

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

Satellite Conference and Live Webcast
Wednesday, August 31, 2016
12:00 – 1:30 p.m. Central Time

Produced by the Alabama Department of Public Health
Video Communications and Distance Learning Division

Faculty

Natasha Horne, CRNP
Chu Clinic
Linden, AL

Funding for this presentation was made possible by the Centers for Disease Control and Prevention Grant No. 1H23IP000960-01 to the National AHEC Organization. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services, nor does the mention of trade names, commercial practices or organizations imply endorsement by the U.S. Government.

Jointly provided by Postgraduate
Institute for Medicine, the National AHEC
Organization, the Western Central
Alabama AHEC, and the Northeast
Mississippi AHEC



In collaboration with:



Continuing Education Credits

- Approved for LIVE webinar ONLY. On-Demand posting will NOT be available for CME/CE credit for these groups.
 - Physicians: 1.0 AMA PRA Category 1 Credit™
 - Pharmacists: 1.0 contact hours (0.10 CEUs) of the Accreditation Council for Pharmacy Education
 - Nursing: 1.0 contact hour provided by Postgraduate Institute for Medicine

Continuing Education Credits

- Please see handout with details on how to obtain CME/CE certificate online

Faculty Disclosure

- Natasha Horne, CRNP
 - Has no real or apparent conflicts of interest to report

Objectives

- Describe the burden of HPV disease
- Define the importance of HPV vaccination for cancer prevention
- Explain the rationale for vaccinating youth at ages 11 or 12
- List the recommendations for HPV vaccine for girls and for boys

Objectives

- Provide useful and compelling information about HPV vaccine to parents to aid in making the decision to vaccinate
- Locate resources relevant to current immunization practice
- Provide appropriate care and counsel for patients and their families

Objectives

- Provide accurate and appropriate counsel as part of the treatment team



Understanding the Burden HPV INFECTION & DISEASE

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

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



That's 1 case every 20 minutes

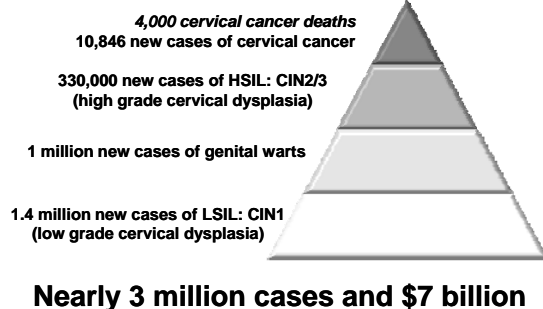
Cervical Cancer

- Cervical cancer is the most common HPV-associated cancer among women
 - 500,000+ new cases and 275,000 attributable deaths world-wide in 2008
 - 11,000+ new cases and 4,000 attributable deaths in 2011 in the U.S.

Cervical Cancer

- 37% cervical cancers occur in women who are between the ages of 20 and 44
 - 13% (or nearly 1 in 8) between 20 and 34
 - 24% (or nearly 1 in 4) between 35 and 44

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



Annual Report to the Nation on the Status of Cancer: HPV-Associated Cancers

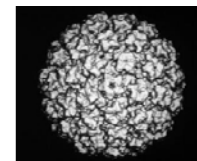
- From 2000 to 2009, oral cancer rates increased
 - 4.9% for Native American men
 - 3.9% for white men
 - 1.7% for white women
 - 1% for Asian men

Annual Report to the Nation on the Status of Cancer: HPV-Associated Cancers

- Anal cancer rates doubled from 1975 to 2009
- Vulvar cancer rates rose for white and African-American women
- Penile cancer rates increased among Asian men

HPV Prophylactic Vaccines

- Recombinant L1 capsid proteins that form “virus-like” particles (VLP)
- Non-infectious and non-oncogenic
- Produce higher levels of neutralizing antibody than natural infection



HPV Virus-Like Particle

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

HPV Vaccination is Routinely Recommended

- 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

- Age
 - Routine vaccination at age 11 or 12 years*
 - Vaccination recommended through age 26 for females and through age 21 for males not previously vaccinated

Updated ACIP Recommendations

- Vaccination recommended for men through age 26 who have sex with men (MSM) or are immunocompromised (including persons HIV-infected)
- Formulation by gender (assuming availability)

