Practical Strategies to Protect our Community from HPV-related Cancers
The Immunization Partnership

The Epidemic of HPV Related Cancers in Men: Why We Must Vaccinate Our Boys

April 19, 2016
Victoria, Texas

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Administrative Co-Leader HPV-Related Cancers Moon Shot
Program Director MD Anderson Oropharynx Program

No conflicts, disclosures, or off-label
Head & Neck Cancer

- Nasopharynx
- Oropharynx
  - tonsil
  - base of tongue or lingual tonsil
- Hypopharynx
- Larynx (voicebox)
- Oral Cavity (mouth)
- Nose/Paranasal Sinuses

Thyroid Cancer, Melanoma & Skin Cancer, Salivary Gland Cancer
Outline

- HPV
- Cancer Epidemic
- Prevention
- Screening
- Plan of Action
Mucosal sites of infection

Cutaneous sites of infection

~40 HPV Types

~80 HPV Types

High risk (oncogenic)
HPV 16, 18 most common

Low risk (non-oncogenic)
HPV 6, 11 most common

Oropharyngeal Cancers
Cervical & Anogenital Cancers
Cancer Precursors

Laryngeal Papillomas
Genital Warts
Low Grade Cervical Disease

Cutaneous Warts
HPV Genital Infection
Most females & males will be infected
- in the US: 80 million currently infected (14M new/yr)
- most without symptoms
- most common in teens & early 20s

HPV Throat Infection
- 5% of women & 15% of men currently infected
- most without symptoms
- highest rates in 50s

Incidence and clearance of oral human papillomavirus infection in men: the HIM cohort study

Aimée R Kreimer,1 Christine M Pierce Campbell,2 Hui-Yi Lin, William Fulp, Mary R Papenfuss, Martha Abrahamsen, Allan Hildesheim, Luisa L Villa, Jorge J Salmerón, Eduardo Lazcano-Ponce, Anna R Giuliano

Figure 1: Kaplan-Meier estimates of the cumulative incidence and time to clearance of any, oncogenic, and type 16 oral human papillomavirus (HPV) infections (A) Incidence of any oral HPV. (B) Incidence of oncogenic oral HPV. (C) Incidence of oral HPV 16. (D) Clearance of any incident oral HPV. (E) Clearance of incident oncogenic oral HPV. (F) Clearance of incident oral HPV 16.
2008 Nobel Prize in Physiology or Medicine

Harold zur Hausen, M.D.
HPV Infection & Progression to Cancer Schematic

NORMAL MUCOSA

SQUAMOUS INTRAEPITHELIAL LESION

Low grade  High grade

Cervical intraepithelial neoplasia

Grade 1  Grade 2  Grade 3

INVASIVE CANCER

- Normal nuclei
- Nuclei with episomal viral DNA
- Nuclei with integrated viral DNA
- Normal cytoplasm
- Expression of early and late genes
- Overexpression of E6 and E7

www.genticel.com

Head & Neck Cancer

Nasopharynx

Oropharynx
- soft palate or uvula
- tonsil
- base of tongue or lingual tonsil
- posterior or lateral oropharyngeal wall

Hypopharynx

Nose/Paranasal Sinuses

Oral Cavity (mouth)

Larynx (voicebox)
Outline

- HPV in Men
- Cancer Epidemic
- Prevention
- Screening
- Plan of Action
The Epidemic of HPV-Associated Oropharyngeal Cancer Is Here: Is It Time to Change Our Treatment Paradigms?

JNCCN–Journal of the National Comprehensive Cancer Network | Volume 9 Number 6 | June 2011
Erich M. Sturgis, MD, MPH, and K. Kian Ang, MD, PhD, Houston, Texas

Epidemic of HPV Cancers in U.S. Men

Age-Adjusted SEER Incidence Rates
By Cancer Site
All Ages, White, Male
1975–2012 (SEER 9)

- Penis: < 1/100,000
- Oropharynx (tongue base): +5%
- Oropharynx (tonsil): +5%
- Anus: +3%
- APC: ~0%
Newly Diagnosed-Uncared Cases Presenting to MD Anderson Each Year

