Anogenital Cancers and Other HPV-Associated Disorders

Maximizing the Population Impact of Vaccines as a Prevention Strategy

Jessica Kahn, M.D. M.P.H.
CCTST Grand Rounds

December 14, 2012
Clinical Case

- Hannah, a 16-year-old, presents for a health maintenance visit; she confides in you that she has recently initiated sex
- At end of visit you recommend HPV vaccination but Hannah is hesitant and her mother declines
  - “I’ve read that vaccine isn’t safe, and I don’t think she really needs the ‘sex shot’ because she’s a responsible kid. Anyway, I’ve heard that girls don’t really need the vaccine if they just get Pap tests.”
Questions Raised by Case

• How effective and safe are HPV vaccines?
• What is uptake like?
• What challenges are clinicians experiencing in recommending HPV vaccines?
• How can we address those challenges to maximize the public health impact of HPV vaccination?
• How much of an impact will we achieve by vaccinating sexually active adolescents?
• How will the introduction of this vaccine affect HPV epidemiology in our community?
Topics/Learning Objectives

- Background on HPV-related disease and HPV vaccine efficacy, safety, and uptake
- Evidence re: factors driving suboptimal vaccination rates in the targeted age group
  - Clinician recommendations
  - Parent/adolescent acceptance
- Implications for addressing delivery challenges and improving vaccine uptake
- Impact of HPV vaccine introduction on HPV epidemiology in our community – key role of community-level research
HPV Acquisition

- Many U.S. adolescents initiate sex at a young age
  - 6% before 13 years of age, 33% of 9th graders (2011)
- Forced sex common
  - 14.5% of 12th grade girls physically forced (2011)
- HPV acquired soon after sexual initiation
  - Study of adolescents with 1 sexual partner
    - Median time from first sex to HPV infection - 3 mos
HPV Epidemiology: Cincinnati
Sexually Experienced 13-26 y/o Women

Shikary, J Clin Virol 2009
Implications for Prevention

- Primary prevention must begin early
- Consider when advising teens and parents who wish to defer HPV vaccination
HPV Types and Clinical Sequelae

~130 types (genetic similarities in L1)

HPV Types

Cutaneous

Mucosal (anogenital, aerodigestive) ~40 types

Low-risk
e.g. 6,11

- Genital warts
- Recurrent respiratory papillomatosis

High-risk
e.g. 16,18

- Cervical precancer, cancer
- Other anogenital cancers
- Oropharyngeal cancers
Genital Warts

~90% caused by HPV-6 and HPV-11
HPV Causally Associated with Cervical Cancer

- Genetic and epidemiologic evidence that HPV is a necessary cause of cancer so strong that genital high-risk HPVs considered human carcinogens
- HPV present in virtually 100% of cervical cancers
- Oncogenic proteins E6 and E7 interfere with tumor suppressor function and cell cycle control

Bosch, J Clin Pathol 2002
Cervical Carcinogenesis

Normal Cervix

HPV-Infected Cervix

Mild Pap abnormalities and/or dysplasia

Precancer

Infection

Clearance

Persistence of HR HPV

Progression

Regression

Invasion

Cervical Cancer

Schiffman, J Natl Cancer Inst Monogr 2003
Pap Screening: Secondary Prevention

- Normal Cervix
- HPV-Infected Cervix
- Mild Pap abnormalities and/or CIN
- Precancer
- Cervical Cancer

- Persistence of HR HPV
- Progression
- Regression
- Clearance
- Infection
- Invasion
HPV Vaccines: Primary Prevention

- Normal Cervix
- HPV-Infected Cervix
- Mild Pap abnormalities and/or CIN
- Persistence of HR HPV
- Progression
- Regression
- Clearance
- Invasion

HPV-Infected Cervix → Precancer → Cervical Cancer

Infection → Clearance

Persistence of HR HPV → Progression → Regression

Invasion
HR HPV Types That Cause Squamous-Cell Cervical Cancer Worldwide

- HPV 16: 52%
- HPV 18: 14%
- HPV 16 and 18: 15%
- HPV 31: 5%
- HPV 45: 3%
- HPV 52: 3%
- HPV 58: 3%
- HPV negative: 2%
- All other HPV types: 3%

## High-Risk HPV Associated with Other Cancers

<table>
<thead>
<tr>
<th>Tissue</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical</td>
<td>100%</td>
</tr>
<tr>
<td>Anal</td>
<td>90%</td>
</tr>
<tr>
<td>Vaginal</td>
<td>50%</td>
</tr>
<tr>
<td>Vulvar</td>
<td>50%</td>
</tr>
<tr>
<td>Penile</td>
<td>50%</td>
</tr>
<tr>
<td>Oropharyngeal</td>
<td>12%</td>
</tr>
</tbody>
</table>

Parkin, Vaccine 2006
Cervical Cancer: U.S.

