What should you know about *Human papillomavirus* (HPV)?

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University of California, Los Angeles School of Nursing
Los Angeles, California
... were to build an HPV lesion...

- *You would need a few essential ingredients*....
Differentiating epithelium

Flattening of the epithelial cells, loss of the nucleus, ghost-like appearance at the outermost layer.
HPV Transmission

Sexual Routes

- Skin-to-skin contact of genital areas\(^1\)
  - Genital-genital, manual-genital, oral-genital contact\(^2-\)\(^4\)
  - Nonpenetrating sexual contact in virgins; rare\(^2\)
- Through sexual intercourse\(^5\)

Nonsexual Routes

- Self-inoculation from an infected site to a previously uninfected site\(^6\)
- Mother to newborn: vertical transmission; rare\(^7\)
- Fomites (eg, undergarments, surgical gloves, biopsy forceps)\(^8,\)\(^9\)
  - Hypothesized, but not well documented
Trauma that allows virus to penetrate to the basal membrane
Infection spreads laterally at first
Infection and consequent atypias begin to ascend
Grade III: Must have mitosis in upper 2/3 of epithelium
Estimated Annual Burden of HPV-Related Diagnoses in the United States

- >11,000-12,700 new cases of cervical cancer, 2007-2011¹
- >4,000 new cases of vulvar cancer¹,c
- >2,500 new cases of vaginal cancer ¹,c
- >5,500 new anal cancer cases among men and women in 2011 ¹,c

- 330,000 new cases of high-grade cervical dysplasia (CIN 2/3)²

- 1.4 million new cases of low-grade cervical dysplasia (CIN 1)²

- 1 million new cases of genital warts³

CIN = cervical intraepithelial neoplasia.

Overall, ~1/3 of women dx’d will die from their Cervical Cancer

## Common HPV Types Associated With Benign and Malignant Genital Disease

<table>
<thead>
<tr>
<th>HPV Types</th>
<th>Manifestations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Low-Risk</strong></td>
<td>6, 11</td>
</tr>
<tr>
<td></td>
<td>Benign low-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>Condylomata acuminata (genital warts)</td>
</tr>
<tr>
<td><strong>High-Risk</strong></td>
<td>16, 18, 31, 33, 45</td>
</tr>
<tr>
<td></td>
<td>Low-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>High-grade cervical changes</td>
</tr>
<tr>
<td></td>
<td>Cervical cancer</td>
</tr>
<tr>
<td></td>
<td>Anogenital and other cancers</td>
</tr>
</tbody>
</table>

HPV Types 6, 11, 16, and 18 in Cervical Cancer, Cervical Dysplasia, and Genital Warts

CIN = Cervical intraepithelial neoplasia
Cancer Types, Other Than Cervical Cancer, Attributable to HPV

Estimated percentage of cancer cases attributable to HPV

- Anal: 70%
- Vulvar: 50%
- Vaginal: 50%
- Penile: 50%
- Oropharyngeal: 20%

Prevalence of HPV in Vulvar and Vaginal Precancers and Cancers

VIN 2/3 (N=183)\(^1\)

- HPV Positive: 92%
- Type 16 or 18 Positive: 76%

ValN 2/3 (N=11)\(^1\)

- HPV Positive: 91%
- Type 16 or 18 Positive: 64%

Vulvar Cancer (N=48)\(^1\)

- HPV Positive: 60%
- Type 16 or 18 Positive: 42%

Vaginal Cancer (N=25)\(^2\)

- HPV Positive: 64%
- Type 16 Positive: 58%

VIN = vulvar intraepithelial neoplasia; ValN = vaginal intraepithelial neoplasia.

HPV Infection in the United States

- ~75% of population exposed to HPV
- 60% Presence of antibodies (negative HPV test)
- 10% Detected by colposcopy
- 4% HPV DNA positive: Colposcopy negative
- 1% Genital warts
- Not currently infected

HPV Infection in Young Women

HPV Infection in Young Women

While the Cumulative Incidence of HPV Infection After Sexual Debut Is High

*Not all HPV-6/11 specimens were individually tested for HPV 6 and HPV 11 separately.
†Types 31, 45, 51, 52, 55, 58, 56, 33, 35, 39, 40, 42, 53, 54.
… the Infection Rate for Any Specific Type Is Lower

*Not all HPV-6/11 specimens were individually tested for HPV 6 and HPV 11 separately.
†Types 31, 45, 51, 52, 55, 58, 56, 33, 35, 39, 40, 42, 53, 54.
Cervical Cancer

Rate per 100,000

Age at Diagnosis

Cervical Cancer Is Not an Equal Opportunity Disease

Healthcare Costs of Cervical HPV

*Average age adjusted to the 1998 US female population; all cost estimates were converted to 2002 dollars. ASC = atypical squamous cells; AGC = atypical glandular cells; LSIL = low-grade squamous intraepithelial lesion; HSIL = high-grade squamous intraepithelial lesion.