	9vHPV	4vHPV	2vHPV
Females	✓	✓	✓
Males	✓	✓	

Updated ACIP Recommendations: Formulations

- 2vHPV, 4vHPV and 9vHPV all protect against HPV 16 and 18, types that cause about 66% of cervical cancers and the majority of other HPV-attributable cancers in the United States
- 9vHPV targets five additional cancer causing types, which account for about 15% of cervical cancers

Updated ACIP Recommendations: Formulations

- 4vHPV and 9vHPV also protect against HPV 6 and 11, types that cause genital warts

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

Updated ACIP Recommendations: Interchangeability

- Males: 4vHPV or 9vHPV may be used to continue or complete the series

ACIP Recommendations: Timing of the Series

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

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 Vaccination Is Safe, Effective, and Provides Lasting Protection

- HPV Vaccine WORKS
 - Population impact against early and mid outcomes have been reported in multiple countries

HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

- 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

VAERS: HPV Vaccine Safety Monitoring

- Syncope (fainting) continues to be reported following vaccination among adolescents
 - Adherence to a 15-minute observation period after vaccination is encouraged

VSD Rapid Cycle Analysis (RCA), 4vHPV

- RCA allows VSD to detect adverse events following vaccination in near real time
- After approx. 600,000 HPV4 doses among females, no significant risk for any of the pre-specified adverse events after vaccination (including GBS, seizures, syncope, appendicitis, stroke, venous thromboembolism, and allergic reactions)

Ongoing HPV Safety Activities at CDC

- Review of reports to VAERS to search for unusual adverse events or changing patterns of adverse events
- VSD addressing HPV vaccine safety in special populations:
 - Safety of 4vHPV among males
 - Inadvertent 4vHPV vaccination during pregnancy

Ongoing HPV Safety Activities at CDC

- VSD addressing HPV vaccine safety concerns that may arise from case reports and/or the media

Non-CDC HPV Vaccine Safety Activities

- Post-licensure commitments from manufacturers
 - Vaccine in pregnancy registries
 - Long term follow-up in Nordic countries

Non-CDC HPV Vaccine Safety Activities

- Official reviews
 - WHO’s Global Advisory Committee on Vaccine Safety 1
 - Institute of Medicine’s report on adverse effects and vaccines, 20112

Key Findings CDC and Non-CDC

- Venous thromboembolism (VTE)¹
 - Study evaluating the risk of VTE in vaccinated persons age 9-26 years
 - Found no increased risk of VTE following 4vHPV

Key Findings CDC and Non-CDC

- Autoimmune and neurologic conditions²
 - Study addressing concerns about autoimmune and neurologic disease following 4vHPV vaccination
 - Found no association between 4vHPV vaccination and 16 autoimmune conditions

Key Findings CDC and Non-CDC

- Injection site reactions and syncope³
 - 4vHPV vaccination may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received
 - No major safety concerns found

IOM Review: Syncope and Anaphylaxis

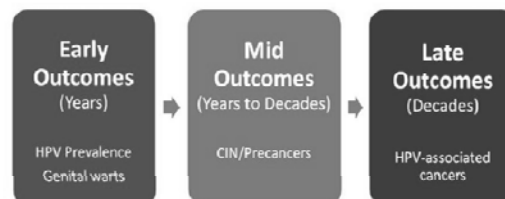
- IOM reviewed possible associations between 8 vaccines and adverse health events. Key findings:
 - Evidence “favors acceptance” of a causal relationship between HPV vaccine and anaphylaxis (rare)
 - Evidence “convincingly supports” a causal relationship between the injection of a vaccine and syncope

IOM Review: Syncope and Anaphylaxis

- Inadequate evidence was found for causal relationships between HPV vaccination and 12 other specific health events studied

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



Monitoring Impact of HPV Vaccine Programs on HPV-Associated Outcomes

HPV VACCINE IMPACT

HPV Vaccine Impact Monitoring

- Post licensure 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 Vaccine Impact Monitoring

- HPV prevalence
 - Australia, Norway, Denmark, Sweden, UK, US
- Cervical lesions
 - Australia, British Columbia, Denmark, Sweden, US

NHANES HPV Prevalence Studies

- National Health and Nutrition Examination Survey (NHANES) data used to compare HPV prevalence
 - Before the start of the HPV vaccination program (2003-2006) &
 - From the first 4 years after vaccine introduction (2007-2010)

NHANES HPV Prevalence Studies

- Results
 - In 14-19 year olds, vaccine-type HPV prevalence decreased 56% (11.5% in 2003-2006 to 5.1% in 2007-2010)
 - Other age groups did not show a statistically significant difference over time
- Vaccine effectiveness for prevention of infection was an estimated 82%

