Latest HPV Science

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Outline:

• Discussion of Latest and Emerging Science
• State of Vaccination and Review of Available Vaccines
• A Focus on Health Care Providers
Papillomaviruses

- Papillomaviruses are small double-stranded DNA viruses that infect squamous epithelia.
- They are species specific.
  - Therefore Human Papillomavirus (HPV) only infects humans.
- This virus is classified according to its tissue tropism (mucosal or cutaneous) and oncogenic potential.
Human Papillomavirus (HPV)

- HPV is a virus family with over 100 types
- 40 types infect human mucosal surfaces
  - These types discussed as sexually transmitted
- Certain types (~25) are **oncogenic** (high risk) and persist to cause cancers
- Certain types are **Non oncogenic** (low risk) cause genital warts (condyloma) and rarely, juvenile-onset recurrent respiratory papillomatosis (RRP)
HPV mucosal types

- **U.S. & Globally HPV is the most common STI**
- **79 million** Americans are currently infected, with **14 million** new cases each year
- **U.S. estimated cost** for preventing and treating HPV diseases is ~$8.0 billion
- **National prevalence data** (documented rates):
  - Females as high as 53.8% (ages 20-24 yrs)
  - Males ranging from 52% to 69%
- **290 million** women globally have HPV
- **Disparities in STIs** exist in the adolescent population - same is true for HPV
  - Approximately 50% of all new HPV infections are among youth ages 15-24

(CDC, 2013; WHO 2014; Dunne, 2011; Giuliano, 2009)
HPV

- Most infections are asymptomatic, transient, intermittent
- The vast majority of infected people will clear mucosal HPV infections without clinical consequences
  - However- its role in the pathogenesis of malignant tumors has been well documented
  - For example: Median duration of cervical infection ranges between 4-20 months
- Re-infection occurs! No building of immunity against subsequent infection- even the same strain
- Also re-activation is possible

(Trottier, 2011)
Example: HPV progression to CA, Cervix

Major Steps in Cervical Carcinogenesis

- Normal Cervix
- Infection/ Clearance
- HPV Infected Cervix
- Persistence (1 to 10 years) → Regression
- CIN-3/ Pre-Cancers
- Mild Cytologic Abnormalities
- Infection → CANCER
HPV Transmission

• Predominate route is via **sexual contact**
  ▫ Genital to genital contact
  ▫ Oral to genital (oral sex)
  ▫ Vaginal and anal intercourse

• Vertical transmission (far less common, but possible)
  ▫ Mother to child- not well understood

• Horizontal transmission and other route?
  ▫ Possible routes include: fingers and mouth, and skin contact outside of sexual contact
  ▫ ? Self inoculation to other sites
HPV Transmission

- Males and females may have HPV and transmit it without knowing
  - Transmission occurs without outward signs and symptoms
- Persons can still have HPV even if they have not had sexual contact for years
- It is possible to carry more than one type of HPV

- It is difficult to determine transmission, duration, and incubation—may take months or years for any abnormalities to appear
Oncogenic HPV

- HPV is the known cause of cancers:
  - Cervical
  - Anogenital neoplasm (anal, vaginal, vulvar, and penile)
  - Oropharyngeal/ head & neck
    - throat, tongue, tonsil
  - Also implicated in non-melanoma skin cancer, and suspected to play a role in a few other neoplasms
U.S. data

HPV Cancers

- In general overall incidence of CA in the U.S. has decreased for men and is stable for women
- However, rates have increased for 2 HPV associated CA: oropharyngeal and anal
- HPV associated CA accounts for
  - 3.3% of cancers in women (~21,700 cases/yr)
  - 2% of cancers in men (~11,700/ yr)
- HPV related cancers for men are on the rise and affect younger men 3:1

Condylomas

- HPV caused anogenital and oral condylomas are pervasive
  - ~ 1 million new cases each year
### CDC: Number of HPV-Attributable Cancer Cases per Year

