secretary for Health
Director, National Vaccine Program Office
U.S. Department of Health and Human Services
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HPV vaccine is recommended for all males up to what age?

a. 12 years
b. 15 years
c. 21 years
d. 26 years

Based on the most recent national estimates of vaccine coverage what percentage of adolescent girls in the United States have received 3 doses of HPV vaccine?

a. 80%
b. 50%
c. 30%
d. 15%

The HPV Immunization Neighborhood is based on building which of the following relationship between immunization stakeholders?

a. Communication, coordination and collaboration
b. Collaboration, cooperation, and communication
c. Networking, communication, and collaboration
d. Networking, coordination, and collaboration
Learning Objectives

- Discuss the prevalence of HPV in the United States and immunization goals established for HPV vaccination rates
- Explain the purpose and components of the HPV immunization neighborhood
- Describe approaches to effectively implement the HPV immunization neighborhood, including strategies to address vaccine initiation and series completion
- Discuss examples of how pharmacists can contribute to the overall goals of the HPV immunization neighborhood, including collaboration with physicians and public health to meet adult and adolescent immunization goals

Human Papilloma Virus

- Small viruses that can cause both benign and malignant transformation of cells
- These viruses infected skin and mucous membranes (oral cavity, larynx, genitourinary tract mucosa, conjunctiva)
- More than 100 different types
- Only a few types cause cancer

Over 100 HPV Types

- Dermal (skin) HPV types (nonsexual contact)
  - "Common" Warts
    - Low-risk types: 6, 11, 42, 43, 44
   - Genital warts
   - Respiratory papillomatosis

- Mucosal (genital) HPV types (sexual contact)
  - "Low-risk" types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58
  - Low grade & high grade cervical abnormalities
  - Cervical cancer
  - Other anogenital cancers

What happens once people get infected with HPV?

- For most people, nothing will happen
  - The body’s immune system usually eliminates HPV infection
  - Cervical HPV becomes undetectable within 2 years in 90% of young women
  - Relatively few will develop symptoms
- Persistent infection with high-risk HPV types is associated with the development of abnormal Paps and cervical cancer


Stages of Cancer Progression

Wright & Schiffman, NEJM 2003.

U.S. HPV Prevalence & Incidence

- Currently infected ~79 million
- New infections/year~14 million
- HPV infection is most common in people in their teens and early 20s
- HPV is the most common STI
- ...but most people never know that they have been infected -- unless a woman has an abnormal pap test with a positive HPV test

Cancers Attributed to HPV, U.S.

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Average number of cancers per year in sites where HPV is often found</th>
<th>Percentage of cancers per year probably caused by HPV</th>
<th>Average number of cancers per year probably caused by HPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anus</td>
<td>Male: 1,549, Female: 2,821, Both sexes: 4,370</td>
<td>91%</td>
<td>Male: 1,400, Female: 2,600, Both sexes: 4,000</td>
</tr>
<tr>
<td>Cervix</td>
<td>0, 11,422, 11,622</td>
<td>91%</td>
<td>0, 10,400, 10,400</td>
</tr>
<tr>
<td>Oropharynx</td>
<td>9,374, 2,441, 12,417</td>
<td>72%</td>
<td>7,200, 1,800, 9,000</td>
</tr>
<tr>
<td>Penis</td>
<td>1,046, 0, 1,046</td>
<td>63%</td>
<td>700, 0, 700</td>
</tr>
<tr>
<td>Vagina</td>
<td>0, 735, 735</td>
<td>75%</td>
<td>0, 600, 600</td>
</tr>
<tr>
<td>Vulva</td>
<td>0, 3,168, 3,168</td>
<td>69%</td>
<td>0, 2,200, 2,200</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12,571, 20,589, 33,160</td>
<td></td>
<td>9,300, 17,600, 26,900</td>
</tr>
</tbody>
</table>

CDC, United States, Cancer Statistics (2006-2010); from CDC You Are the Key campaign


HPV vaccines: Virus-like particles - VLPs

- L1 major capsid protein can self-assemble into structures resembling whole virus
- HPV vaccines are based on type-specific antibody production to VLPs

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HPV Vaccines: 3 products


HPV vaccines work


HPV vaccines work
### Prevalence of HPV 6, 11, 16, 18* in Cervicovaginal Swabs, by Age Group, NHANES, 2003-2006 and 2007-2010, U.S.

