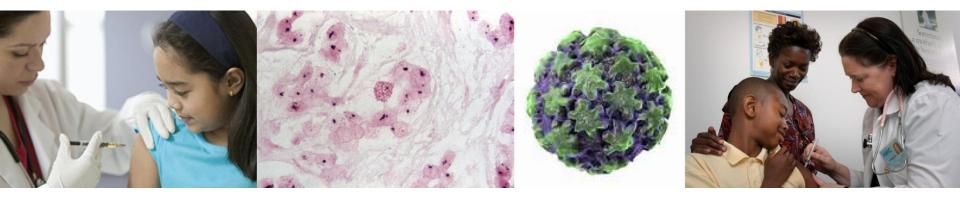
Public Health Importance of Human Papillomavirus Infection and Disease



Accessible version: https://youtu.be/Z80AgLojsy0

Mona Saraiya, MD MPH

Associate Director for Global Cancer Division of Cancer Prevention and Control National Center for Chronic Disease Prevention and Health Promotion



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Human Papillomaviruses

Double-stranded DNA virus

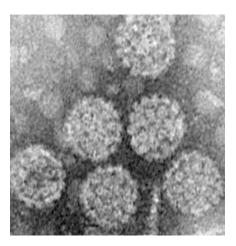
- More than 120 closely related viruses
 - Types numbered in order of discovery

HPV infection confined to epithelium

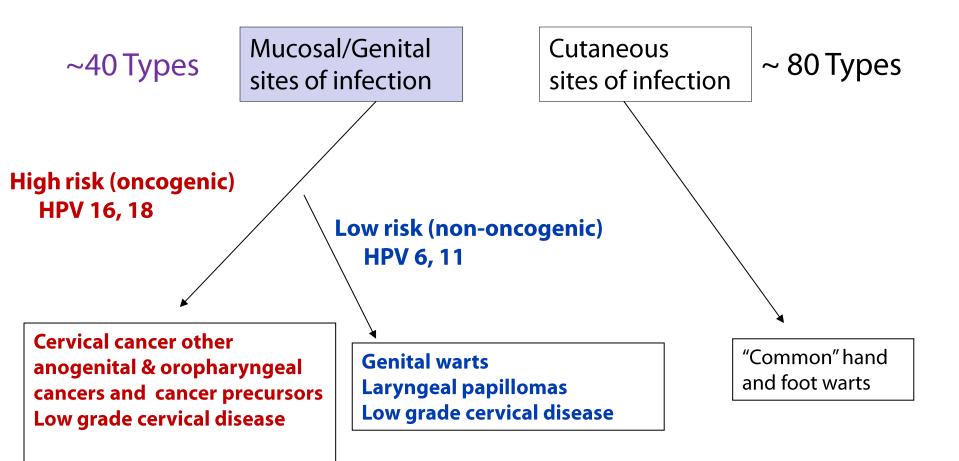
Begins in base of epithelium, cells proliferate and are not killed

Humoral and cellular immune responses identified

Antibodies detected in less than 70% of females infected



HPV Types Differ in their Disease Associations



Overview of HPV Epidemiology and Natural History

HPV infection is very prevalent in the population

- Almost all sexually active persons will acquire HPV
- In the US:
 - ~79 million infected
 - 14 million new infections per year