<table>
<thead>
<tr>
<th>Cancer site</th>
<th>Average number of cancers per year in sites where HPV is often found (HPV-associated cancers)</th>
<th>Percentage probably caused by HPV</th>
<th>Number probably caused by HPV†</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Both Sexes</td>
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<tr>
<td>Anus</td>
<td>1,549</td>
<td>2,821</td>
<td>4,370</td>
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<tr>
<td>Cervix</td>
<td>0</td>
<td>11,422</td>
<td>11,422</td>
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<tr>
<td>Oropharynx</td>
<td>9,974</td>
<td>2,443</td>
<td>12,417</td>
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<td>Penis</td>
<td>1,048</td>
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<td>1,048</td>
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<td>Vagina</td>
<td>0</td>
<td>735</td>
<td>735</td>
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<td>Vulva</td>
<td>0</td>
<td>3,168</td>
<td>3,168</td>
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<td>TOTAL</td>
<td>12,571</td>
<td>20,589</td>
<td>33,160</td>
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</table>

†Individual cells may not sum to total due to rounding.
Men’s HPV Related Cancers

• Rates are on the rise and numbers under represent actual problem due to lack of screening and knowledge in male population

• Oropharyngeal cancers obviously concerning
  ▫ Accounts for 78.2% of all HPV cancers for men
  ▫ Risks: engaging in oral sex, multiple sex partners, marijuana use, cigarette use

CDC, 2011; NCI, 2011; Jemal et al. 2013
Cervical Cancer

• In U.S. cervical cancer death rate has decreased by 74% (1955-1992) due to Pap screening for cervical cancers

• Disparities exist in the U.S. (socioeconomic, region, racial/ethnic)

• Disparities even more evident globally:
  ▫ Developing countries- Access to screening is low
  ▫ 2nd/3rd most common cancer diagnosis
  ▫ 4th leading cancer causing death
HPV associated cancers

![Pie charts showing the distribution of HPV associated cancers by gender.]

Total (N = 34,788)
- Oropharynx: 32.7% (n = 11,388)
- Anus: 2.1% (n = 734)
- Cervix: 9.3% (n = 3,242)
- Vagina: 15.6% (n = 5,434)
- Vulva: 2.9% (n = 1,001)
- Penis: 37.3% (n = 12,989)

Men (N = 13,446)
- Oropharynx: 78.2% (n = 10,511)
- Anus: 7.4% (n = 1,001)
- Cervix: 14.4% (n = 1,934)

Women (N = 21,342)
- Oropharynx: 11.6% (n = 2,478)
- Anus: 16.4% (n = 3,500)
- Cervix: 53.4% (n = 11,388)
- Vagina: 3.4% (n = 734)
- Vulva: 15.2% (n = 3,242)
Non-Oncogenic HPV Infections

• Genital Warts (condylomata acuminate)
• Low-grade squamous intraepithelial lesions LSIL (found on cervical cytology)
• Oral papillomas
• Conjunctival papillomas
• Rare instance of recurrent respiratory papillomatosis (RRP)
Non-Oncogenic HPV Infections

- **Genital warts (condyloma)**
  - caused by HPV type 6 or 11
  - **S/S:** asymptomatic, but depending on size/location they can be painful or itch
  - **Location:** generally near introitus (female) or under foreskin or on shaft of penis (male)
    - Can also occur on the cervix, vagina, urethra, perineum, perianal skin, anus or scrotum
  - **Treatment:** patient applied creams/gels, cryotherapy, podophyllin resin, TCA, BCA, or surgical removal
Non-Oncogenic HPV Infections

- Juvenile onset recurrent respiratory papillomatosis (RRP)
  - Rare occurrence, but most common benign neoplasm of children’s larynx
  - Impact to quality of life - dysphonia (hoarseness, may also become short of breath) and numerous surgical therapies
  - Condyloma in pregnancy is highly predictive
    - Evidence suggests vertical transmission (6 & 11)
  - Incidence is hard to determine
    - About 820 children per year
Vaccination has been established as the primary preventative strategy to reduce HPV related diseases.