Number of Cases

- Oropharynx
- Cervix
- Anus
- Vulva
- Penis
- Vagina
An Evolution in Demographics, Treatment, and Outcomes of Oropharyngeal Cancer at a Major Cancer Center

Kristina R. Dahlstrom, MS¹; Gabriel Calzada, MD¹; Jennifer D. Hanby, MD¹; Adam S. Garden, MD²; Bonnie S. Glisson, MD³; Guojun Li, MD, PhD⁴; Dianna B. Roberts, PhD⁴; Randal S. Weber, MD¹; and Erich M. Sturgis, MD, MPH⁴

**No. of Patients (%)**

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<thead>
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<tbody>
<tr>
<td>n</td>
<td>473</td>
<td>666</td>
<td>657</td>
<td>850</td>
<td>1245</td>
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<tr>
<td>Age, y</td>
<td></td>
<td></td>
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<tr>
<td>&lt;46</td>
<td>23 (4.9)</td>
<td>42 (6.3)</td>
<td>52 (7.9)</td>
<td>91 (10.7)</td>
<td>174 (14)</td>
<td>&lt; .001</td>
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<tr>
<td>46-55</td>
<td>135 (28.5)</td>
<td>176 (26.4)</td>
<td>142 (21.6)</td>
<td>218 (25.7)</td>
<td>462 (37.1)</td>
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<tr>
<td>56-65</td>
<td>173 (36.6)</td>
<td>257 (38.6)</td>
<td>262 (39.9)</td>
<td>201 (34.2)</td>
<td>346 (27.8)</td>
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<td>&gt;65</td>
<td>142 (30)</td>
<td>191 (28.7)</td>
<td>201 (30.6)</td>
<td>250 (29.4)</td>
<td>263 (21.1)</td>
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Median Age = 60

= 55

**MDACC Prospective Database**
(No. = 1,457)

Median Age = 55

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<th>95-99</th>
<th>00-04</th>
<th>05-09</th>
<th>10-14</th>
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<tr>
<td>Median</td>
<td>54</td>
<td>55</td>
<td>56</td>
<td>56</td>
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MDACC Prospective Database
(No. = 1457)

Dahlstrom & Sturgis, Oral Oncology 2015
Socioeconomic Distribution

Income
- Low: <$50K
- Mid: $50-$100K
- High: >$100K

Education
- Low: ≤HS/GED
- Mid: Tech/Voc
- High: ≥Bachelor’s

SES Composite
- Low: Lowest 1/3
- Mid: Middle 1/3
- High: Highest 1/3

Dahlstrom & Sturgis, Oral Oncology 2015
Oropharyngeal Cancer
SEER Age-adjusted Incidence

Males

Oropharyngeal Cancer

“Typical” Presentation

- Middle-aged White Male
- Nonsmoker or Former Smoker
- Middle to High Socioeconomic
- No Throat Symptoms
- Neck Mass (ie Stage IV)
Outline

- HPV in Men
- Cancer Epidemic
- Prevention
- Screening
- Plan of Action
HPV Prophylactic Vaccines

- Recombinant L1 capsid proteins that form “virus-like” particles
- Non-infectious and non-oncogenic
- Produce higher levels of neutralizing antibody than natural infection
HPV Vaccine Recommendation

Girls and Boys can start HPV vaccination at age 9

Should finish HPV vaccine series by 13th birthday

Catch-up Vaccination:
girls 13-26 years old who have not started or finished

Catch-up Vaccination:
boys 13-21 years old who have not started or finished
### HPV Vaccines Currently Licensed in U.S.

<table>
<thead>
<tr>
<th></th>
<th>Bivalent 2vHPV (Cervarix)</th>
<th>Quadrivalent 4vHPV (Gardasil)</th>
<th>9-Valent 9vHPV (Gardasil 9)</th>
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<tbody>
<tr>
<td><strong>Manufacturer</strong></td>
<td>GSK</td>
<td>Merck</td>
<td>Merck</td>
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<tr>
<td><strong>HPV Types Included</strong></td>
<td>16, 18</td>
<td>6, 11, 16, 18</td>
<td>6, 11, 16, 18, 31, 33, 45, 52, 58</td>
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<tr>
<td><strong>Contraindications</strong></td>
<td>Hypersensitivity to latex*</td>
<td>Hypersensitivity to yeast</td>
<td>Hypersensitivity to yeast</td>
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<tr>
<td><strong>Dose Schedule</strong></td>
<td>3 dose series: 0, 1, 6 months</td>
<td>3 dose series: 0, 2, 6 months</td>
<td>3 dose series: 0, 2, 6 months</td>
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</table>