...for men, our original thoughts...

...results from new studies changed ideas about infection....
In males, unlike females, genital HPV infections appear to be common across the age span.

Figure 2. Prevalence of anal human papillomavirus (HPV) infection, by age, among 1305 men who have sex with women (MSW) and 176 men who have sex with men (MSM) in the HPV in Men (HIM) Study.

...genital HPV infections in men are differentially affected by HIV infection.
Table 3. Multivariate association between sociodemographic and behavioral factors and acquisition of human papillomavirus (HPV) infection.

<table>
<thead>
<tr>
<th>Factor</th>
<th>HPV infection, adjusted HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Any* (n = 285)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>High-school graduate or less</td>
<td>...</td>
</tr>
<tr>
<td>Some college/vocational school</td>
<td>...</td>
</tr>
<tr>
<td>College graduate/graduate school</td>
<td>...</td>
</tr>
<tr>
<td>Cigarette smoking</td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>1.0</td>
</tr>
<tr>
<td>Formerly</td>
<td>0.7 (0.3–1.6)</td>
</tr>
<tr>
<td>Currently</td>
<td>1.5 (0.7–2.9)</td>
</tr>
<tr>
<td>Age at first sexual intercourse (per-year increase)</td>
<td>...</td>
</tr>
<tr>
<td>Circumcised</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
</tr>
<tr>
<td>Yes</td>
<td>0.8 (0.4–1.9)</td>
</tr>
<tr>
<td>Lifetime no. of sex partners</td>
<td></td>
</tr>
<tr>
<td>0–4 partners</td>
<td>1.0</td>
</tr>
<tr>
<td>5–8 partners</td>
<td>2.4 (0.9–6.4)</td>
</tr>
<tr>
<td>9–16 partners</td>
<td>1.3 (0.5–3.4)</td>
</tr>
<tr>
<td>&gt;16 partners</td>
<td>2.8d (1.1–7.1)</td>
</tr>
</tbody>
</table>

**NOTE.** CI, confidence interval; HR, hazard ratio.

* Adjusted for cigarette smoking, circumcision, and lifetime no. of sex partners.
* Adjusted for age at first sexual intercourse, circumcision, and lifetime no. of sex partners.
* Adjusted for education and lifetime no. of sex partners.
* Statistically significant (P < .05).

Table 5. Multivariate association between sociodemographic and behavioral factors and clearance of human papillomavirus (HPV) infection.

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<tr>
<td></td>
<td>Any(^a) (n = 285)</td>
<td>Oncogenic(^b) (n = 285)</td>
<td>Nononcogenic(^c) (n = 285)</td>
<td></td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
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<td>Currently</td>
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<td>...</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td><strong>Age at first sexual intercourse (per-year increase)</strong></td>
<td>...</td>
<td>1.1 (1.0–1.2)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td><strong>Circumcised</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>1.0</td>
<td>1.0</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3.1(^d) (1.2–8.2)</td>
<td>6.5(^d) (2.1–19.7)</td>
<td>...</td>
<td></td>
</tr>
<tr>
<td><strong>Lifetime no. of sex partners</strong></td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td></td>
</tr>
<tr>
<td>0–4 partners</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
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<td>1.8 (0.7–4.6)</td>
<td></td>
</tr>
<tr>
<td>9–16 partners</td>
<td>0.7 (0.3–1.8)</td>
<td>1.8 (0.5–6.0)</td>
<td>1.5 (0.6–3.9)</td>
<td></td>
</tr>
<tr>
<td>&gt;16 partners</td>
<td>0.7 (0.3–2.0)</td>
<td>4.9(^d) (1.2–19.8)</td>
<td>1.9 (0.7–5.5)</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE.** CI, confidence interval; HR, hazard ratio.

\(^a\) Adjusted for cigarette smoking, circumcision, and lifetime no. of sex partners.