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Prevalence (%) 2003-2006</th>
<th>Prevalence (%) 2007-2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-19</td>
<td>0.5%</td>
<td>0.4%</td>
</tr>
<tr>
<td>20-24</td>
<td>2.0%</td>
<td>2.1%</td>
</tr>
<tr>
<td>25-29</td>
<td>2.4%</td>
<td>2.5%</td>
</tr>
<tr>
<td>30-39</td>
<td>3.4%</td>
<td>3.5%</td>
</tr>
<tr>
<td>40-49</td>
<td>5.2%</td>
<td>6.6%</td>
</tr>
<tr>
<td>50-59</td>
<td>6.3%</td>
<td>6.6%</td>
</tr>
</tbody>
</table>

*weighted prevalence


### Anogenital Wart Prevalence per 1000 person-years, US Private Insurance Enrollees, by Age, 2003-2010

<table>
<thead>
<tr>
<th>Age group (years)</th>
<th>Females</th>
<th>Males</th>
</tr>
</thead>
<tbody>
<tr>
<td>16-19</td>
<td>0.5%</td>
<td>0.3%</td>
</tr>
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<td>20-24</td>
<td>2.0%</td>
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</table>

### HPV vaccines work

**Protocol 001: Pivotal efficacy trial in females aged 16–26 years in per protocol population**

<table>
<thead>
<tr>
<th>HPV vaccine type</th>
<th>Incidence in females</th>
<th>Incidence in males</th>
<th>Vaccine efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>13,18</td>
<td>3.0%</td>
<td>6.4%</td>
<td>54%</td>
</tr>
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</table>

**Anogenital wart**

*Incidence of anogenital warts per 1000 person-years in females, vaccine-eligible females, after 6 months of follow-up.


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HPV vaccine hurts

Injection-site AEs (Incidence 3%) – Protocol 006
(16 years of Age)

<table>
<thead>
<tr>
<th>Injection-site AEs</th>
<th>HPV Vaccine (N=802)</th>
<th>Placebo (N=802)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>245 (30.9)</td>
<td>118 (20.8)</td>
</tr>
<tr>
<td>Swelling</td>
<td>596 (74.4)</td>
<td>19 (5.8)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>237 (29.5)</td>
<td>28 (5.9)</td>
</tr>
<tr>
<td>Nausea</td>
<td>42 (5.1)</td>
<td>42 (5.1)</td>
</tr>
<tr>
<td>Inflammation</td>
<td>29 (3.5)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Irritability</td>
<td>4 (0.5)</td>
<td>5 (0.6)</td>
</tr>
<tr>
<td>Fever</td>
<td>7 (0.9)</td>
<td>15 (1.5)</td>
</tr>
<tr>
<td>Syncope</td>
<td>7 (0.9)</td>
<td>3 (0.4)</td>
</tr>
</tbody>
</table>

*Most injection-site AEs were of mild to moderate intensity.