- Genital Warts, ~70% of Cervical Cancers, & ~90% of HPV+ OP & Anal Cancers
- Genital Warts, ~70% of Cervical Cancers, & ~90% of HPV+ OP & Anal Cancers
- Genital Warts, ~85% of Cervical Cancers, & ~90% of HPV+ OP & Anal Cancers
HPV Vaccination Is Safe, Effective, and Provides Lasting Protection

• SAFE
  – Benefits far outweigh any potential risks
  – Similar to safety reviews of MCV4 and Tdap vaccination

• EFFECTIVE
  – Population impact against early and mid outcomes are already being reported in multiple countries

• LASTING PROTECTION
  – No evidence of waning protection

Quadrivalent HPV vaccine efficacy against disease related to vaccine and non-vaccine HPV types in males


External Genital Lesions (N=2,545)

- Placebo
- qHPV vaccine

AIN or worse (N=255 MSM)

- Placebo
- qHPV vaccine

* Among MSM only.

Fig. 2. Analysis of time to (A) EGL and (B) AIN or worse regardless of HPV detection among men in the naïve population.
# Reduced Prevalence of Oral Human Papillomavirus (HPV) 4 Years after Bivalent HPV Vaccination in a Randomized Clinical Trial in Costa Rica

Rolando Herrero¹*, Wim Quint², Allan Hildesheim³, Paula Gonzalez⁴, Linda Struijk², Hormuzd A. Katki³, Carolina Porras⁴, Mark Schiffman³, Ana Cecilia Rodriguez⁴, Diane Solomon⁵, Silvia Jimenez⁴, John T. Schiller⁶, Douglas R. Lowy⁶, Leen-Jan van Doorn², Sholom Wacholder³, Aimée R. Kreimer³ for the CVT Vaccine Group

<table>
<thead>
<tr>
<th>Arm</th>
<th>Number of women</th>
<th>Number of women with infection*</th>
<th>Prevalence</th>
<th>95%CI</th>
<th>Vaccine efficacy 95%CI</th>
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<tr>
<td>HPV16/18</td>
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<td></td>
<td></td>
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<tr>
<td>HPV</td>
<td>2910</td>
<td>1</td>
<td>0.0</td>
<td>0.00:2</td>
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<tr>
<td>Control</td>
<td>2924</td>
<td>15</td>
<td>0.5</td>
<td>0.3:0.8</td>
<td>93.3%</td>
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<td>HPV16</td>
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<tr>
<td>HPV</td>
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<td>1</td>
<td>0.0</td>
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<tr>
<td>Control</td>
<td>2924</td>
<td>12</td>
<td>0.4</td>
<td>0.2:0.7</td>
<td>91.6%</td>
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<td>HPV18</td>
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<tr>
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<td>0.0</td>
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<tr>
<td>Control</td>
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<td>4</td>
<td>0.1</td>
<td>0.00:3</td>
<td>100%</td>
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<td>61</td>
<td>2.1</td>
<td>1.6:2.7</td>
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<tr>
<td>Control</td>
<td>2924</td>
<td>219</td>
<td>7.5</td>
<td>6.6:8.5</td>
<td>72.0%</td>
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</table>
National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13–17 Years — United States, 2014

Sarah Reagan-Steiner, MD¹; David Yankey, MS¹; Jenny Jeyarajah, MS¹; Laurie D. Elam-Evans, PhD¹; James A. Singleton, PhD¹; C. Robinette Curtis, MD¹; Jessica MacNeil, MPH²; Lauri E. Markowitz, MD³; Shannon Stokley, MPH¹ (Author affiliations at end of text)

FIGURE 1. Estimated vaccination coverage with selected vaccines and doses among adolescents aged 13–17 years, by survey year — National Immunization Survey–Teen, United States, 2006–2014