- Organized Pap screening program
- 9th most common cancer in women
- ~12,000 women diagnosed, ~4,000 die annually
- Direct medical costs > $4 billion, indirect $1.3 billion

WHO/ICO, 2009; Hildesheim, 1999; Insigna, 2005
Few countries have organized Pap screening

Cervical cancer second most common cancer in women worldwide, most common in many low-income countries

Rates are rising

~ 490,000 new cases, 270,000 deaths/year

Disease of women in 30s-50s → largest single cause of years of life lost to cancer in the developing world

WHO/ICO, 2009
Limitations of Current Primary/Secondary Prevention Strategies

- Abstinence and condoms reduce risk but limited use restricts their population-level impact
- Organized Pap screening programs nonexistent in most low and middle income countries
- Pap screening program in U.S. not a panacea
  - Racial/ethnic/economic disparities in Pap screening and cervical cancer mortality
  - ~27% of screened women do not return for ≥ 5 years
  - Screening and treatment of precancerous lesions is costly and associated with morbidity
HPV Vaccines

- Antigen is HPV L1 capsid protein
- Expressed using recombinant technology – proteins self-assemble into virus-like particles (VLPs)
- Quadrivalent vaccine (Gardasil®) - HPV-6, 11, 16, 18 VLPs
- Bivalent vaccine (Cervarix®) – HPV-16, 18 VLPs
- VLPs identical to HPV virions, but no viral DNA core
  - Induce virus-neutralizing Ab response, but no infectious or oncogenic risk
HPV Vaccine Clinical Trials

- Quadrivalent vaccine
  - Women 9-45 yrs, men 9-26 yrs

- Bivalent vaccine
  - Women 10-55 yrs, men 10-18 yrs

- Trials evaluate efficacy for prevention of surrogate endpoints for cancer; e.g. precancers
Immune Responses

- Seroconversion rates high: $\geq 97.5\%$ for both vaccines
- Both vaccines induce high concentrations of type-specific neutralizing antibodies to L1, logarithmically higher than after natural infection
- Responses 1.7-2.7 x higher in younger vs. older
- Vaccination appears to induce immunologic memory

Clinical Efficacy

- **Bivalent/quadrivalent vaccines**: >90% efficacy in preventing persistent HPV infection and anogenital precancers caused by HPV-16, 18 in women

- **Quadrivalent vaccine**: >90% efficacy in preventing external genital lesions and anogenital precancers caused by HPV-6, 11, 16, 18 in men and women

- *IF* ...
  - Naïve to vaccine types when vaccinated
  - Received all doses according to schedule

Villa 2006; Garland 2007; Brown 2009; Paavonen 2009
**BUT ...**

- Efficacy lower for conditions caused by any HPV type, and among those who may have already been infected with HPV
- In those currently infected (HPV DNA+), vaccines have no efficacy, do not facilitate clearance

**THUS ...**

- Vaccination must occur prior to sexual initiation to maximize effectiveness
Established/Potential Health Impact of Vaccination

<table>
<thead>
<tr>
<th>Established</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical/vulvar/vaginal precancers</td>
<td>Women</td>
</tr>
<tr>
<td>Anal and penile precancers</td>
<td>Men</td>
</tr>
<tr>
<td>Genital warts</td>
<td>Women, Men</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Potential</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical, vulvar, vaginal cancer</td>
<td>Women</td>
</tr>
<tr>
<td>Anal and penile cancer</td>
<td>Men</td>
</tr>
<tr>
<td>Recurrent respiratory papillomatosis</td>
<td>Women, Men</td>
</tr>
<tr>
<td>Other HPV-associated cancers (head/neck)</td>
<td>Women, Men</td>
</tr>
</tbody>
</table>
Vaccine Safety: Clinical Trials Data

- > 50,000 enrolled in clinical trials
- Both HPV vaccines generally safe and well-tolerated
- **Mild local** adverse events - *common*
  - Pain, redness, swelling
- **Mild systemic** adverse events - *uncommon*
  - Headache, muscle aches, fever
- **Serious** adverse events – *rare*
  - *No* increased risk vaccine vs. placebo
Vaccine Safety: Post-Marketing Data