Genital HPV is first acquired soon after onset of sexual activity

40% infected within 2 years

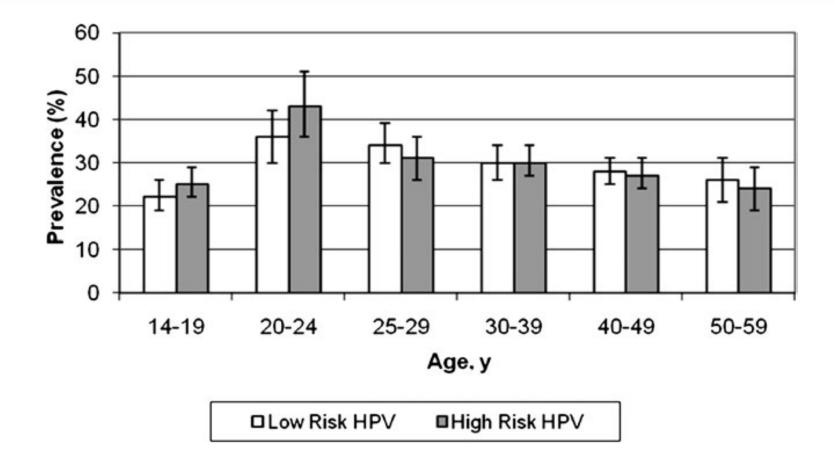
Infection is usually transient, asymptomatic

Cancer is a rare outcome

Requires persistent infection with high risk HPV types

Satterwhite CL et al. STD 2013;40:187-93 Winer RL et al. Am J Epidemiol 2003;157:218-26

Weighted Prevalence of HPV in US Women (14-59 years) – NHANES 2003-2006



Burden of Disease Caused by Low-Risk HPV

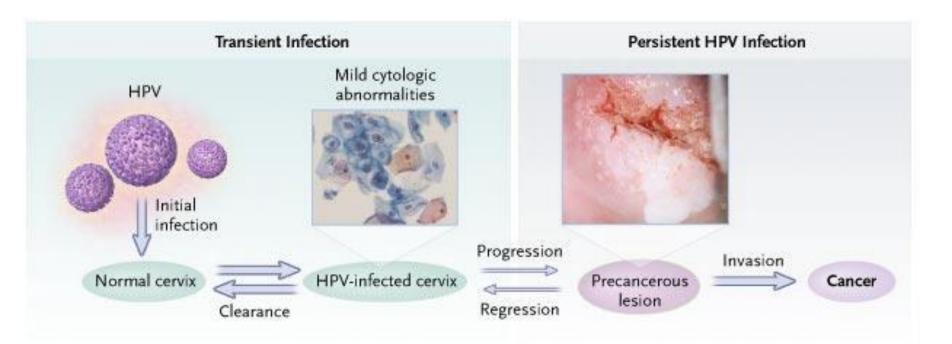
🖵 Genital Warts

- Over 300,000 new cases a year in the US
- > Peak incidence in persons aged 20-29 years
- Recur 40% of the time and lead to repeat clinical visits, treatments and psychosocial stigma

Recurrent respiratory papillomatosis (RRP)

- > Rare condition in which warts grow in the throat
- Occur in children (juvenile-onset) and adults (adult-onset)
- > Can result in airway obstruction requiring multiple surgeries

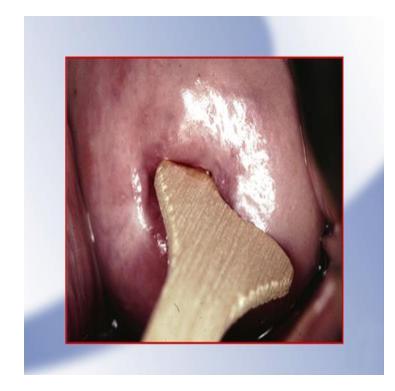
HPV: Natural History of Cervical Infection



- Persistent infection with high-risk types required for progression to precancer and cancer
- Peak incidence of precancers in late 20's and of cancers in mid to late 40's

Wright TC Jr, Schiffman M. N Engl J Med 2003;348:489-90

Cervical Cancer Screening Pap (Papanicolaou) Test



- A test which collects cells from the surface of the cervix and looks for abnormal cells
- Precancer can be detected and treated before cervical cancer develops
- HPV testing added as part of screening, resulting in improved sensitivity while safely allowing for extension of screening intervals

