HPV in the U.S.- Where are we now?

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Conflicts of Interest

I have no disclosures to make of any conflicts of interest associated with this presentation.
Outline

• Background and Epidemiology of HPV

• HPV Immunization and stalled uptake
  o Poor access for adolescents
  o Unsupported morality concerns
  o Unjustified safety concerns
  o Weak recommendations from MDs/ poor motivation
  o Poor reimbursement for immunization

• Innovative approaches to immunization

• Potential next steps
Background and Epidemiology of HPV in the United States
Human Papillomavirus (HPV)

- A group of viruses that infect the skin
- There are more than 100 types of HPV
- Each year in the U.S., HPV causes an estimated:

  360,000 cases of genital warts
  10,300 cervical cancers
  6,700 oropharyngeal cancers in men
  2,800 anal cancers in women
  2,100 vulvar cancers
  1,700 oropharyngeal cancers in women
  1,500 anal cancers in men
  500 vaginal cancers
  600 penile cancers

Information from CDC
http://www.cdc.gov/std/HPV/STDFact-HPV.htm
Risk factors for HPV infection

“Anyone who is having (or has ever had) sex” - CDC
How HPV is spread

- HPV is spread by skin-to-skin contact, not exchange of bodily fluid.
- Condoms: very effective against pregnancy and infections spread through bodily fluids (HIV, gonorrhea).
  - Less likely to prevent infections that spread by skin-to-skin contact (HPV, herpes)
  - Simply, they do not cover the entire genital area of either sex
  - Contact between these areas can transmit HPV
HPV is COMMON

- According to the CDC, 100% of sexually active men and women will acquire genital HPV at some point in their lifetime.

- Approximately 20 million people are currently infected with genital HPV in the U.S.
  - HALF of these are adolescents and young adults ages 15-24

- An estimated $1.7 billion is spent each year in the U.S. in direct medical costs to treat genital HPV-infections alone.
HPV is COMMON

- In 2010, in the United States:
  - 11,818 women were diagnosed with cervical cancer
  - 3,939 died

Statistics from CDC: http://www.cdc.gov/cancer/cervical/statistics
HPV Immunization
HPV is Preventable

• First FDA licensed indications, June 8, 2006

• For females ages 9-26 years, quadrivalent HPV vaccines is indicated for prevention of the following diseases caused by HPV types 6, 11, 16, and 18:
  
  o Genital warts
  o Cervical cancer
  o Cervical adenocarcinoma in situ
  o Cervical intraepithelial neoplasia grade 2 and grade 3
  o Cervical intraepithelial neoplasia grade 1
  o Vulvar intraepithelial neoplasia grade 2 and grade 3
  o Vaginal intraepithelial neoplasia grade 2 and grade 3
HPV is Preventable

• A bivalent vaccine was licensed October 26, 2009

• For females ages 10-25 years, the bivalent HPV vaccines is indicated for prevention of the following diseases caused by HPV types 16, and 18:

  o Cervical cancer
  o Cervical adenocarcinoma in situ
  o Cervical intraepithelial neoplasia grade 2 and grade 3
  o Cervical intraepithelial neoplasia grade 1
Current ACIP and AAP Recommendations

• Routine immunization of males and females aged 11-12 years
  o Immunization may be initiated as young as age 9 years
  o Catch-up immunization for females aged 13-26 years
  o Catch-up immunization for males aged 13-21 years
  o Immunization of males aged 22-26 if not previously immunized
    • Not a strong recommendation due to lack of cost-efficacy models

• Previous sexual activity is not a contraindication to HPV immunization
HPV Vaccines, 2013: Where are we now?

- HPV vaccines are safe—more than 140 countries have now licensed HPV vaccines
  - Occasionally, patients faint when immunized
    - Not specific to HPV vaccines
    - Some patients complain of fever or headache

- HPV immunization of females and younger males is cost-beneficial

- The community is accepting HPV immunization of females
  - What is happening with boys is less clear
HPV Vaccines, 2013: Where are we now?