Fainting and HPV vaccine

- Increased incidence of fainting in adolescents
- 463 reports to VAERS January 2005-July 2007
- HPV was the most common vaccine associated with fainting
- Serious secondary injuries occur
- Observe your patient for 15 minutes following vaccination

http://www.cdc.gov/vaccinesafety/Concerns/syncope.html

Immunization Recommendations

- Routine immunization at age 11-12 years for all
- All Females aged 13-26 years
- All Males aged 13-21 years
- Men who have sex with men aged 13-26 years
- All Males aged 22-26 years may be vaccinated

MMWR 2015; 64:300-304
Rationale for vaccinating early: Protection prior to exposure to HPV

Immunization Recommendations

- Females
  - 2vHPV vaccine
  - 4vHPV vaccine
  - 9vHPV vaccine
- Males
  - 4vHPV vaccine
  - 9vHPV vaccine

HPV Vaccination Schedule

- All the currently available vaccines are given as a 3-dose schedule
- Minimum of a 1 month interval between dose #1 and dose #2
- Minimum of a 3 month interval between dose #2 and dose #3
- Minimum of a 6 month interval between dose #1 and dose #3
HPV vaccine not recommended

- Pregnant women
- History of immediate hypersensitivity reaction to any vaccine component
- 2vHPV should not be used in latex allergic individuals

HPV 9 issues

- What should we do with people who have already had 3 doses of HPV2 or HPV4?
- What should we do with people who have had only some of their HPV doses?
- Cost
- Can this be used as a 2-dose vaccine?

HPV Vaccination

How are we doing?
HPV Vaccine Coverage rates are low

National estimated vaccination coverage levels among adolescents 13-17 years
NIS-Teen, 2006-2013


HPV Vaccination: Where we could be

MMWR. July 25, 2014 / 63(29);620-4
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm

HPV Vaccine – Non-vaccination Reasons

MMWR. July 25, 2014 / 63(29);620-4
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6329a3.htm
Receipt of HPV vaccine does not make you go out and have sex!

- Kaiser Permanente Center for Health Research
- 1,398 girls who were 11 or 12 in 2006, 30% of whom were vaccinated, followed through 2010
- No difference in markers of sexual activity, including
  - Pregnancies
  - Counseling on contraceptives
  - Testing for, or diagnoses of, sexually transmitted infections

Bednarczyk Pediatrics Oct 2012

HPV Vaccine is an Anti-Cancer Vaccine

- Reduction in prevalence of vaccine-type HPV by 56% in girls age 14-19 with vaccination rate of just ~30%
- Our low vaccination rates will lead to 50,000 girls developing cervical cancer – that would be prevented if we reach 80% vaccination rates
- For every year we delay increasing vaccination rates to this level, another 4,400 women will develop cervical cancer

Barriers to HPV Vaccination

- Health Care Professionals
  - Parent attitudes and concerns
  - Financial concerns
  - Knowledge gaps
  - Inadequate insurance coverage and compensation
  - Preference for
    - vaccinating older adolescents
    - girls

Barriers to HPV Vaccination

- Parents
  - Not receiving a health care professional recommendation
  - Need for more information
  - Belief that child is too young to be vaccinated
  - Concerns about adverse effects, safety and newness
  - Cost
  - Concerns about finding a clinic that offers


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Barriers to HPV Vaccination

- Underserved Populations
  - Limited knowledge
  - Lack of insurance coverage
  - Not receiving a health care professional recommendation
  - Distrust of the health care system
  - Cultural factors
  - Immigration status


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Barriers to HPV Vaccination

- Completion of 3-dose series
  - Lack of insurance coverage
  - Lack of a regular medical home
  - Lack of a health care professional recommendation
  - Little contact with the medical system
  - Being unaware or forgetting about the need for additional doses

Call to Action!!