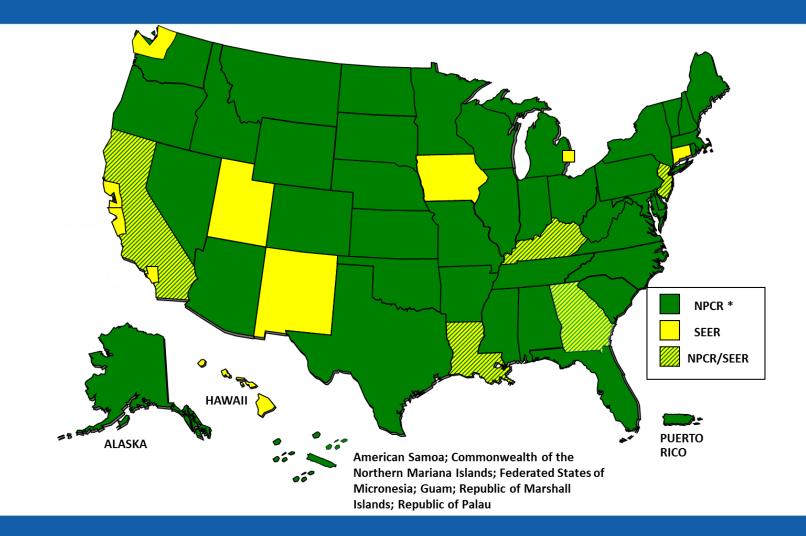
New Cervical Cancer Screening Guidelines: ACS, USPSTF, ACOG

| | ACS 2012 | USPSTF 2012 | ACOG 2012 |
|-------------------------------------|---|---|--|
| Age to start | Age 21 years | Age 21 years | Age 21 years |
| Women ages 21-29 years | Pap every 3 years | Pap every 3 years | Pap every 3 years |
| Women ages 30-65 years | Cotesting every 5 years (preferred) or Every 3 years with Pap alone | Cotesting every 5 years or Every 3 years with Pap alone | Cotesting every 5 years (preferred) or Every 3 years with Pap alone |
| Screening among fully vaccinated | | Not reviewed | Same as for non-vaccinated |

*All guidelines recommend that women who have been adequately screened can discontinue Pap at age 65.

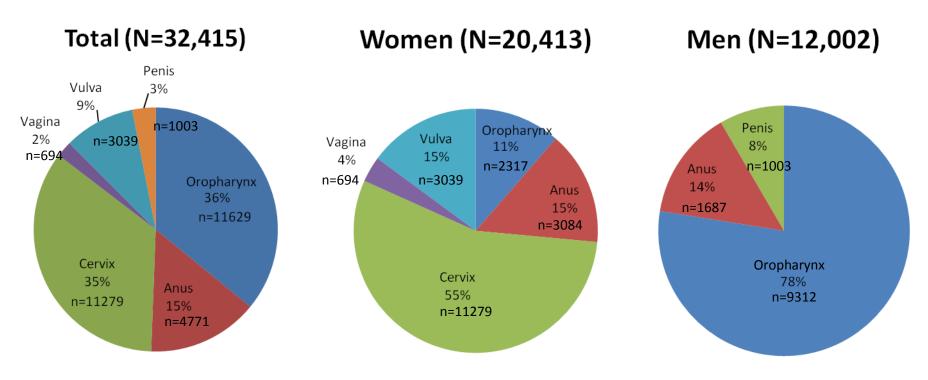
ACS: American Cancer Society USPSTF: US Preventive Services Task Force ACOG: American College of Obstetricians and Gynecologists

Federally Funded Cancer Registries, 2013



NPCR: National Program of Cancer Registries (CDC) SEER: Surveillance, Epidemiology, and End Results Program (National Cancer Institute)