“HPV vaccination, one of the most remarkable discoveries of the past decade, is currently implanted all around the world and is expected to prevent a substantial proportion of cervical and other HPV-related cancers in the future”

(Trottier, 2011)
CDC/ACIP HPV Vaccine Recommendation

- All children (male & female) age 11-12 yrs
- Catch up vaccination for females up thru age 26
- Catch up vaccination for males up thru age 21
  - Vaccination for males thru age 26 if: MSM or immunocompromised
- Vaccine given in 3-dose series (0, 2, 6 months)
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<tr>
<th>Vaccines</th>
<th>Birth</th>
<th>1 mo</th>
<th>2 mos</th>
<th>4 mos</th>
<th>6 mos</th>
<th>9 mos</th>
<th>12 mos</th>
<th>18 mos</th>
<th>19-23 mos</th>
<th>2-3 yrs</th>
<th>4-6 yrs</th>
<th>7-10 yrs</th>
<th>11-12 yrs</th>
<th>13-15 yrs</th>
<th>16-18 yrs</th>
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<tr>
<td>Hepatitis B&lt;sup&gt;1&lt;/sup&gt; (HepB)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
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<td>4&lt;sup&gt;th&lt;/sup&gt; dose</td>
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<td>Rotavirus&lt;sup&gt;2&lt;/sup&gt; (RV)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; dose</td>
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<td>Diphtheria, tetanus, &amp; acellular pertussis&lt;sup&gt;3&lt;/sup&gt; (DTaP; &lt;7 yrs)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
<td>3&lt;sup&gt;rd&lt;/sup&gt; dose</td>
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<td>Tetanus, diphtheria, &amp; acellular pertussis&lt;sup&gt;3&lt;/sup&gt; (Tdap; ≥7 yrs)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
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<td>Haemophilus influenzae type b&lt;sup&gt;4&lt;/sup&gt; (Hib)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
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<td>Pneumococcal conjugate&lt;sup&gt;5,6&lt;/sup&gt; (PCV13)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
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<td>2&lt;sup&gt;nd&lt;/sup&gt; dose</td>
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<td>Measles, mumps, rubella&lt;sup&gt;9&lt;/sup&gt; (MMR)</td>
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<td>Varicella&lt;sup&gt;10&lt;/sup&gt; (VAR)</td>
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<tr>
<td>Human papillomavirus&lt;sup&gt;12&lt;/sup&gt; (HPV2: females only; HPV4: males and females)</td>
<td>1&lt;sup&gt;st&lt;/sup&gt; dose</td>
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</table>

**Footnotes:**

1. **HepB**: Hepatitis B vaccine.
2. **RV**: Rotavirus vaccine.
3. **DTaP**: Diphtheria, tetanus, and acellular pertussis vaccine.
4. **Hib**: Haemophilus influenzae type b vaccine.
5. **PCV13**: Pneumococcal conjugate vaccine (13-valent).
6. **PPSV23**: Pneumococcal polysaccharide vaccine (23-valent).
7. **IPV**: Inactivated poliovirus vaccine.
8. **MMR**: Measles, mumps, rubella vaccine.
9. **VAR**: Varicella vaccine.
10. **HepA**: Hepatitis A vaccine.
11. **HPV2**: Human papillomavirus vaccine (2-valent: females only).
12. **HPV4**: Human papillomavirus vaccine (4-valent: males and females).

**Legend:**

- **Range of recommended ages for all children**
- **Range of recommended ages for catch-up immunization**
- **Range of recommended ages for certain high-risk groups**
- **Range of recommended ages during which catch-up is encouraged and for certain high-risk groups**
- **Not routinely recommended**
HPV Vaccines

• Bivalent Vaccine (Cervarix®)(HPV2)
  ▫ HPV 16 and 18
    • HPV related pre-cancers and cancers

• Quadrivalent Vaccine (Gardasil®)(HPV4)
  ▫ HPV 6, 11, 16 and 18
    • HPV related pre-cancers and cancer
    • Genital warts in women and men

• Nanovalent Vaccine (Gardasil 9®)(HPV9)
  ▫ HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58
    • HPV related pre-cancers and cancer
    • Genital warts in men and women
    • Now ~90% coverage for cervical cancers
Relative Contribution of HPV Types in 9vHPV Vaccine to Cervical Cancers Worldwide

Vaccine Safety

• According to the National Cancer Institute there has not been any serious side effects and the most common problems have been brief soreness and/or local symptoms at the injection site

• The most common adverse events have been reported as (rate per 100,000 doses):
  ▫ Syncope (8.2), local site reactions/pain (7.5), dizziness (6.8), nausea (5.0), headache (4.1), hypersensitivity (3.1), itching (2.6)
  ▫ These events not greater than any other vaccine