• Most pediatric practices are giving HPV vaccines routinely to girls
  o Some have started giving the vaccine to boys

• Insurance is paying for HPV vaccination of girls
  o Most are also covering boys

Catch-up immunization of females ages 13-26 years has been disappointing

Acceptance of male immunization remains low

![Graph showing uptake of adolescent vaccines from 2006 to 2012.](image)
Barriers to HPV Immunization Uptake
The “Window Period” of Adolescence: A Gap in US Healthcare

Adolescent window period
Ages 12 – 21 years

Pediatricians
0 - 12 years

Internists and Gynecologists
21 years - death
The “Window Period” of Adolescence: A Gap in US Healthcare

Adolescent window period
Ages 12 – 21 years

Pediatricians  Vaccines  Internists and Gynecologists

0 - 12 years  21 years - death
Economic Barriers and Access To Care

• Despite programs such as Vaccines for Children (VFC), adolescents are more likely to be uninsured or underinsured for vaccines than other groups

• Access to care
  - Many adolescents lack medical homes (common in south side Chicago)
  - Parents are ultimately responsible for the health of their children, which includes taking them to their healthcare provider for preventative care visits

• Government requirements for parental/guardian consent
  - Lack of uniformity between states
  - In Illinois, for example, unless a child is seeking treatment for an STI (HPV immunization would be considered preventative care, not treatment), parental consent is required for immunization
Unsupported Morality Concerns

My 9-12 year old needs an HPV shot?!

la la la la... I can’t hear you!
Unsupported Morality Concerns

• Discussing immunization forces us to confront many of the messy issues that arise during the transition between childhood and adulthood

• Our risk-based mindset
  o Makes us think “not my patients”
  o Makes us give the wrong information to parents

• Parents’ risk-based mindset
  o Makes us think “not my children”
Unsupported Morality Concerns

Personal experience

“This is a vaccine for ‘bad girls’ and immoral people”
Re-visiting the prevalence of HPV…

According to the CDC, 100% of sexually active men and women will acquire genital HPV at some point in their lifetime

Risk Factors: “Anyone who is having (or has ever had) sex” - CDC
Unsupported Morality Concerns

"Giving the HPV vaccine to young women could be potentially harmful because they may see it as a license to engage in premarital sex."

Bridget Maher,
The Family Research Council
Unsupported Morality Concerns

Human Papillomavirus Vaccine and Sexual Behavior Among Adolescent and Young Women

**Purpose:** Explore sexual behavior and demographic correlates of HPV vaccine initiation from a nationally representative survey of adolescent and young adult women.

**Methods**

- In 2007–2008, a total of 1243 girls/women aged 15–24 years responded to questions about receiving HPV vaccine in the National Survey of Family Growth.
- In 2010, demographic and sexual behavior correlates were evaluated in bivariate and multivariate analyses by age.
Unsupported Morality Concerns

Human Papillomavirus Vaccine and Sexual Behavior Among Adolescent and Young Women

Results

- HPV vaccination was not associated with being sexually active or number of sex partners at either age.
- Among sexually active adolescents aged 15–19 years, those who received HPV vaccine reported that they were more likely to always use a condom.
Unsupported Morality Concerns

Sexual Activity–Related Outcomes After Human Papillomavirus Vaccination of 11- to 12-Year-Olds
Bednarczyk et al., Published On-line, Pediatrics 10/15/2012

**Purpose:** Measure sexual activity-related clinical outcomes after adolescent vaccination

**Results**

- HPV vaccination in the recommended ages was not associated with increased sexual activity–related outcome rates.
Many laypeople don’t understand how vaccines work.

They want to know.

