

February NVAC HPV Session Review

Summary of presentations by:

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HPV-ASSOCIATED CANCERS UNITED STATES, 2004-2008

| Anatomic Area | Average annual number of cases* | Estimated ⁺ | |
|------------------------|------------------------------------|------------------------|---------------------------|
| | | HPV attributable | HPV 16/18 attributable |
| Cervix | 11,967 | 11,500 | 9,100 |
| Vagina | 729 | 500 | 400 |
| Vulva | 3,136 | 1,600 | 1,400 |
| Anus (F) | 3,089 | 2,900 | 2,700 |
| Oropharynx (F) | 2,370 | 1,500 | 1,400 |
| Total (Females) | 21,291 | 18,000 | 15,000 |
| Penis | 1,046 | 400 | 300 |
| Anus (M) | 1,678 | 1,600 | 1,500 |
| Oropharynx (M) | 9,356 | 5,900 | 5,600 |
| Total (Males) | 12,080 | 7,900 | 7,400 |

- Defined by histology and anatomic site; Watson M et al. Cancer 2008. Data source: National Program of Cancer Registries and SEER, covering 100% coverage of US population. + Gillison ML, et al. Cancer 2008 .
- Ref: Watson et al, Human Papillomavirus-Associated Cancers MMWR 2012;61(15):258-261.

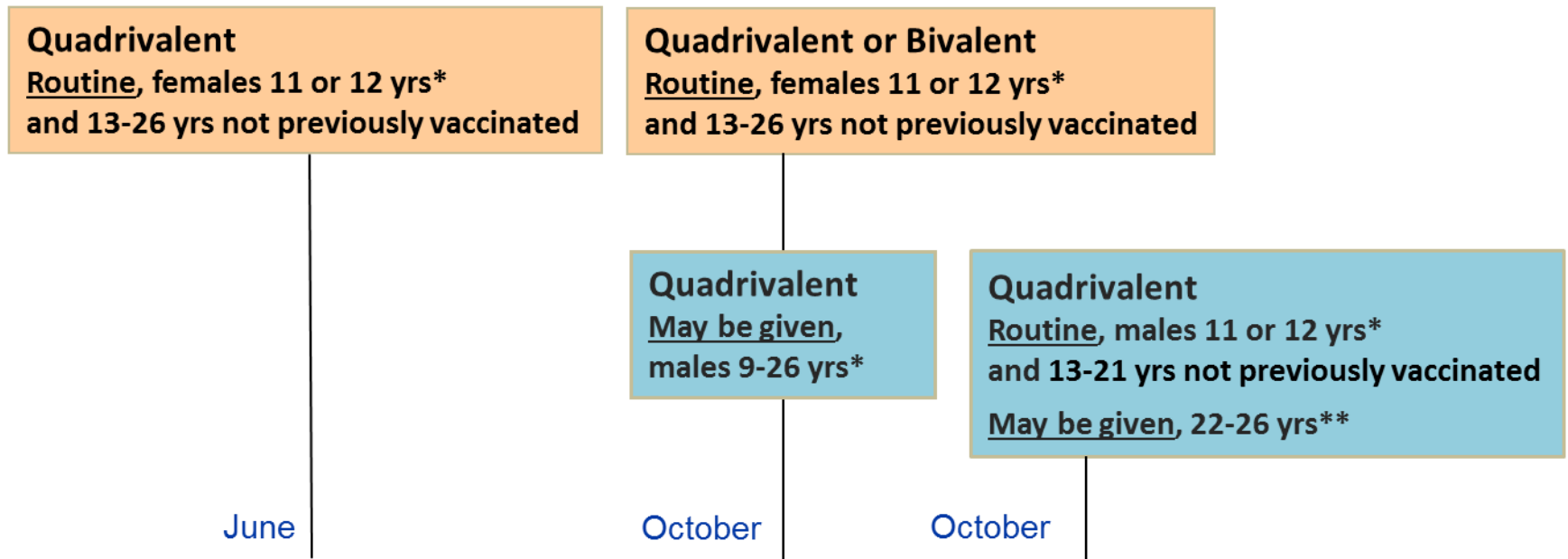
HPV VACCINES

| | Quadrivalent (Gardasil) | Bivalent (Cervarix) |
|--------------------------|-------------------------------------|-------------------------------|
| Manufacturer | Merck | GlaxoSmithKline |
| VLP types | 6, 11, 16, 18 | 16, 18 |
| Schedule (IM) | 3 doses | 3 doses |
| | Estimated to protect against | |
| Genital warts | 90% | - |
| Cervical cancers* | 70% | 70% |