\(^b\) Adjusted for age at first sexual intercourse, circumcision, and lifetime no. of sex partners.

\(^c\) Adjusted for education and lifetime no. of sex partners.

\(^d\) Statistically significant (\(P < .05\)).

With National Consensus: Strategies for Prevention

- In females:
  - Vaccination to prevent cervical, vaginal, vulvar and anal high-grade squamous intraepithelial lesions (HSILs) and genital warts
    - Quadrivalent HPV vaccine (Gardasil, Merck & Co., Inc.)
    - Bivalent HPV vaccine (Cervarix, GlaxoSmithKline)
  - Screening to detect cervical atypias
  - Treatment of HSILs to prevent cancers

- In males:
  - Vaccination to prevent genital warts and anal HSIL
    - Quadrivalent HPV vaccine (Gardasil, Merck & Co., Inc.)
  - Digital anorectal exam, annually
  - Treatment for cancers
HPV Vaccines are:

- **Active Constituents:** Laboratory produced proteins, adjuvant
  - The L1 proteins self-assemble into VLPs.
  - Purified VLPs are adsorbed on aluminum-containing adjuvant.

- **Protein:** Recombinant DNA strategies
  - Gardasil® (HPV4): Saccharomyces cerevisiae; HPV6, 11, 16, 18
  - Cervarix® (HPV2): Bacilovirus; HPV16, 18

- **Adjuvant:**
  - Gardasil®: Amorphous aluminum hydroxyphosphate sulfate
  - Cervarix®: aluminum hydroxide & monophosphoryl lipid A (MPL)
Assembly of VLPs$^1$-$^3$

ACIP Recommendations: FEMALES

• Routine vaccination of 11 & 12 year old females with HPV4, in 3-doses
  – Vaccination as early as age 9 years
  – Vaccination recommended 13-26 year olds
    • not previously vaccinated
    • not completed the 3-dose series.

1. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). (2010). *MMWR Morb Mortal Wkly Rep*, 59(20), 626-629. doi: mm5920a4 [pii]
ACIP Recommendations: MALES

• Routine vaccination of 11 & 12 year old males with HPV4, in 3-doses
  – Vaccination as early as age 9 years
  – Vaccination recommended 13-21 year olds
    • not previously vaccinated
    • not completed the 3-dose series.
• Permissive: 22-26 year olds may be vaccinated

ACIP Recommendations: Timing

- For Doses 1 and 2
  - >4 weeks between dose 1 and 2
  - 8 weeks, optimally

- For Doses 2 and 3:
  - >12 weeks between dose 2 and 3

- Overall, time between doses 1 and 3
  - > 24 weeks.

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2. FDA licensure of quadrivalent human papillomavirus vaccine (HPV4, Gardasil) for use in males and guidance from the Advisory Committee on Immunization Practices (ACIP). (2010). MMWR Morb Mortal Wkly Rep, 59(20), 630-632. doi: mm5920a5 [pii]
Data published in 2010 show:

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Vaccine No.</th>
<th>Vaccine Cases</th>
<th>Control No.</th>
<th>Control Cases</th>
<th>Vaccine efficacy %</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per protocol efficacy†,§</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV 6, 11, 16, and/or 18-related</td>
<td>1,397</td>
<td>3</td>
<td>1,408</td>
<td>28</td>
<td>89.4</td>
<td>(65.5–97.9)</td>
</tr>
<tr>
<td>Intent to treat efficacy¶</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HPV 6, 11, 16, and/or 18-related</td>
<td>1,943</td>
<td>24</td>
<td>1,937</td>
<td>72</td>
<td>67.2</td>
<td>(47.3–80.3)</td>
</tr>
<tr>
<td>Any type-related</td>
<td>1,943</td>
<td>32</td>
<td>1,937</td>
<td>83</td>
<td>62.1</td>
<td>(42.4–75.6)</td>
</tr>
</tbody>
</table>

1. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). (2010). *MMWR Morb Mortal Wkly Rep*, 59(20), 626-629. doi: mm5920a4 [pii]
Data published in 2011 show:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Control No.</th>
<th>Control Cases</th>
<th>Vaccine No.</th>
<th>Vaccine Cases</th>
<th>Vaccine efficacy %</th>
<th>(95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genital warts</td>
<td>1,404</td>
<td>28</td>
<td>1,394</td>
<td>3</td>
<td>89.3</td>
<td>(65.3-97.9)</td>
</tr>
<tr>
<td>AIN1/2/3</td>
<td>208</td>
<td>24</td>
<td>194</td>
<td>5</td>
<td>77.5</td>
<td>(39.6-93.3)</td>
</tr>
<tr>
<td>AIN2/3</td>
<td>208</td>
<td>13</td>
<td>194</td>
<td>3</td>
<td>74.9</td>
<td>(8.8-95.4)</td>
</tr>
</tbody>
</table>

ACIP Recommendations: Coadministration of Vaccines

- Live or killed vaccines may be coadministered with Gardasil (HPV4) or Cervarix (HPV2)
  - Before, together with or after HPV vaccines
  - Rationale: HPV vaccine is neither killed or live vaccine strategy
  - Not all vaccines have been tested for coadministration in trials
  - See CDC recommendations for coadministration of multiple vaccines

1. FDA licensure of bivalent human papillomavirus vaccine (HPV2, Cervarix) for use in females and updated HPV vaccination recommendations from the Advisory Committee on Immunization Practices (ACIP). (2010). MMWR Morb Mortal Wkly Rep, 59(20), 626-629. doi: mm5920a4 [pii]
Conditional Completion Rate of HPV* Female Adolescents Aged 13-17 Years Old, 2012

Note 1: *Human Papillomavirus Vaccine, either quadrivalent or bivalent. Percentage of female adolescents who received 3+ doses HPV vaccine among females receiving 1+ dose with at least 24 weeks between the first dose and the time of household interview.

Note 2: Includes female adolescents born between January 1994 and February 2000
Source: National Immunization Survey - Teen (NIS - Teen)
Baseline HPV Status of Women Enrolled in Clinical Trials for GARDASIL

73% of subjects were naïve to all 4 vaccine HPV types.
Among subjects who were positive to a vaccine HPV type, most were positive to only 1 type.
Inclusion criteria included 4 or fewer sexual partners.

Data available on request from Merck & Co., Inc. Please specify information package 20651717(4)-GRD.
Baseline HPV Status of Women Enrolled in Clinical Trials for GARDASIL

Subjects Exposed to Any Vaccine HPV Type at Enrollment

Efficacy Studies—Combined Population

Baseline HPV Status

- 73% of subjects were naïve to all 4 vaccine HPV types.
- Among subjects who were positive to a vaccine HPV type, most were positive to only 1 type.
- Inclusion criteria included 4 or fewer sexual partners.

93% of subjects were naïve to ≥3 vaccine HPV types (6, 11, 16, or 18) at enrollment.

Data available on request from Merck & Co., Inc. Please specify information package 20651717(4)-GRD.
Baseline HPV Status of Women Enrolled in Clinical Trials for GARDASIL

Subjects Exposed to Any Vaccine HPV Type at Enrollment

Efficacy Studies—Combined Population

Baseline HPV Status:
- Naïve to all 4 types: 73%
- Positive to 1 type: 20%
- Positive to 2 types: 6%
- Positive to 3 types: 1.2%
- Positive to 4 types: 0.1%

27% of subjects had evidence of prior exposure to or ongoing infection with at least 1 of the 4 vaccine HPV types.

- 73% of subjects were naïve to all 4 vaccine HPV types.
- Among subjects who were positive to a vaccine HPV type, most were positive to only 1 type.
- Inclusion criteria included 4 or fewer sexual partners.

Data available on request from Merck & Co., Inc. Please specify information package 20651717(4)-GRD.
Baseline HPV Status of Women Enrolled in Clinical Trials for GARDASIL

### Subjects Exposed to Any Vaccine HPV Type at Enrollment

#### Efficacy Studies—Combined Population

#### Baseline HPV Status

- **Naïve to all 4 types**
- **Positive to 1 type**
- **Positive to 2 types**
- **Positive to 3 types**
- **Positive to 4 types**

Only 0.1% of subjects had evidence of prior infection with the 4 HPV types included in the vaccine.

- 73% of subjects were naïve to all 4 vaccine HPV types.
- Among subjects who were positive to a vaccine HPV type, most were positive to only 1 type.
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- Positive to 1 type
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Data available on request from Merck & Co., Inc. Please specify information package 20651717(4)-GRD.
Impacts

- HPV vaccines are prophylactic vaccines!