They confuse the vaccine and the disease.
Unjustified safety concerns
Unjustified safety concerns

People continue to mistake a temporal association for a causal association
HPV vaccine's suspected side effects cause concern

12:31 PM CDT on Friday, June 6, 2008

By JESSICA MEYERS / The Dallas Morning News
jmeyers@dallasnews.com

Katherine Kimzey started suffering debilitating headaches, fainting spells and arthritis-like stiffness last November.

Six weeks later, the 14-year-old Dallas resident became so dizzy she could barely walk. She was hospitalized and missed three weeks of school.

Then, she had a seizure. For weeks, she bounced back and forth between specialists and was eventually diagnosed with epilepsy.
Unjustified safety concerns

“The events reported were consistent with events expected in healthy adolescent and adult populations.”

_Gardasil_ Prescribing Information

“Causes of death among subjects were consistent with those reported in adolescent and adult female populations.”

_Cervarix_ Prescribing Information

**What is the leading cause of death in adolescents who receive HPV vaccination?**
Unjustified safety concerns
Unjustified safety concerns

If it’s bad, a vaccine must have caused it, right?
Unjustified safety concerns

All this because I got a flu shot last week!!!
Unjustified safety concerns

Safety of Quadrivalent Human Papillomavirus Vaccine Administered Routinely to Females

CONCLUSIONS :

• The quadrivalent human papillomavirus vaccine was associated with:
  
  o Same-day syncope.
  o Skin infections in the 2 weeks after vaccination.
  o This study did not detect evidence of new safety concerns among females 9 to 26 years of age secondary to vaccination with HPV4.
Unjustified safety concerns

WE HAVE MET THE ENEMY AND HE IS US.
Unjustified safety concerns

How do people make decisions- on the basis of facts that they know, or based on experiences that they have had?

• The rationale for HPV immunization that means something to us may mean little to parents

• Education is an ineffective way to change behavior

Education and logic take you only so far.
Unjustified safety concerns
Weak recommendations from MDs

Risk-based immunization is a failed strategy that leaves the unimmunized at risk of cancer.
Weak recommendations from MDs

Parents have a great desire to protect their children. Mothers believe that their children are at risk.

Most parents decide on the basis of experience, not on facts. Many of those experiences were frightening, and some involved watching someone they loved suffer.
Weak recommendations from MDs

Our messages to parents may need to be less scientific and more personal and emotional.
Weak recommendations from MDs

A risk-based approach:

- HPV stands for human papillomavirus
- HPV causes genital warts and cervical cancer
- HPV is a sexually-transmitted disease
- Many adolescents become sexually active by age 13
- Do you want this vaccine for your 11 year-old?
Weak recommendations from MDs

An emotional approach:

• Has anyone that care about had cancer?
• What was it like for them? For you?
• We can reduce the chances of your son or daughter having a cancer experience.
• Do you want to reduce the chances of your son or daughter having cancer
Weak recommendations from MDs

The “Stop talking” approach:

• Your child is ready for their recommended 11-12 year old immunizations, which include:
  o Tdap
  o HPV
  o Meningococcal
  o Influenza

• Do you have any questions today?
Weak recommendations from MDs

People need to be reminded what recommended means.

• Sometimes, we are unclear about our immunization priorities.

• At other times, we have the wrong priorities, particularly when we let parents negotiate a delay in HPV immunization.
Weak recommendations from MDs

Public Perceptions and Priorities

• Meningitis!!!

• Isn’t that gone?

• Last time I had one, it gave me the flu.

• Isn’t that for drug addicts?

• Huh?
Weak recommendations from MDs

In 2009...

• **Invasive meningococcal disease** affected about 850 Americans
  
  o Approximately 110 died

• Nearly 17,000 cases of pertussis were reported in the U.S.
  
  o Approximately 25 **pertussis-related deaths** occur each year in the US (>90% are infants)

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Weak recommendations from MDs

Earlier we saw….