Abbreviations: Tdap = tetanus toxoid, reduced diphteria toxoid, and acellular pertussis; MenACWY = meningococcal conjugate; HPV = human papillomavirus; ACIP = Advisory Committee on Immunization Practices; APD = adequate provider data.
Completion of 3 dose series = 40%

Completion of 3 dose series = 22%
Outline

- HPV in Men
- Cancer Epidemic
- Prevention
- Screening
- Plan of Action
George Papanikolaou (1883-1962)

Screening & Treatment (excluding cancer) Costs: $6.5 billion/year
Median Age at Presentation:

45yo 55yo
Trends in Cancer Incidence & Number
Oropharynx vs. Cervix
International Burden of HPV Cancer (cervical cancer)

2015: 1 in 6 live in Africa
2050: 1 in 4
2100: 2 in 5

The African bulge
Population, bn

Ranking incidence of cervical cancer
- 1st
- 2nd to 3rd
- 4th to 5th
- 6th and more
- No data

Source: UN
Outline

- HPV in Men
- Cancer Epidemic
- Prevention
- Screening
- Plan of Action
HPV Moon Shot:
Foundation in GYN, H&N, GU, and GI Programs

- 2011: Cervical Cancer Control Program
- 2012: Stiefel Oropharynx Research Program
- 2013: Monthly HPV Oral-Ano-Genital Lecture Series
- 2014: Inaugural HPV-Cancers Working Group

Expert Panel: M. Saraiya (CDC), J. Schiller (NCI), P. Howley (Dana-Farber), D. Lowy (NCI)

150 participants from across the Texas Medical Center

Developed *Four Priorities*
Four Priorities

- Vaccinate
- Diagnose Earlier & Easier
- Improve Treatment Efficacy
- Reduce Treatment Toxicity
HPV Moon Shot
$5 million (+ Platform Support) for Year 1: September, 2015

**Flagship #1**
Prevention & Screening
- Policy & Education (Lois M. Ramondetta)
- Screening (Kathleen M. Schmeler)

**Flagship #2**
Discovery
- Genomics (Curtis R. Pickering)
- Target Discovery (Faye M. Johnson)

**Flagship #3**
Immunotherapy & Novel Trials
- Rare Tumors (Cathy Eng)
- GYN (Michael M. Frumovitz)
- Head & Neck (William N. William)

**Cancer Prevention and Control Platform:**
- Health Policy
- Government Relations
- Professional Education
- Public Education

**Platforms:**
- Cancer Genomics Lab
- Institute for Applied Cancer Sciences
- Center for Co-Clinical Trials
- Immunotherapy
Conclusions

- HPV cancer epidemic in men:
  Oropharyngeal and Anal

- HPV vaccination is imperative:
  Further Delay = Exponential Costs & Suffering

- Without novel screening/treatment of premalignancy:
  30 years of increasing incidence

- Less toxic (& more effective) therapies are needed:
  Must integrate our efforts across disease sites
Thank You

esturgis@mdanderson.org

George Harrison
1943 - 2001
Oropharynx Cancer
Strategies on Giving a Strong Recommendation and Addressing Concerns Regarding HPV Vaccination

Presented by Robyn Correll Carlyle, MPH
Objectives

• Explain the importance of provider recommendation
• Give a confident and concise recommendation to encourage HPV vaccine uptake at 11-12 years
• Address concerns regarding HPV vaccination with patients and parents
Adolescent Vaccination Coverage Rates, 2014

Sources: Estimated vaccination coverage with selected vaccines and doses among adolescents aged 13–17 years, by state/area — National Immunization Survey–Teen (NIS-Teen), United States, 2014
Influenza vaccination coverage estimates by State, HHS Region, and the United States, National Immunization Survey (NIS) and Behavioral Risk Factor Surveillance System (BRFSS), 2013-14 influenza season
Figure 1. Estimated Deaths in the United States and Texas from Pertussis, Bacterial Meningitis and Selected HPV-Associated Cancers. HPV infection is thought to be responsible for 91% of anal and cervical cancers and 72% of oropharyngeal cancers. Source: National Cancer Institute. HPV and cancer. \textsuperscript{4,8-13}
By increasing 3-dose HPV vaccination coverage to 80%, an estimated additional 53,000 cases of cervical cancer could be prevented over the lifetimes of those aged ≤12 years.