* And majority of other HPV- associated cancers

VLP – virus like particle; IM - intramuscular

Evolution of recommendations for HPV vaccination in the United States



Quadrivalent (HPV 6,11,16,18) vaccine; Bivalent (HPV 16,18) vaccine

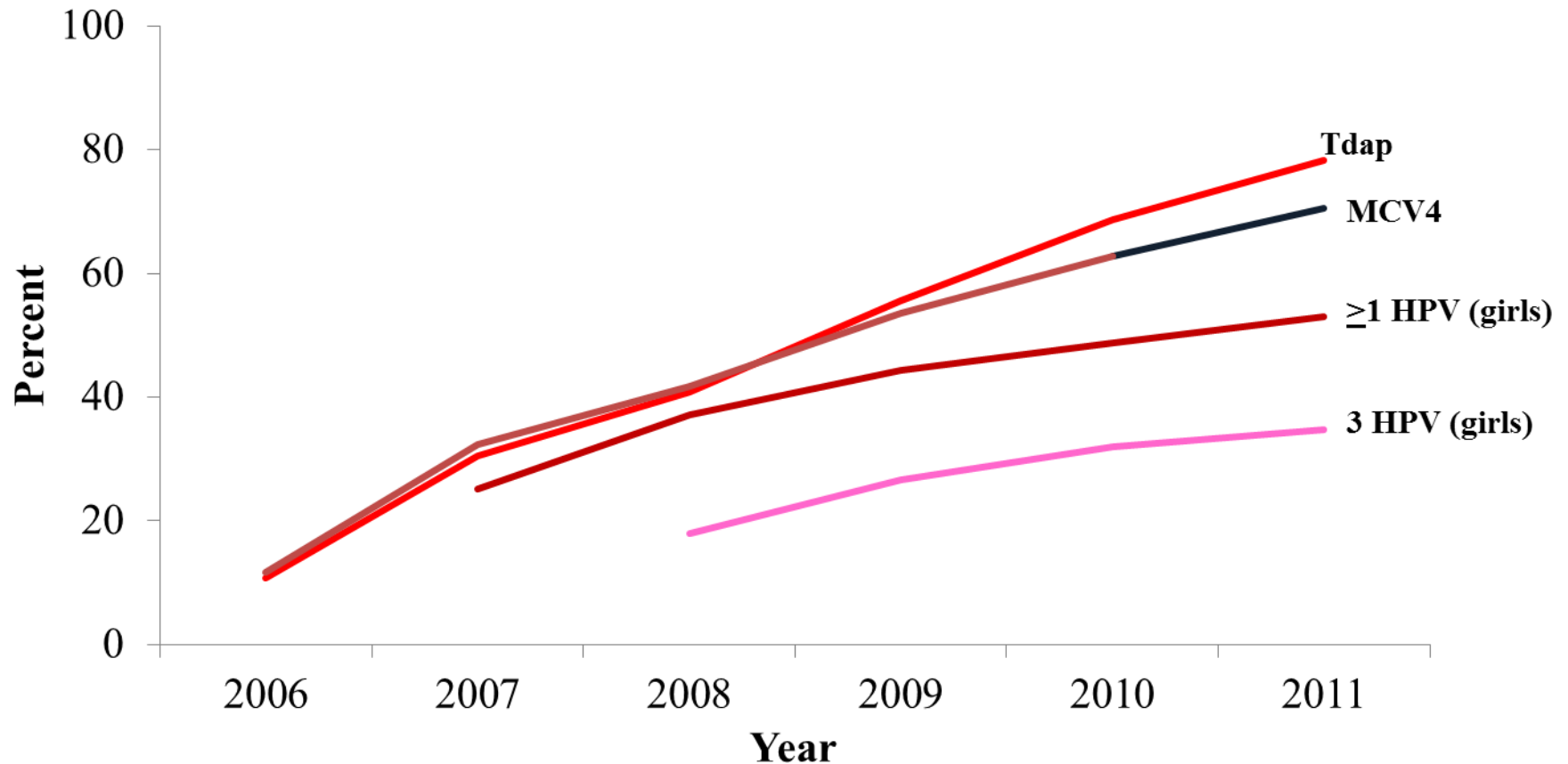
* Can be given starting at 9 years of age; ** For MSM and immunocompromised males, quadrivalent HPV vaccine through 26 years of age

US HPV Vaccination Program

- ❑ HPV is one of several vaccines recommended for the adolescent age group**
- ❑ Majority of vaccines are administered in primary care provider offices and publicly funded clinics**
- ❑ National survey of physicians found that 98% of pediatricians and 88% of family physicians stocked and administered HPV vaccine***
- ❑ Vaccine covered by most private health insurance companies and government insurance programs**
- ❑ In 2011, 39.4% of adolescents 13-17 years of age were eligible for VFC vaccine**

*Daley et al. Pediatrics. 2010;126:425-433.