• Each year in the U.S., HPV causes an estimated:

  360,000 cases of genital warts
  10,300 cervical cancers
  6,700 oropharyngeal cancers in men
  2,800 anal cancers in women
  2,100 vulvar cancers
  1,700 oropharyngeal cancers in women
  1,500 anal cancers in men
    500 vaginal cancers
    600 penile cancers
Weak recommendations from MDs

My Priorities

• HPV vaccine

• Influenza

• Adolescent/ Adult pertussis vaccine

• Meningococcal vaccine
Poor reimbursement

• Reimbursement for immunizations are often low, making immunization-only visits a financial loss for doctors’ offices
  
  o Ex: In Illinois, the reimbursement rate for administering a VFC vaccine is $6.50

• Perhaps as a result, private doctors offices are often not effective at immunizing adolescents
The Need for Innovative Approaches to Immunization
School-located immunization

At-School Immunizations have occurred in the U.S. in the past…

• Single vaccine
  o Influenza vaccine
• Often catch-up focused
  o Hepatitis B
• Occasionally outbreak-driven
  o Meningococcal conjugate
  o Tdap
• Successful
  o Many with immunization rates as high as 70%
School-located immunization

At-School Immunizations have occurred in the U.S. in the past...

• Impermanent
  o Ends with completion of catch-up

• Transiently funded
  o Grants/initiatives
  o Volunteers
  o Added burden to existing resources

• Patchwork of participants
School-located immunization

At-school immunizations have proven successful in countries like Australia, where in 2010 they reached coverage rates for HPV, among girls, of:

- 83% for 1\textsuperscript{st} dose HPV
- 80% for 2\textsuperscript{nd} dose HPV
- 73% for 3\textsuperscript{rd} dose HPV
School-located immunization

As of 2012, here in the U.S., we have immunization rates among girls of:

- 54% for 1st dose HPV
- No data for 2nd dose HPV
- 33% for 3rd dose HPV
School-located immunization

Addressing the barriers we previously identified that hinder HPV immunization uptake among adolescents….

- Poor access for adolescents
- Unsupported morality concerns
- Unjustified safety concerns
- Weak recommendations from MDs/ poor motivation
- Poor reimbursement for immunization
School-located immunization

Poor access to care

○ School-located immunization services bring preventative care directly to where the majority of adolescents in the U.S. can be found – at school.

○ Policy implications continue to influence the ability to provide Vaccines For Children (free of charge) to adolescents underinsured for vaccines

  ○ For example, this year, restrictions on VFC prohibit using this stock for underinsured children. Thus, poor adolescents with minimal health insurance still face lack of coverage for these recommended immunizations.
School-located immunization

Poor access to care

• Government requirements for parental/guardian consent
  
  o Non-standardized requirements among states leave many adolescents’ ability to be immunized with any vaccine, including HPV vaccine, to the consent of their parents.

  This remains a substantial barrier to SLV-programs
School-located immunization

Unsupported Morality and Safety Concerns

- School-located immunization services will continue to face the same barriers among education and provision of information to parents that do doctors offices.

  **However, provision of immunization at schools normalizes vaccines.**
School-located immunization

Weak recommendations from MDs

- A letter sent home to parents from school sends a strong message that immunizations are a normal part of keeping school-aged children healthy.

- School-located programs not only normalize immunizations, but make it convenient for parents and adolescents alike.

- Varying promotional approaches allow the school-located program to choose the “conversation”
  
  - Risk-based
  - Emotional approach
  - Stop talking approach
School-located immunization

Poor Reimbursement

- Poor reimbursement for immunizations continues to be a huge barrier to both private doctors offices and school-located programs.

- School-located programs have the advantage of lumping the overhead of a vaccine-only visit into a mass immunization clinic.

- Innovative approaches and collaborations are necessary to make these programs financially sustainable.
Potential Next Steps
Potential Next Steps

- Policies recognizing the need for higher immunization reimbursement?
- School-located immunization as the national norm for all adolescent vaccines?
- Reassessment of provider-patient communication around HPV?