- Centers for Disease Control and Prevention

What’s going on?
Top five reasons for not vaccinating adolescents w/HPV vaccine

**Parents of girls**
1. Lack of knowledge
2. Not needed or necessary
3. Safety concerns/ Side effects
4. **Not recommended**
5. Not sexually active

**Parents of boys**
1. **Not recommended**
2. Not needed or necessary
3. Lack of knowledge
4. Not sexually active
5. Safety concerns/ Side effects

Provider Recommendation

• A strong recommendation from you is the main reason parents decide to vaccinate

• Many moms in focus groups stated that they trust their child’s doctor and would get the vaccine for their child as long as they received a recommendation from the doctor

Source: MMWR 2014; 63(29);625-633; Unpublished CDC data, 2013.
Provider Recommendation

- In 2013, **64.4%** of parents of girls and **41.6%** parents of boys reported receiving a recommendation for the HPV vaccine from their provider.

- Parents of vaccinated teens were more likely to report having received a recommendation from their provider.
Strategies for a Strong Recommendation

- **Same way**: Effective recommendations group all of the adolescent vaccines
  - Recommend HPV vaccination the *same way* you recommend Tdap & meningococcal vaccines.

- **Same day**: Recommend HPV vaccine *today*
  - Recommend HPV vaccination the *same day* you recommend Tdap & meningococcal vaccines.

Unpublished CDC data, 2013.
Top five reasons for not vaccinating adolescents w/HPV vaccine

Parents of girls
1. Lack of knowledge
2. Not needed or necessary
3. Safety concerns/
   Side effects
4. Not recommended
5. Not sexually active

Parents of boys
1. Not recommended
2. Not needed or necessary
3. Lack of knowledge
4. Not sexually active
5. Safety concerns/
   Side effects

Source: Human Papillomavirus Vaccination Coverage
Among Adolescents, 2007–2013, and Postlicensure Vaccine
Safety Monitoring, 2006–2014 — United States
“Lack of knowledge”

• About HPV
  – What is it?
  – What does it do?

• About the vaccine itself
  – What are the benefits?
  – Who really needs it and why?
  – Is it safe?
“Not needed or necessary”

• “Required” vs. “Recommended”
• Age
• Sexual activity
• Risk
“Safety concerns and side effects”

Say NO to the #HPVvaccine #Gardasil #VaccineDangers #VaccineInjury #Gardasilvaccine

MARY JO PERRY @MaryJo___Perry
Do your research on this vaccine. Would you want this mandated for your son or daughter to attend school? That is... fb.me/4qC4IiDoM

Thanks, Dr. Coldwell! #Gardasil #Vaccines

Vaccines Are Used to Sterilize and Cull the Population

"... All these 100's of 1,000's of young girls that get it (Gardasil) will be probably infertile but 90% will have cancer along the way. We have girls that dropped with the needle still in them. We have 1,000's of girls that died from it. We have 1,000's of girls that have permanent neurological conditions and diseases from the Gardasil vaccine, even if the producers, of course, say it's not related. It happened directly afterwards to a healthy child but there's no correlation of course. (laughs)"

Dr. Leonard Coldwell
NMD DNM PhD D.HUM CNHP
Board Certified Doctor of Natural Medicine
Board Certified Alternative Medical Practitioner
Board Certified Holistic Health Practitioner
IOM Review: Syncope & Anaphylaxis

- IOM reviewed possible associations between 8 vaccines and adverse health events. Key findings:

  - Evidence “favors acceptance” of a causal relationship between HPV vaccine and anaphylaxis (rare)
  - Evidence “convincingly supports” a causal relationship between the injection of a vaccine and syncope

- Inadequate evidence was found for causal relationships between HPV vaccination and 12 other specific health events studied.

