Protecting Both the Goose and the Gander: New Research on HPV Vaccine Acceptance

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Objectives

1. To review current HPV vaccine recommendations for males and females and address the discrepancies between the two sets of recommendations.

2. To summarize reasons for the low HPV vaccination rates in general, and the particularly low rates for males.

3. To present findings from recent research in Indiana and the U.S. regarding HPV vaccination of males and discuss the clinical and public health implications of these findings.
HPV IN MALES
HPV in males

- Highly prevalent infection in males (likely 50%-70%)
- Infection of genital area associated with:
  - Non-circumcision
  - Non-condom use
  - History of smoking
  - Multiple sexual partners
- Longer duration of infection associated with:
  - Younger age
  - More sexual partners

HPV-related diseases in males

- **Genital warts (principally caused by HPV 6 & 11)**
- **Anal cancers (HPV 16 & 18)**
  - 80% or more are HPV-related
  - Incidence slightly higher in women than men
  - Highest incidence in MSM & HIV positive men
- **Penile cancers (HPV 16 & 18)**
  - Rare, but at least 40% are HPV-related
- **Head and neck cancers (Mainly HPV 16)**
  - About 30%-70% HPV-related

CURRENT STATUS OF HPV VACCINE RECOMMENDATIONS
HPV vaccine licensure: FDA

- Quadrivalent Vaccine
  (HPV types 6, 11, 16, 18)
  - Females 9-26 years old (licensed in 2006)
  - Males 9-26 years old (licensed in 2009)

- Bivalent Vaccine
  (HPV types 16 & 18)
  - Females 9-26 years old (licensed in 2009)
ACIP HPV vaccine recommendations for FEMALES

- **Quadrivalent:**
  - For prevention of vaginal, vulvar, and cervical precancers and cancers, genital warts, and anal cancers

- **Bivalent:**
  - For prevention of cervical precancers and cancers

- **Both vaccines:**
  - Routine administration for 11-12 year old girls
  - Administration for 9-10 year old girls at provider’s/parental discretion
  - Administration for 13-26 year old females not previously vaccinated
ACIP HPV vaccine recommendations for MALES

- **Quadrivalent vaccine only:**
  - 2009 – permissive recommendation; 2011 – routine recommendation
  - For prevention of genital warts & anal cancers
  - Routine administration for 11-12 year old boys
  - Administration for 9-10 year old boys at provider’s/parental discretion
  - Administration for 13-21 year old males not previously vaccinated
  - Males 22-26 may get vaccinated (permissive recommendation)
  - Men who have sex with men (MSM) should be immunized up to 26 years
WHY HAS MALE VACCINATION BEEN CONTROVERSIAL?
Resistance to male HPV vaccination

- **A victim of the research and licensing processes**
  - Clinical trials data available for women first
  - Question became: “Is adding male vaccination worthwhile?” rather than, “Is vaccinating all young people worthwhile?”

- **Questions about cost-effectiveness**
  - Including males less cost-effective than female-only vaccination
  - But, cost-effectiveness of gender-neutral approach better in the context of lower female vaccination rates (e.g., in the U.S.)*
  - But, some say we need to simply work harder to vaccinate more females

- **Questions about limited resources**
  - Particularly a concern for developing countries
  - Also an issue with rising health costs everywhere
  - HPV vaccines are expensive

*Chesson et al. *Vaccine* 2011*
But...

- What about protecting MSM?
- Vaccinating males ensures greatest protection for women
- Gender-neutral approach is more equitable
- Genital warts & HPV-related cancers in males very costly
- In U.S. relatively poor coverage of females suggests male vaccination would be helpful
- Vaccination policy & health policies in general are not always driven by cost-effectiveness research (e.g., MCV4)
- From a public health perspective, isn’t the goal of vaccination to work toward herd immunity as quickly as possible?
WHY IS THIS VACCINE DIFFERENT FROM ALL OTHER VACCINES?

Ma nishtana hahisoon haza mikol hahisoonim?
With other vaccines we haven’t focused so intensely on cost-effectiveness modeling.

Medline Search:

“Cost-Benefit Analysis” AND “Meningococcal Vaccines”

# of Studies

0 50 100 150 200 250

Meningococcal

48
Why is there so much focus on modeling with HPV vaccines?

Medline Search:

“Cost-Benefit Analysis”

AND

“HPV Vaccines”

With other vaccines we haven’t focused so intensely on attitudinal research.

Medline Search:

“Attitude” or “Attitude towards Health” AND “Meningococcal Vaccines”

# of Studies

0 50 100 150 200 250

13
Why is there so much research on attitudes with HPV vaccines?

Medline Search:

“Attitude” or “Attitude towards Health” AND “HPV Vaccines”

With other vaccines clinicians don’t spend a lot of time discussing infection & modes of transmission:

- Diphtheria
- Tetanus
- Rubella
- Hepatitis B
- Hepatitis A
- Mumps
Why is there so much concern about informing patients about HPV infection and transmission?
A TALE OF THREE MISTAKES
"Right now it's still a big drive to get the girls vaccinated," said Dr. M., a family medicine doctor. "It hasn't been a big drive to get the boys vaccinated."

