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

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)

3 million cases and $7 billion

American Cancer Society. 2008; Schiffman Arch Pathol Lab Med. 2003; Koshiol Insinga, Pharmacoeconomics, 2005
These HPV Types Cause:

- **Genital warts**
- ~66% of Cervical Cancers
- ~15% of Cervical Cancers

HPV Vaccine Comparison

<table>
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<th>HPV Types Included in Vaccine</th>
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- **Bivalent**
- **Quadrivalent**
- **9-valent**
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 13-26 years old who haven’t started or finished HPV vaccine series
Current ACIP Recommendations

- Routine vaccination at age 11 or 12 years* and series can begin at age 9.
- 3-dose series (0, 1–2, 6 months)
- Vaccination recommended through **age 26 for females** and through **age 21 for males** not previously vaccinated
- 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)

<table>
<thead>
<tr>
<th></th>
<th>9vHPV</th>
<th>4vHPV</th>
<th>2vHPV</th>
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<tbody>
<tr>
<td>Females</td>
<td>✔</td>
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<td>Males</td>
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NEW! 2-dose schedule

What is the new recommendation?
- FDA Approval, Oct 2016
- Males & females 9-14
- 9v vaccine; 0 and 6-12 months (≥6 months apart)

Why change the recommended schedule?
- High serologic response to vaccination
- Streamline vaccination schedule
- May facilitate implementation & increase acceptability
HPV VACCINE SAFETY

Vaccine efficacy: Ability of a vaccine to work as intended to protect from illness.

Vaccine-associated risk: Probability increased adverse event that harm the individuals or population.
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.

MMWR. 2014;63(RR05);1-30.
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
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

Among Girls in High-Income Countries

United States

HPV VACCINE COVERAGE
Adolescent Vaccination Coverage
United States, 2006-2013

MMWR 2014; 63(29);625-633.
Impact of Eliminating Missed Opportunities by Age 13 Years in Girls Born in 2000

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

FRAMING THE CONVERSATION
Clinicians Underestimate the Value Parents Place on HPV Vaccine

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.