- Interesting results have been published since the first vaccine studies. These are not related to (FDA) on-label recommendation for vaccination:
  - Risk for high-grade cervical dysplasia in women vaccinated when asymptomatic but infected with HPV16/18 was lower than in placebo recipients.¹
  - One recently published small study shows longer time to recurrence for men who were HPV-vaccinated at the time high-grade anal dysplasia was treated.²

- More research is needed....

¹ who

Bridging the Efficacy of GARDASIL® From Young Adult Women to Adolescent Girls

- **Adolescent Girls**
  - 9 to 15 years of age
  - N = 1,121

- **Young Adult Women**
  - 16 to 26 years of age
  - N = 4,229

*GMT = Geometric mean titer in mMU/mL (mMU = milli-Merck units).
Prevalence of HPV in Sexually Active Women 18 to 26 Years of Age in National Longitudinal Study of Adolescent Health

- Can we discern behavioral and socio-demographic characteristics to help us target “high risk” young adult females for vaccination?

n=3,276 women 18 to 26 years of age

PCR<sup>a</sup> negative to all 4 vaccine types (6, 11, 16, 18)

PCR positive to at least 1 of the vaccine types (6, 11, 16, 18)

<sup>a</sup>PCR = polymerase chain reaction.
Prevalence of HPV in Sexually Active Women 18 to 26 Years of Age in National Longitudinal Study of Adolescent Health

- Can we discern behavioral and socio-demographic characteristics to help us target “high risk” young adult females for vaccination?
  - 3,276 18 - 26 years
  - National Longitudinal Study of Adolescent Health

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Prevalence of HPV in Sexually Active Women 18 to 26 Years of Age in National Longitudinal Study of Adolescent Health

- Can we discern behavioral and socio-demographic characteristics to help us target “high risk” young adult females for vaccination?
  - 

- Answer: probably not.
  - 0/3276 HPV 6, 11, 16, and 18 positive.
  - Coinfection with HPV 16/18 rare (0.4%).
  - Prevalence of any HPV infection - 27% using PCR assay.

PCR\textsuperscript{a} negative to all 4 vaccine types (6, 11, 16, 18)

PCR positive to at least 1 of the vaccine types (6, 11, 16, 18)

\textit{n=3,276 women 18 to 26 years of age}

\textsuperscript{a}PCR = polymerase chain reaction.
Prevalence of HPV in Sexually Active Women 18 to 26 Years of Age in National Longitudinal Study of Adolescent Health

- Usual risk factors were associated with HPV positivity for HPV6, 11, 16 & 18
  - Sex partner > 2 years older
    - ORadj=2.1 (1.3, 3.4)
  - > 3 lifetime sex partners
    - ORadj=1.7 (1.0-2.7)
  - New sex partner last 12 months
    - ORadj=2.1 (1.3-3.2)

n=3,276 women 18 to 26 years of age

PCR\(^a\) negative to all 4 vaccine types (6, 11, 16, 18)
PCR positive to at least 1 of the vaccine types (6, 11, 16, 18)

Prevalence of HPV in Sexually Active Women 18 to 26 Years of Age in National Longitudinal Study of Adolescent Health

91%

9%

• MORE IMPORTANT:

• In this sample, previously published data and these prevalence data show *everyone* would have benefited by vaccination

  • 0/3274 were positive for all 4 types

PCR\(^a\) negative to all 4 vaccine types (6, 11, 16, 18)

PCR positive to at least 1 of the vaccine types (6, 11, 16, 18)

\(n=3,276\) women 18 to 26 years of age

\(^a\)PCR = polymerase chain reaction.
Estimated Population-Level Impact of Not Vaccinating Women With >3 Lifetime Sex Partners

- Of the estimated 2.5 million women with >3 sex partners:
  - 12% would already be currently infected with 1 or more HPV vaccine types.
  - 88% would not be currently infected with 6, 11, 16, and/or 18.

- The population-level impact of not vaccinating women with >3 lifetime sex partners means an estimated 2.2 million women who could potentially benefit would not be vaccinated.

Vaccination based upon *risk-factor analysis* would cause HPV vaccines to be withheld from a large number of women without evidence of current infection.

– Albeit that analyses for males have not been performed, no current evidence suggests risk-factor based vaccination is credible.

The presence or absence of risk factors for infection seems a poor strategy for HPV catch-up vaccination of young adults.

The ACIP does not recommend a risk-based immunization strategy for HPV vaccination.

Thank you!