- > 46 million doses distributed in U.S. as of June 2012
- Pregnancy safety registry – Merck
  - No concerns to date
- CDC - VAERS
  - Most frequently reported symptoms: fainting (13%), dizziness (11%), nausea (9%), pain (8%)
  - Rare reports of serious illness or death have been investigated – none to date shown to be causally associated with vaccination
Reviewed safety in 2009 and concluded -

- Both vaccines well tolerated, good safety profiles
- No serious adverse events of consequence
<table>
<thead>
<tr>
<th></th>
<th>Girls</th>
<th>Boys</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bivalent vaccine</td>
<td>• Routine vaccination of 11-12 year-olds</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>• Vaccination of 13-26 year-olds not previously vaccinated</td>
<td>• Routine vaccination of 11-12 year-olds</td>
</tr>
<tr>
<td>Quadrivalent</td>
<td></td>
<td></td>
</tr>
<tr>
<td>vaccine</td>
<td></td>
<td>• Vaccination of 13-21 year-olds not previously vaccinated</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Vaccination of 22-26 year-olds if MSM or immunocompromised</td>
</tr>
</tbody>
</table>
HPV Vaccine Uptake, 2009-2012
Females Receiving ≥ 1 Dose

CDC sentinel site data, presented at ACIP meeting June 2012
HPV Vaccine Uptake, 2009-2012
Males Receiving ≥ 1 Dose

CDC sentinel site data, presented at ACIP meeting June 2012
Summary

- HPV is common, acquired soon after sexual initiation
- HPV vaccines highly effective, safe and well-tolerated
- Targeted age group for vaccination of girls and boys is 11-12 years, but uptake is suboptimal – **why?**
- Potential public health impact globally is tremendous if high vaccination rates can be achieved among girls and boys who have not yet initiated sex – **how?**
Strategy Unlikely to Work with Adolescents

Slowly he would cruise the neighborhood, waiting for that occasional careless child who confused him with another vendor.
Public Health Impact Depends on Effective Systems for Vaccine Delivery and Uptake

- Approval by the FDA
- Recommendations by ACIP, professional organizations
  - Vaccine supply
  - Affordability/access
  - Provider recommendation
  - Parent, adolescent acceptance
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Provider Recommendations for HPV Vaccination to Girls, 2009 and 2011

National samples of primary care physicians in 2009 (N=1013) and 2011 (N=928)

Vadaparampil et al., unpublished data
## Factors Associated with Recommendation

<table>
<thead>
<tr>
<th>Predictor</th>
<th>AOR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty</td>
<td></td>
</tr>
<tr>
<td>Family Physician</td>
<td>1.0 (Ref)</td>
</tr>
<tr>
<td>Pediatrician</td>
<td>3.3 (2.3–4.7)</td>
</tr>
<tr>
<td>Ob/Gyn</td>
<td>2.0 (1.2–3.3)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
</tr>
<tr>
<td>50+</td>
<td>1.0 (Ref)</td>
</tr>
<tr>
<td>40–49</td>
<td>1.0 (0.7–1.5)</td>
</tr>
<tr>
<td>25–39</td>
<td>2.0 (1.3–3.1)</td>
</tr>
<tr>
<td>Perceived barriers related to HPV vaccination</td>
<td></td>
</tr>
<tr>
<td>High</td>
<td>1.0 (Ref)</td>
</tr>
<tr>
<td>Medium</td>
<td>1.7 (1.1–2.6)</td>
</tr>
<tr>
<td>Low</td>
<td>2.4 (1.6–3.6)</td>
</tr>
<tr>
<td>Number of strategies to ensure completion of series</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>1.0 (Ref)</td>
</tr>
<tr>
<td>1</td>
<td>2.3 (1.2-4.3)</td>
</tr>
<tr>
<td>2+</td>
<td>3.3 (1.9-5.7)</td>
</tr>
</tbody>
</table>

Vadaparampil et al., unpublished data
Vaccine Recommendations, 11-12 y/o girls: Texas Physicians, 2 Years Post-Licensure (N=1122)

Kahn, Cancer Epi Biomark Prev 2009
## Factors Associated with Recommendation to 11-12 y/o Girls

<table>
<thead>
<tr>
<th>Factor</th>
<th>Adjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Academic vs. nonacademic practice</td>
<td>2.1</td>
</tr>
<tr>
<td>Office procedures to maximize vaccination</td>
<td>1.3</td>
</tr>
<tr>
<td>HPV knowledge</td>
<td>1.3</td>
</tr>
<tr>
<td>Info from professional organizations</td>
<td>1.9</td>
</tr>
<tr>
<td>Belief in mandated vaccination</td>
<td>5.4</td>
</tr>
</tbody>
</table>