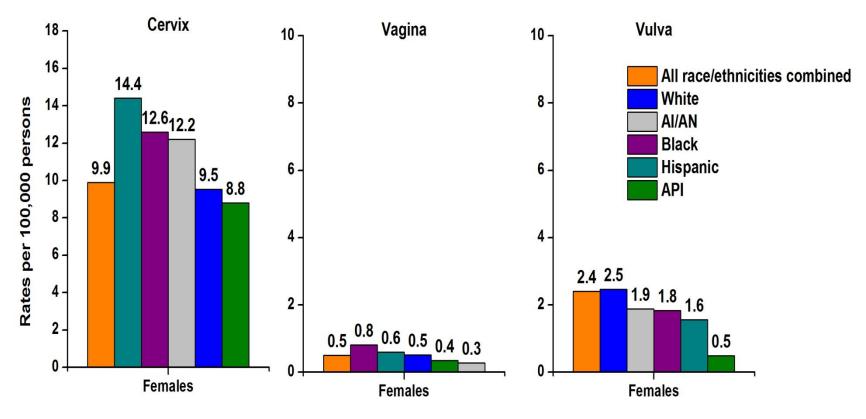
Average Number of New HPV-associated Cancers Overall, and by Sex, in the United States, 2005-2009



Jemal A et al. J Natl Cancer Inst 2013;105:175-201

*In addition: Cervical disease and pre-invasive cancers: CIN1,2,3~ 1.4 million; AIN3~4300; VIN3~27,000, VAIN3~7600 (CDC, unpublished data)

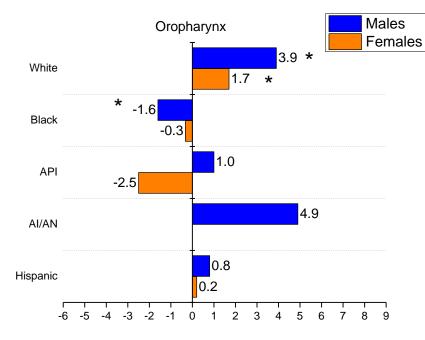
Cervical, Vaginal and Vulvar Cancers in the United States by Race and Ethnicity, 2005–2009



Y axis scale is different for cervical cancer.

Jemal A et al. J Natl Cancer Inst 2013;105:175-201

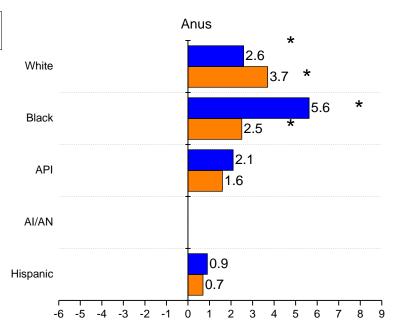
Trends in Oropharyngeal and Anal Cancer by Sex, Race, and Ethnicity in the United States, 2000–2009





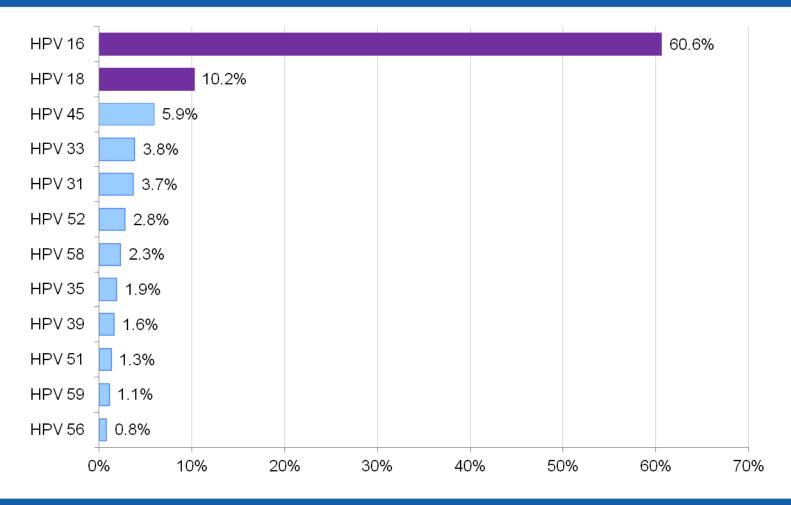
*statistically significantly different from zero at P<0.05

Jemal A et al. J Natl Cancer Inst 2013;105:175-201 API: Asian/Pacific Islander Al/AN: American Indian/Alaskan Native