What is an Immunization Neighborhood?
- Collaboration, coordination, and communication among immunization stakeholders dedicated to meeting the immunization needs of the patient and protecting the community from vaccine-preventable diseases

Supporting Elements for Immunization Neighborhood
- Increase immunization access points
- Provide enhanced and more consistent patient education and communication
- Document outcomes in patient medical records, IIS, and track quality measures
- Improve collaboration
- Simplify and broaden payment models
RM2 patient medical records, IIS, and track....
Rothholz, Mitch, 5/5/2015
Immunization Neighborhood Stakeholders

- Pediatrician
- Nurse Practitioner
- OB/GYN
- Parent
- Physician Assistant
- Health Department
- Pharmacist
- OBGYN
- Schools
- Payer
- Patient
- Welcome to the Neighborhood

Building Relationships

- Networking
- Communicating
- Coordination
- Cooperation
- Collaboration

Three C’s and HPV Immunization

- Collaboration
- Coordination
- Communication
Pharmacist Administered Vaccines
Patient-Age Limitations

Number of states / territories

<table>
<thead>
<tr>
<th>Age Limitations</th>
<th>Number of states / territories</th>
</tr>
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<tbody>
<tr>
<td>&gt;18yo</td>
<td>2</td>
</tr>
<tr>
<td>&gt;15yo</td>
<td>10</td>
</tr>
<tr>
<td>&gt;10yo</td>
<td>20</td>
</tr>
<tr>
<td>&gt;7yo</td>
<td>30</td>
</tr>
<tr>
<td>&gt;5yo</td>
<td>40</td>
</tr>
<tr>
<td>Any age</td>
<td>50</td>
</tr>
</tbody>
</table>

*Scope varies

Pharmacist Administered Vaccines
Authority to Administer HPV

Number of states / territories

<table>
<thead>
<tr>
<th>Has Authority</th>
<th>Number of states / territories</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>47</td>
</tr>
<tr>
<td>No</td>
<td>5</td>
</tr>
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</table>

*Via Rx only

Pharmacist Administered Vaccines
Patient-Age Limitations – for HPV Vaccination

Number of states / territories

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<td>13</td>
</tr>
<tr>
<td>&gt;10yo</td>
<td>22</td>
</tr>
<tr>
<td>&gt;7yo</td>
<td>31</td>
</tr>
<tr>
<td>&gt;5yo</td>
<td>40</td>
</tr>
</tbody>
</table>

*Younger ages under prescription/protocol

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Communication

- Pharmacist role
  - Education/training
  - Success with other vaccines
  - Access
  - Education of public
  - Coordination
  - Collaboration

Communication: Advocate and Educate

- Recommend HPV vaccine with same strength and conviction
- Communicate colleagues and staff to deliver same message
- Communicate vaccination benefits to parents, adolescents and adults at EVERY opportunity

The New York Times

Let's Not Talk About Sex

By PAUL A. OFFIT  AUG. 19, 2014
Communication Venues - Patients

- Personal
- In-store
  - Shelf-talkers
  - Signage (inside and outside store)
  - Receipt messaging
  - Handouts
  - Videos

Newer Communication Venues - Patients

- Social Media
  - Twitter #preventcancer #HPV
  - Facebook
  - Instagram
- “There’s an APP for that”
Communication – Documentation

• Communication back to medical home
  – How does the provider want the info?
    • FAX
    • Mail
    • Email
    • Technology interface
• Technology interface among stakeholders
  – PHR
  – EHR
  – VIIS

Coordination

• HPV immunization services as a priority
  – Within the pharmacy
  – Outside the pharmacy

Coordination

• Inside the pharmacy
  – Every patient encounter*
    • Recommendation
    • Education
  – Administration/Referral
  – Focused messaging
    • Shelf-talkers
    • Signage
    • Handouts/flyers
    • Videos

*Adults, Adolescents and Parents of Adolescents
Coordination

- Inside the pharmacy
  - Access with extended immunization hours
  - Protocols/standing orders
  - Patient reminder-recall
  - Documentation
  - Quality Measures
  - Immunization Champion

- Outside the Pharmacy
  - Other providers/Medical Home
  - Establish a referral process
  - Create education/reminder piece for patients regarding well visits with their primary care provider
  - Go where the patients are...
    - Schools
    - PTA Meetings
    - Malls
    - Community events
    - Underserved communities