"With girls we see the cancer benefit. With boys, the only indication is for genital warts. I don't think we look at it the same because it's a prevention of cancer versus prevention of warts."
Email exchange between me & reporter

- **Zimet**: “Dr. M. is absolutely wrong that the only indication for males is prevention of genital warts. The vaccine is also indicated for prevention of anal pre-cancers and cancers in males and females.”

- **Reporter**: “As for Dr. M.'s quote, ... I will note that the main page of the Gardasil website itself only lists genital warts when it comes to males.”
Home page (www.gardasil.com)

“In boys and young men ages 9 to 26, GARDASIL helps protect against 90% of genital warts cases.”
Learn about Gardasil (www.gardasil.com/what-is-gardasil/index.html)

“The future will be here before you know it. And chances are you’ve already started planning it. If those plans don’t include cervical cancer or genital warts, you should know how GARDASIL can help protect against diseases caused by human papillomavirus (HPV).”

“In boys and young men ages 9 to 26, GARDASIL helps protect against 90% of genital warts cases.”
The CDC states that GARDASIL can be given to boys and young men ages 9 through 26, if you and the doctor decide it’s right for your son.
3 Mistakes

- Dr. M.’s failure to stay current with HPV vaccine recommendations
- Reporter’s failure to adequately fact-check her story and to acknowledge her errors in reporting
- Merck’s decision to avoid putting anal cancer prevention on the website has unintended consequences
THESE KINDS OF MISTAKES CAN HAVE CONSEQUENCES
HPV vaccination rates for 13-17 year olds in the U.S.*

*From the National Immunization Survey Results:
RECENT U.S. & INDIANA RESEARCH
HPV vaccination:
Risk Compensation/Sexual disinhibition

- Frequently cited in the media as a concern with HPV vaccine*
- Rarely cited by parents as a concern**
- 6 studies published in 2012 show no evidence of disinhibition, including 2 studies using STI outcomes***

** Schuler et al. Sex Transm Infect 2011.
Even if there was evidence for risk compensation, it would be unethical to withhold HPV vaccine.

Risk compensation is not a rationale for non-vaccination. It is a rationale for ensuring adequate pre- and post-vaccination education.
Survey: HPV Knowledge & Attitudes*

- U.K., Australia, U.S. survey conducted from January – March, 2011 (Survey Sampling International)
- Not nationally-representative samples
- 509 U.S. Adults, 18-70 years of age

*Marlow et al. Vaccine. 2013
Selected responses

- Recommended for Females 11-26 (T): 81.5%
- Licensed for Women 30-45 (F): 25.5%
- Offered for Males 11-26 (T): 23.6%
- Usually Given in School (F): 35.0%
Parent-son qualitative study*

- 21 parent-son pairs interviewed in urban, community adolescent health clinic context
- Boys were 13-17 years of age
- Parents and sons interviewed separately after appointment
- 19 of 21 sons vaccinated

*Alexander et al. BMC Pediatrics 2012
Parent-son qualitative study

- Sons participated in decision-making process and were pleased to have an active role

- Some misperceptions
  - A few boys thought they would get an injection in the penis

- Providers in these clinics make the recommendation in a matter-of-fact manner

- While at the same time encouraging discussion between parent and son
Evaluation of brief (5-10 min) group education intervention
- HPV infection, transmission, diseases, and vaccination

131 young adults (18-26 yrs old) randomized to complete survey either before or after education

Survey
- Knowledge – 15 items
- Intent to get vaccinated

*Kester et al. Presented at the 2013 meeting of the Society for Adolescent Health & Medicine
Results

- 70% female
- Mean age = 21.8
- Vaccination status
  - 37% had 1 or more doses of HPV vaccine
  - 19% had completed the 3-dose series
- Randomization
  - 52% in intervention group
  - 48% in control group
HPV Knowledge Scores

F = 22.53, p < .001
Intention to vaccinate in vaccine non-initiators (n = 79)

OR = 3.09 (95% CI 1.02-9.36), p<.05
Conclusion

- Brief educational intervention increased knowledge of HPV and intent to get vaccinated
WHAT NOW?
Health care providers

- May be the most important focus

- Possible approaches:
  - More effective education of HCPs about indications
  - More active/aggressive publicizing of practice guidelines by professional organizations (AAP, AAFP, SAHM)
  - Practice-based interventions/education
  - Setting certain rates of HPV vaccination as a benchmark for quality practice
If parents and adolescent males ask for HPV vaccination, most providers will gladly administer vaccine.

How can we activate parents and adolescents?

- Public health advertisements
- Dissemination of information via social media
- Dissemination of information at health fairs, state fairs, etc.
Slow progress towards equity

- We have made some progress in vaccinating males and the U.S. currently leads the world in HPV vaccination of males.
- But, we have a long way to go.
- Will need to think creatively about solutions to the unacceptably low vaccination rates in males,

So that...
… we protect both the goose and the gander!
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