• More than 46 million does of vaccine have been distributed in the US as of June 2012 (primarily Gardasil®)

• HPV9 reports similar safety profile
HPV vaccines are effective

- HPV4 and HPV2 available ~ 10 years
- Largest multinational trials of HPV4 efficacy:
  - Women > 1 dose, 100% efficacy against cervical precancers (16&18) and 93% efficacy against all precancers irrespective of type
  - Males 90.4% efficacy to external genital lesions and nearly 80% efficacy against anal intraepithelial neoplasia
- In a large international clinical trial of Gardasil9, reported efficacy for the 5 additional HPV types was documented at 96.7%
In the U.S.

- Hi efficacy has been found for prevention of vaginal and vulvar pre-cancers and genital warts
- Large pre-licensure trials of HPV4
  - Tracked incidence of cervical pre-cancers
  - No cases of cervical pre-cancers in more than 8000 females (ages 16-23) who received HPV4 compared to 53 cases in age-matched placebo controls
- In the 4 yrs post availability in U.S. prevalence of types 6, 11, 16, & 18 in females (ages 14-19) decreased by 56%
Australia: world leader in vaccination

• 90% of Australian adults view vaccines as positive
• Broad national school based vaccine programs are effective
• Australia has achieved over 83% vaccine coverage in females ages 12-13 having ≥ 1 dose
• This has lead to **near elimination** of HPV **6 & 11** and **75% decreased incidence** of **16 & 18**
• Current 2014 national incidence of genital warts for those <21 = 0%; previous rates at 25%
The near disappearance of genital warts in young women 4 years after commencing a national human papillomavirus (HPV) vaccination program (2011) 

Sexually Transmitted Infection
Early effect of the HPV vaccination programme on cervical abnormalities in Victoria, Australia: an ecological study

*The Lancet*, 2011

![Image of graphs showing incidence of high-grade cervical abnormalities by age group](image-url)
WE FALL WELL BEHIND OTHER DEVELOPED COUNTRIES

WE FALL SHORT OF U.S. NATIONAL GOALS
Vaccine uptake in U.S.

• CDC’s Advisory Committee on Immunization Practices (ACIP) is concerned about current rate of vaccination

• Not on target to meet *Health People 2020 goals* - 80%

  ▪ **39.7% females** 13-17 years ≥ 3 doses; 60% ≥ 1 dose
  ▪ **21.6% males** 13-17 years ≥ 3 doses; 41.7% ≥ 1 dose

(MMWR 2015, 2014 NIS-Teen)
Rates in U.S. vary drastically

• After experiencing no progress 2011 & 2012 now seeing modest increases with bigger CDC push

• 2015 data for ≥ 1 dose- Females
  ▫ ≥ 1 dose: RI 76% to Kansas 38.3%
  ▫ ≥ 3 dose: DC 56.9% to Tennessee 20.1%

• In late 2014, DC expanded existing school requirement for HPV to included males and females thru 12th grade

• We are seeing pattern of providers delaying vaccine, and not giving when recommended.
Figure 2: Completion of 3-dose HPV series in US females 13-17 years of age, 2013

Overall US coverage among female adolescents is 37.6%

Source: CDC. MMWR Wkly Rep. 2014;63;29
Why vaccinate at age 11-12

- Simultaneous administration of all recommended vaccines at age 11-12 increases likelihood of adolescent receiving all vaccines on schedule
- ***Younger adolescents (before age 15/pubertal changes) have 2 to 3 fold higher HPV antibody levels after immunization as compared to older adolescents/young adults***
  - This is why 2 dose vaccine will only be recommended for those 9-13 years of age
- Lastly, vaccination prior to ANY sexual activity/contact has been demonstrated to provide greatest effectiveness
On the horizon... *changes in dosing?*

- Current dosing **HPV4** and **HPV9**- IM- 3 doses (0, 2, 6 month schedule)
- World Health Organization (WHO) (2014) now recommend a 2-dose schedule (0 and 6 months)
  - This recommendation was following the results of a systematic review of 3 randomized studies reporting non-inferior immunogenicity among females ages 9-14 years
  - WHO’s new recommendation is: 2-dose schedule for females and males ages 9 to 13 years and 3-dose schedule for those ≥ 14 years
- The 2-dose alternative is currently being discussed and evaluated by the ACIP
- The FDA has not currently approved a 2-dose schedule; however a 2 verses 3 dose trial of HPV9 has been initiated
Factors contributing to parents not vaccinating their child

- Lack of clear HPV recommendation from HCP
- Not aware vaccine is recommended - particularly for males
- Concerns for safety
- Lack of knowledge about number and types of cancers HPV causes
- Son or daughter too young/ not sexually active
- Cost
A Focus on HCP!