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

Challenges in Monitoring HPV Vaccine Impact on Cervical Lesions

- Detected through cervical cancer screening
- Changing screening recommendations
- Lack of cervical cancer screening registries in some countries
- Incomplete linkages with vaccination registries

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

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

Make an Effective Recommendation

- Same way: Effective recommendations group all of the adolescent vaccines
 - Recommend HPV vaccination the same way you recommend Tdap and meningococcal vaccines

Make an Effective Recommendation

- Same day: Recommend HPV vaccine today
 - Recommend HPV vaccination the same day you recommend Tdap and meningococcal vaccines

Some Parents Need Reassurance

- Many parents simply accept of 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)

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

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

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

If main concern is "why now, let's wait until child is older," try saying:

- HPV vaccination provides the best protection when given at age 11 or 12, which is why I recommend starting the HPV vaccine series today

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

- Studies 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 gave it to my child (or grandchild, etc.) 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.

If main concern is “possible effects on fertility,” try saying:

- There is no data to suggest that getting HPV vaccine will have an effect on future fertility
- However, persistent HPV infection can cause cervical cancer and the treatment of cervical cancer can leave women unable to have children
- Even treatment for cervical pre-cancer can put a woman at risk for problems with her cervix during pregnancy causing preterm delivery or problems

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

- To work, Robert needs the full HPV vaccine series, so...
When you check out, please make sure to make an appointment for about 6 weeks from now for the next shot, and put that appointment on your calendar before you leave the office today!

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

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

Be sure everyone in the office understands the mission

ShotByShot.org
Prevention of Cervical Cancer and HPV Infection



- Human stories often influence people more than statistics
To understand the human stories behind HPV, listen to survivors
 - Shot By Shot
 - Unprotected People on www.immunize.org

Standing Orders

- Empower non-physician personnel to vaccinate patients (after assessing for specific contraindications) without direct physician involvement
- Practices should have on file preapproved orders to vaccinate
- Templates available for all routine vaccines at:
– www.immunize.org/standing-orders

Standing Orders

- To save physicians time, staff have to be aware of the standing orders and be trained to use it

Review Question # 1

- HPV vaccine is recommended for the following persons:
 - A. All adolescents at the 11 to 12 year old visit
 - B. Females only at the 13 year old visit
 - C. Males only at the 11 to 12 year old visit
 - D. Females only at the 11 to 12 year old visit

Review Question # 1

- HPV vaccine is recommended for the following persons:
 - A. All adolescents at the 11 to 12 year old visit
 - B. Females only at the 13 year old visit
 - C. Males only at the 11 to 12 year old visit
 - D. Females only at the 11 to 12 year old visit

Review Question # 2

- Why should males receive HPV vaccine?
 - A. Prevention of infection with HPV types 6, 11, 16, 18
 - B. Prevention of genital warts caused by HPV types 6 and 11
 - C. Prevention of anal cancer caused by HPV types 16 and 18
 - D. All of the above

Review Question # 2

- Why should males receive HPV vaccine?
 - A. Prevention of infection with HPV types 6, 11, 16, 18
 - B. Prevention of genital warts caused by HPV types 6 and 11
 - C. Prevention of anal cancer caused by HPV types 16 and 18
 - D. All of the above

Review Question # 3

- Which of the following HPV vaccine recommendations for a child aged 11 or 12 years is the most likely to be successful?

Review Question # 3

- A. Ask parent if child is sexually active and then discuss importance of HPV vaccination
- B. Tell parent that their child needs three vaccinations to prevent meningitis, HPV cancers, and pertussis
- C. Tell parent about the vaccinations that are mandatory for school entry and ask if they also want HPV vaccine
- D. Ask parent if they want to get HPV vaccination for their child or wait until the child is older

Review Question # 3

- A. Ask parent if child is sexually active and then discuss importance of HPV vaccination
- B. Tell parent that their child needs three vaccinations to prevent meningitis, HPV cancers, and pertussis
- C. Tell parent about the vaccinations that are mandatory for school entry and ask if they also want HPV vaccine
- D. Ask parent if they want to get HPV vaccination for their child or wait until the child is older

Want to Know When We Have New Resources and Tools?

**Send us an email to request our newsletter:
PreteenVaccines@cdc.gov**

We can help provide speakers for grand rounds and continuing education events, as well.

HPV Vaccine is Cancer Prevention

And YOU Are the Key!

#WeCanStopHPV