Kahn, Cancer Epi Biomark Prev 2009
### Barriers to Recommending HPV Vaccines

<table>
<thead>
<tr>
<th>Reason</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parental refusal due to concerns about safety</td>
<td>69</td>
</tr>
<tr>
<td>Inadequate insurance coverage</td>
<td>67</td>
</tr>
<tr>
<td>Parental lack of education about HPV</td>
<td>65</td>
</tr>
<tr>
<td>Parental refusal due to negative media reports</td>
<td>60</td>
</tr>
<tr>
<td>Parental mistrust of vaccines in general</td>
<td>60</td>
</tr>
<tr>
<td>Parental concern consent condones premarital sex</td>
<td>54</td>
</tr>
<tr>
<td>Parental concern will lead to riskier sex behaviors</td>
<td>46</td>
</tr>
</tbody>
</table>

*Kahn, Cancer Epi Biomark Prev 2009*
Evidence Re: Provider Recommendations and Implications for Interventions

• Missed opportunities to vaccinate
  ➢ < 50% consistently recommending to 11-12 y/o girls

• Target modifiable predictors of vaccination to increase recommendations
  ➢ Systems
    ▪ Office procedures to maximize vaccination
    ▪ Insurance coverage
  ➢ Knowledge about vaccination
  ➢ Positive attitudes about vaccination
  ➢ Fewer perceived barriers to vaccination; e.g. parental lack of knowledge and concerns (safety/moral)
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Mothers’ Intention to Vaccinate Daughters, Themselves

National sample of U.S. nurses with daughters (N=7,207)

Kahn, Pediatrics 2009
### Variables Associated with Intention to Vaccinate Daughters

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adjusted OR</th>
</tr>
</thead>
<tbody>
<tr>
<td>History of HPV in mother</td>
<td>1.3</td>
</tr>
<tr>
<td>Daughter had Pap past year</td>
<td>1.4</td>
</tr>
<tr>
<td>Belief daughter should get Pap</td>
<td>1.3</td>
</tr>
<tr>
<td>Beliefs about HPV vaccines (7 items)</td>
<td>50.0</td>
</tr>
</tbody>
</table>

Kahn, Pediatrics 2009
Beliefs About HPV Vaccines: Components

- Benefits of vaccination
  - HPV vaccine best protection against cancer
  - Vaccines good way to protect daughter’s health
- Fewer barriers to vaccination
  - Would not lead to riskier sexual behaviors
  - Would not lead to avoidance of Pap screening
- Severity of HPV
- Susceptibility to HPV
- Clinician would recommend HPV vaccination

Kahn, Pediatrics 2009
Mothers’ Reasons for Accepting/Declining Vaccination of Daughters

• Reason for accepting
  ➢ Desire to prevent illness
  ➢ Belief that vaccines protect daughter’s health
  ➢ Physician recommendation
  ➢ High perceived risk of HPV infection

• Reasons for declining
  ➢ Lack of knowledge about HPV
  ➢ Belief that daughter is too young/low perceived risk
  ➢ Concern about vaccine safety
  ➢ Concern about risk perceptions and behaviors

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  ➢ Concern about risk perceptions and behaviors

CRITICS CLAIM HPV VACCINATION WILL LEAD TO PROMISCUITY

I AM SO TURNED ON RIGHT NOW.
Risk Perceptions at the Time of HPV Vaccination in Young Women

- 30-month longitudinal study of 13-21 year-old girls (N=339), mothers, clinicians
- Some perceived themselves at less risk for STIs other than HPV
- Vast majority reported continued need for safer sexual behaviors; associated factors included:
  - Adolescents - higher knowledge, higher concern about HPV
  - Mothers - higher knowledge, maternal communication about the HPV vaccine
- Implications - education about HPV vaccines and encouraging communication between girls and their mothers may prevent adolescent misperceptions

Mullins et al., Arch Ped Adol Med, 2012
### What about Risk Perceptions and Subsequent Sexual Behaviors?

<table>
<thead>
<tr>
<th>Baseline risk perceptions</th>
<th>Sexual behaviors over next 6 months</th>
<th>Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sexually inexperienced</td>
<td>Lower perceived risk of other STI</td>
<td>Less condom use</td>
</tr>
<tr>
<td></td>
<td>Lower perceived need for safer</td>
<td>Higher number of sex partners</td>
</tr>
<tr>
<td></td>
<td>sexual behaviors</td>
<td>NS</td>
</tr>
<tr>
<td></td>
<td>Sexual initiation</td>
<td>NS</td>
</tr>
<tr>
<td>Sexually experienced</td>
<td>Lower perceived risk of other STI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lower perceived need for safer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>sexual behaviors</td>
<td></td>
</tr>
</tbody>
</table>