- Provider recommendation has been established as the single most important predictor of vaccine uptake
  - Youth whose HCP recommended HPV vaccination are 5 to 23 times more likely to be vaccinated than those who did not
  - Large national surveys show rates of consistent vaccine recommendation for females ranging from only 30 to 52%
  - Recommendation is even lower for males, <15% of providers report “always recommending” to males ages 11-12 years
- Culture of vaccine hesitancy in U.S.
Factors contributing to HPC HPV vaccine hesitancy

- Lack of HPV knowledge and understanding of HPV diseases—especially for males
- Safety concerns
- Concerns re administration reimbursement
  - Leads to preference for vaccinating older adolescents
- Anticipated parental resistance
- Lack of time
- Lack of systems to remind them to offer vaccine
Responding to Parental/Patient Concerns

- HPV vaccines do not increase promiscuity
  - There is no data to support this idea and few parents actually believe it; however parents will frequently justify non-vaccination with this belief (liddon et al, 2012; Bednarczyk et al, 2012; Forster et al, 2012; Brewer et al, 2011; Schuler et al, 2011)
- HPV vaccines do not cause more pain than other vaccines (Reiter et al., 2009)
- HPV vaccines do not cure or treat existing HPV infections or cancer
  - They are effective only when given before exposure to HPV
Parents and patients want providers to exhibit high levels of confidence in and knowledge about HPV vaccines

Parents want to know if provider would recommend HPV vaccine to their family members

If a provider recommended HPV vaccine they would get vaccinated or have their child vaccinated

Parents were under educated about HPV diseases for males and females

Parents were unaware of vaccine availability for males
Strength of Communication & Recommendations

1. Recommend HPV vaccine with same strength and conviction as other adolescent vaccines
   ▫ Consider alternating order in which vaccines are recommended
   ▫ Parents respond better to direct communication rather than participatory discussions

2. Educate YOURSELF about HPV and HPV vaccines

3. Inform your colleagues and staff so that everyone in the practice is delivering the same message
Strength of Communication & Recommendations

4. Communicate vaccination benefits to parents and adolescents

5. Make vaccination procedures routine and focus on ways to reduce missed opportunities
   - Bundling of services to support vaccination, consider vaccinating at:
     - Any other Vaccine Visit (including Flu)
     - With any Annual Exam or School/Sports Check
     - With any STI check, HIV test, or Pap Test
Supporting 3-dose completion

- Be flexible and creative
- Set up a reminder system for the office and patient/patient family
  - Call backs, texts, etc.
- Consider prompts in the EMR
- Don’t be too strict on vaccine dosing regimen
  - **Ideal**: Dose 1, then Dose 2 at 2 months, then Dose 3 at 6 months after the first dose.
  - There is NO maximum interval between doses- if series is interrupted you do not need to restart- just continue on
HPV vaccine precautions & contraindications:

- Pregnancy
  - If found pregnant after dose 1, just complete the last 2 doses after delivery
- History of immediate hypersensitivity to any vaccine component
  - Yeast*
- Moderate or severe illness
- Don’t use Cervarix for people with latex allergy- it has latex in rubber stopper

*Note: you can give HPV vaccine to patients who are lactating, have minor acute illnesses, positive pap tests or genital warts, immunocompromised
Lessons learned

- Herd immunity is important
- Need high levels of vaccination to achieve effect, predicted to need at least 50-70% completion rates of vaccination to reduce or nearly eliminate genital warts
- Need higher levels to achieve significant reductions in cervical, oral, and anal cancers (70% vaccine complete)
- Potentially even higher to achieve effect for MSM
- Early impact data in U.S. is emerging, showing a decline in 6, 11, 16, & 18 of 56% among females after vaccine introduction