Key Findings – CDC and Non-CDC

- **Venous thromboembolism (VTE)**
  - Study evaluating the risk of VTE in vaccinated persons age 9-26 years
  - *Found no increased risk of VTE following 4vHPV*

- **Autoimmune and neurologic conditions**
  - Study addressing concerns about autoimmune and neurologic disease following 4vHPV vaccination.
  - *Found no association between 4vHPV vaccination and 16 autoimmune conditions*

- **Injection site reactions and syncope**
  - 4vHPV vaccination may be associated with skin infections where the shot is given during the two weeks after vaccination and fainting on the day the shot is received
  - *No major safety concerns found*

---

1. Gee et al., Vaccine 2011
Number of serious and nonserious reports of adverse events after administration of quadrivalent human papillomavirus (HPV4) vaccine in females, by year — Vaccine Adverse Event Reporting System, United States, June 2006–March 2013

CASE Method

• Developed by the Autism Science Foundation
• Helps those working with vaccine-hesitant patients and caregivers to address any questions or concerns
• Is a framework to guide the conversation
CASE Method

• **Corroborate**
  *Acknowledge the parents’ concern and find some point on which you can agree. Set the tone for a respectful, successful talk.*

• **About Me**
  *Describe what you have done to build your knowledge base and expertise.*

• **Science**
  *Describe what the science says.*

• **Explain/Advise**
  *Give your advice, based on the science.*

Some Parents Need Reassurance

- Many parents simply accept this bundled recommendation.

- Some parents may be interested in vaccinating, yet still have questions. Interpret a question as they need additional reassurance from YOU, the clinician they trust with their child’s health care.

- Ask parents about their main concern (be sure you are addressing their real concern).

Unpublished CDC data, 2013.
Clinicians can give a strong and effective HPV vaccine recommendation by announcing:

Sophia is due for three vaccines today. These will help protect her from meningitis, HPV cancers, and pertussis. We’ll give those shots at the end of the visit.
If main concern is “Why does my child need this vaccine” try saying:

**HPV vaccine is very important because it prevents cancer.**

I know we’d like to protect Maureen from cancer and I’d feel better if she got her first dose of the HPV vaccine series today.
If main concern is “My daughter will wait for marriage/won’t be exposed”, try saying:

HPV is so common that almost everyone will be infected at some time. When your daughter marries, she could catch HPV from her husband. He might have been infected before he ever met her.
If main concern is “why now, let’s wait until child is older,” try saying:

*HPV vaccine produces a more robust immune response in preteens than in older teens which is why I recommend starting the HPV vaccine series today.*
If main concern is “HPV vaccine will be a green light for sex,” try saying:

*Studies have shown that getting the HPV vaccine doesn’t make kids more likely have sex, or to have sex at a younger age.*
If main concern is “would you give it to your child,” try saying:

Yes, I gave it to my child (or grandchild, etc) because I think preventing cancer is very important.
If main concern is “side effects,” try saying:

Vaccines, like any medication, can cause side effects. With HPV vaccine most are mild, primarily pain or redness in the arm. This should go away quickly.

HPV vaccine has not been linked with any serious or long-term side effects.
If main concern is “possible effects on fertility,” try saying:

There is no data to suggest that getting HPV vaccine will have an effect on future fertility.

However, persistent HPV infection can cause cervical cancer and the treatment of cervical cancer can leave women unable to have children.

Even treatment for cervical pre-cancer can put a woman at risk for problems with her cervix during pregnancy causing preterm delivery or problems.
Before leaving the exam room, remind parents when to come back. Try saying:

To work, Robert needs the full HPV vaccine series, so . . .
Please make sure to make appointments for the next shot on the way out, and put that appointment on your calendar before you leave the office today!
Additional Strategies

- Reduce missed opportunities by making every visit a vaccination visit
- Reminder/Recall
- Provider Alerts
- Standing Orders
- Declination Forms
HPV PORTAL FOR PROVIDERS

cdc.gov/vaccines/YouAreTheKey
Want to know when the CDC has new resources and tools? Send an email to request their newsletter: 

PreteenVaccines@cdc.gov

They can help provide speakers for grand rounds and continuing education events, as well.
Acknowledgements

• Thank you to the Centers for Disease Control and Prevention for many of the slides and information included in this presentation.
Contact Information:

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281-400-3689