Average Annual Percent Change

Percentage of Cervical Cancers Attributed to HPV types, Worldwide



de Sanjose S et al. Lancet Oncol 2010;11:1048-56

Percentages of HPV DNA-positive Cancers, United States, 1999-2005

| | Any HPV | HPV 16/18 |
|---------------|----------|-----------|
| <u>Cancer</u> | <u>%</u> | <u>%</u> |
| Cervix | 90 | 66 |
| Vaginal | 75 | 55 |
| Vulvar | 69 | 49 |
| Anal | 91 | 79 |
| Penile | 63 | 48 |
| Oropharyngeal | 72 | 62 |

HPV attributable cancers = 26,000 cancers HPV 16/18 attributable cancers= 21,000 cancers

Data presented by Saraiya M, 28th International Papillomavirus Conference 2012, Puerto Rico

Annual Cost of HPV-associated Disease, in 2010 U.S. Dollars

| Health outcome | Cost (\$ billions) |
|----------------------------|--------------------|
| Cervical cancer screening* | 6.6 |
| Cervical cancer | 0.4 |
| Other anogenital cancers | 0.2 |
| Oropharyngeal cancer | 0.3 |
| Anogenital warts | 0.3 |
| RRP** | 0.2 |
| TOTAL | 8.0 |

*Cervical cancer screening costs: ~ 80% routine screening, ~20% follow-up **RRP costs: ~ 70% juvenile-onset, ~ 30% adult-onset

Chesson H et al. Vaccine 2012;30: 6016-19 RRP: recurrent respiratory papillomatosis

Summary

HPV is a common infection and cause of malignant and non-malignant diseases

> Causes cancer at a variety of anatomic sites

Outcomes are burdensome, costly and stigmatizing

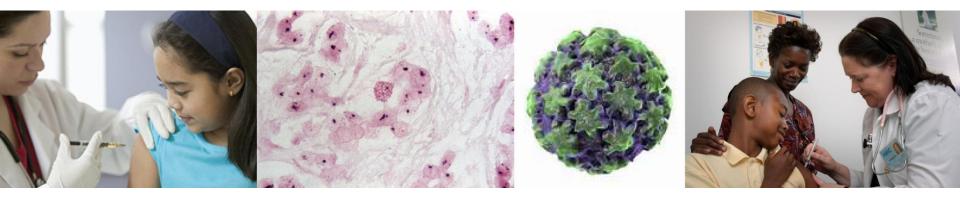
Approximately 26,000 HPV-attributable cancers

- > 21,000 are vaccine preventable
- Trends for anal and oropharngeal cancers increasing
- Racial and ethnic disparities exist

Cervical cancer screening guidelines

- Newly harmonized
- > Unchanged for vaccinated individuals, but may change in future

Overview of HPV Vaccines and Impact Monitoring



Eileen F. Dunne, MD, MPH

Medical Officer Division of STD Prevention National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

HPV Vaccines Licensed by FDA

| | Quadrivalent (Gardasil®) | Bivalent (Cervarix®) |
|---|------------------------------|-------------------------|
| Manufacturer | Merck | GlaxoSmithKline |
| VLP types | 6, 11, 16, 18 | 16, 18 |
| Licensed in US | Females -2006 Males -2009 | Females - 2009 |
| Schedule in months from first vaccination | 0, 1-2, 6 | 0, 1-2, 6 |

FDA: Food and Drug Administration VLP: virus like particle

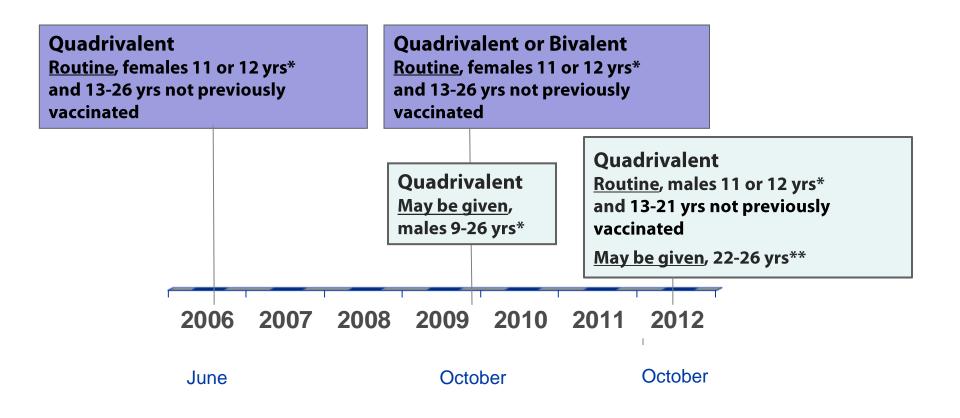
HPV Vaccine Efficacy in Randomized Controlled Trials