Coordination – Yearly HPV Immunization Plan*

<table>
<thead>
<tr>
<th>January</th>
<th>February</th>
<th>March</th>
<th>April</th>
<th>May</th>
<th>June</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical Cancer Awareness Month</td>
<td>World Cancer Day</td>
<td>Spring Break Campaign</td>
<td>Immunization Week</td>
<td>Women’s Health Week</td>
<td>School’s Out Campaign</td>
</tr>
<tr>
<td>July</td>
<td>August</td>
<td>September</td>
<td>October</td>
<td>November</td>
<td>December</td>
</tr>
<tr>
<td>Back to School Campaign</td>
<td>Back to School Campaign</td>
<td>Immunization Awareness Month</td>
<td>Back to School Campaign</td>
<td>Tie to Flu Vaccine Activities</td>
<td>Tie to Flu Vaccine Activities</td>
</tr>
</tbody>
</table>

*Identify and recommend during patient encounters:
- OTC recommendations
- Prescriptions – (e.g., Birth control, antibiotics)
Collaboration

- Medical Home
- Other providers
  - OB/Gyn
- Public Health
- Immunization Coalitions
- Community Outreach

Implementation of HPV Immunization Neighborhood

1. Pharmacy identifies adolescent HPV vaccine gap
2. First dose administered at pharmacy
3. Refer to medical home for first dose/well visit
4. Second dose administered at pharmacy
5. Second dose in medical home
6. Third dose administered at pharmacy
7. Third dose in medical home
8. Well visit
9. All doses entered in IIS
10. Communicated to medical home

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Implementation of HPV Immunization Neighborhood

Pharmacy identifies adolescent HPV vaccine gap
First dose administered at pharmacy
Refer to medical home for first dose/Well visit
Second dose administered at medical home
Third dose administered at pharmacy
All doses entered in IIS, communicated to medical home

Implementation of HPV Immunization Neighborhood

Pharmacy identifies adolescent HPV vaccine gap
“Coverage/Cost Issues”
Refer to VFC provider for first dose/Well visit
Second dose administered at pharmacy
Third dose administered at pharmacy
Pharmacist follows up to remind for future doses

Implementation of HPV Immunization Neighborhood

Medical home identifies adolescent HPV vaccine gap
First dose administered at medical home, Well visit
Second dose administered at medical home
Third dose administered at pharmacy
All doses entered in IIS, communicated to medical home
Implementation of HPV Immunization Neighborhood

First Dose Administered Pharmacy

Second Dose Administered Pharmacy

Third Dose Administered Pharmacy

Pharmacy Identifies Adult HPV Vaccine Gap* Refer to Medical Home/Health Department

Second Dose Medical Home/Health Dept

Third Dose Medical Home/Health Dept

All doses entered in IIS Communicated to Medical Home

*Coverage issues - PAP

Inclusion within the Pharmacist’s Patient Care Process

Best Practices

- Initiation of series
  - Recommendation
  - Education
- Completion of series
  - Patient recall
  - Access with extended hours for immunization
  - Outreach
Tips to Enhance the HPV Immunization Neighborhood

1. Communication
   – Advocacy and Education
2. Coordination
   – Targeted immunization services for HPV vaccine
3. Collaboration with Medical Home
   – Facilitate initiation and completion

Pharmacist Challenges to the Immunization Neighborhood

- Pharmacist authority to immunize adolescents
- Documentation/Communication
  – Technology limitations
- Payment and coverage for service

HPV vaccine is recommended for all males up to what age?

a. 12 years
b. 15 years
c. 21 years
d. 26 years
Based on the most recent national estimates of vaccine coverage what percentage of adolescent girls in the United States have received 3 doses of HPV vaccine?

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The HPV Immunization Neighborhood is based on building which of the following relationship between immunization stakeholders?

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Closing Comments
Attendance Code
HPV
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- Pharmacist.com/live-activities
- Login
- Click “claim credit”
- “Enroll” in the activity
- Complete the assessment and evaluation

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