Mayhew et al., unpublished
Decision-Making about HPV Vaccination: 11-12 Year-Old Girls and their Mothers

• Longitudinal qualitative study of 11-12 year-old girls (N=33), mothers, clinicians

• Perspectives about HPV vaccine-related decision-making
  ▪ Most mothers think it is their decision
  ▪ Most daughters think it is a mutual decision
  ▪ Perception that decision mutual driven by discussion

• Factors influencing mothers’ decisions to vaccinate 11-12 year-old daughters against HPV
  ▪ Mother’s health-related beliefs and experiences
  ▪ Interactions with clinicians, friends, family
  ▪ Media/marketing exposure (+/-)

Griffioen et al., Clinical Pediatrics, 2012
What Do 11-12 Year-Old Girls and their Mothers Want to and Actually Communicate About?

• Girls and mothers reported girls need information about vaccine efficacy and risks/benefits of vaccination
• 1/3 of mothers thought that sexual health should be discussed in context of vaccine visit
• Clinicians and parents were the preferred sources of vaccine information
• High concordance between girls and mothers re: discussion of vaccine efficacy; lower concordance about sexual health topics

Mullins et al., unpublished data
Implications of Evidence for Interventions to Improve Parental Acceptance

- Develop brief KEY MESSAGES that address beliefs that drive decisions about vaccination
  - Vaccines effective, should prevent most HPV-associated anogenital cancers, safe
  - HPV-related diseases serious and adolescents susceptible
  - Critical to vaccinate girls and boys before they initiate sex
  - Clinicians support vaccination

- Elicit and address concerns if parents refuse
  - Be aware that media may be a driver of concerns
  - Vaccination unlikely to lead to riskier behaviors

- Encourage parents to use vaccination visit as an opportunity
  - To educate, involve teens in decision-making, foster teens taking responsibility for their health
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Measuring the “Real-World” Impact of Vaccination

• Challenging to predict impact of vaccination on HPV prevalence rates in a community based on clinical trials data
  ▪ Vaccination rates are difficult to predict
  ▪ Trials conducted in healthy women with few sexual partners; most uninfected with vaccine-type HPV and compliant with vaccination

• Surveillance studies needed to explore impact of HPV vaccine introduction on HPV epi in a community

• Aims - to compare prevalence rates of HPV in young women before and after HPV vaccine introduction to determine:
  1) Whether vaccine-type HPV infection decreased
  2) Whether there was evidence of herd protection
Methods

• Young women 13-26 years of age who had had sexual contact recruited from two primary care clinics
  ▪ Pre-vaccination surveillance study: 2006-2007
    ➢ N=368, none vaccinated
  ▪ Post-vaccination surveillance study: 2009-2010
    ➢ N=409, 59% vaccinated

• Completed questionnaire and tested for cervicovaginal HPV

• HPV prevalence rates compared pre- vs. post-surveillance
  ▪ Chi-square tests and propensity score weighting to balance differences in covariates between the two studies
Prevalence for Vaccine-Type HPV (HPV-6, 11, 16, 18)
Pre-Vaccination vs. Post-Vaccination

Kahn, Pediatrics 2012
Prevalence for Vaccine-Type HPV (HPV-6, 11, 16, 18)

Pre-Vaccination vs. Post-Vaccination

Substantial decrease in vaccine-type HPV prevalence and evidence of herd protection 4 years after vaccine introduction

Kahn, Pediatrics 2012
Future Work

- Conduct 2 additional surveillance studies in 2013 and 2016
- To include boys as well as girls
- Aims - to better characterize the epidemiologic impact of HPV vaccine introduction in our community among girls and boys, and to explore mechanisms of herd immunity after HPV vaccination
Learning Objectives

- To describe recent data on HPV vaccine efficacy, safety, and uptake
- To recognize HPV vaccine delivery challenges
- To be able to utilize evidence to successfully address delivery challenges
- To recognize the importance of community-level research to define HPV epidemiology and the population impact of HPV vaccine introduction
With Gratitude to Collaborators

David Bernstein
Greg Zimet
Susan Rosenthal
Dennis Fortenberry
Tanya Mullins
Bin Huang
Lili Ding
Lea Widdice
... and a Fabulous Research Team!

Lisa Higgins

Charlene Morrow

Susan Glynn
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  - NIAID, NCI, NICHD
- World Health Organization
- American Cancer Society
- CCHMC Board of Trustees
- Fifth/Third Bank, Cincinnati
  - Charlotte R. Schmidlapp Trust
- Fleet Feet Sports, Cincinnati