National Estimated Vaccination Coverage Levels among Adolescents 13-17 Years, NIS-Teen 2006-2011



HPV Vaccination Uptake among Adolescents

❑ **Completion of the series**

- Below 40% for girls
- Below 10% for boys

❑ **Unusual disparities by race and SES**

- Higher coverage among black and Hispanic adolescents
- Higher coverage among adolescents living below the poverty level

Perceived Barriers

❑ **Provider**

- Not giving a strong recommendation
- Delaying vaccination and/or missed opportunities
- Limited time for discussion with parents
- Reimbursement
- Access to adolescents – many do not schedule routine visits at this age

❑ **Patients**

- Knowledge
- Perceptions (STD, not needed, child not yet sexually active, not safe)
- Cost

❑ **Vaccine**

- 3 doses over 6 months does not fit into any adolescent's scheduled doctor visits
- New vaccine
- No cultural norm or expectation established for this vaccine

❑ **Policy/System**

- Mandates are not there
- HP2020 only covers females

Recommendations

❑ Provider

- CDC
 - Promote providers in giving a strong recommendation
 - End missed opportunities
 - Do not delay vaccination
 - Implement evidence-based strategies to improve vaccine delivery
- Panel
 - Educate providers about cancer prevention benefit, safety and efficacy to promote more doctors giving a strong recommendation
 - End missed opportunities
 - Alternative sites (Pharmacies, Clinics, Schools, etc.)
- 2008 NVAC Adolescent vaccination working group recommendation
 - Alternative sites (Pharmacies, Clinics, Schools, etc.)

School located vaccinations have been tried and there are challenges

- Adolescent participation is low
- The cost to provide vaccination in schools can be quite high
- Billing health plans is challenging and may not be sufficient to recover program costs

Recommendations

□ Patients

- CDC
 - Increase awareness
 - Reframe: HPV vaccine is a tool to help prevent cancer; it is most effective if given before exposure to the HPV virus
- Panel
 - Targeted media campaign for specific populations
 - Reframe as vaccine for cancer prevention
 - Create adolescent health platform, like the childhood immunization platform so parents have an expectation of which vaccines are required
- 2008 NVAC recommendations
 - Targeted media campaign for specific populations

Recommendations

□ Vaccine

▪ Panel

- Research to evaluate whether 3 doses is necessary
- New vaccine – continue to monitor safety

Recommendations

❑ Policy/System

- Panel
 - Reminder/recall
 - Registries (alternative sites would be required to use registries)
 - Mandates
 - Adolescent consent
- 2008 NVAC Recommendation
 - Mandates
 - Adolescent Consent
 - Financing – lower cost
 - Surveillance
 - More detailed data needed on coverage rates, provider recommendations, public attitudes, etc. for specific populations/locations

HPV working group charge

The Assistant Secretary for Health (ASH) asks the National Vaccine Advisory Committee (NVAC) to review the current state of HPV immunization, to understand the root cause(s) for the observed relatively low vaccine uptake (both initiation and series completion), and to identify existing best practices all with a goal of providing recommendations on how increase use of this vaccine in young adolescents.

| Member | Organization |
|-----------------------------|---|
| NVAC Members | |
| Sarah Despres | NVAC Chair |
| Wayne Rawlins | NVAC Chair |
| Walt Orenstein | NVAC |
| Philip Hosbach | NVAC |
| Vish Viswanath | NVAC |
| Julie Morita | NVAC |
| Mitch Rothholtz | NVAC |
| Richard Beigi | NVAC |
| NVAC Liaison Members | |
| Anne Bailowitz | NACCHO |
| David Salisbury | UK Department of Health |
| External Members | |
| Nancy Lee | HHS Office of Women's Health |
| Valerie Borden | HHS Office of Women's Health |
| Kim Martin | ASTHO |
| Jamie Loehr | AAFP |
| Douglas Lowy | NIH/NCI |
| Rodney Willoughby | AAP |
| Jessica Kahn | Society of Adolescent Health and Medicine |
| Mary Beth Hance | CMS/CMCS |
| Linda Eckert | ACOG |
| James Turner | American College Health Association |
| Noel Brewer | UNC |
| Nicole Bobo | National Association of School Nurses |
| Rebecca Gold | CDC |
| NVPO | |
| Bruce Gellin | NVPO |
| Sharon Bergquist | NVPO |
| Katy Seib | Emory |