| Outcome | Vaccine | Sex | Vaccine Efficacy |
|--------------------------|------------------------------|------|------------------|
| Cervical precancer | Bivalent and Quadrivalent | F | >92% |
| Vaginal/Vulvar precancer | Quadrivalent | F | 100% |
| Anal precancer | Quadrivalent | Μ | 75% |
| Genital warts | Quadrivalent | F, M | >89% |

No evidence of efficacy against existing HPV infection or disease

Paavonen J et al. Lancet 2009;374:301-14, Kjaer S et al. Cancer Prev Res 2009;2:868-78, Hildesheim A et al. JAMA 2007;298:743-53, Future I/II Study Group, BMJ 2010;341, The Furture II Study Group Lancet 2007;369:1861-8, Palefsky J et al. NEJM 2011;365:1576-85 Gardasil Package Insert, page 504 Table 12

Evolution of Recommendations for HPV Vaccination in the U.S.



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

Current ACIP HPV Vaccine Recommendations Females and Males

Routine vaccination of females aged 11 or 12 years with 3 doses of either bivalent or quadrivalent HPV vaccine

Also for 13 through 26 year olds who have not been vaccinated previously or who have not completed the 3-dose series

Routine vaccination of males aged 11 or 12 years with 3 doses of quadrivalent HPV vaccine

- Also for 13 through 21 year olds who have not been vaccinated previously or who have not completed the 3-dose series
- Gay, bisexual and other men who have sex with men are recommended to receive vaccine through age 26 years

www.cdc.gov/vaccines/pubs/ACIP-list.htm#hpv ACIP: Advisory Committee on Immunization Practices

Monitoring of HPV Vaccines

| Objectives | Methods | Examples |
|---|------------------------------|--|
| Vaccine Safety | Surveillance and Research | VAERS, VSD, CISA |
| Vaccine Impact on Infection and Disease Burden | Surveillance and Research | NHANES, Administrative data HPV-IMPACT, Cancer Registries |
| Vaccine Coverage | National Surveys, Registries | NIS-Teen, Immunization Registries |
| Behaviors and Attitudes | National Surveys | NSFG, NHANES |

VAERS: Vaccine Adverse Event Reporting System VSD: Vaccine Safety Datalink NHANES: National Health and Nutrition Examination Survey NIS-Teen: National Immunization Survey, Teen Component NSFG: National Survey of Family Growth

Post-licensure Vaccine Safety Monitoring: Rationale

High safety standards expected for vaccines

- Products given to healthy populations for prevention of disease
- Pre-licensure trials are often too small to detect rare events and special populations may not be adequately represented
- Critical to maintain public confidence in immunization, provide timely information

Post-licensure Vaccine Safety Systems

Vaccine Adverse Event Reporting System (VAERS)

- Collaboration between CDC and FDA
 - National spontaneous reporting system
 - Can detect potential vaccine safety concerns (signals) but not designed to assess causality

Vaccine Safety Datalink (VSD)

- Collaboration between CDC and 9 managed care organizations
 - ~9.2 million insured members under active surveillance annually
 - Rates, risks estimates calculated
 - Near real time evaluation through Rapid Cycle Analysis (RCA)

Clinical Immunization Safety Assessment (CISA)

- Collaboration between CDC and 7 academic medical centers
 - For clinically complex vaccine adverse events and research on biologic mechanisms

Iskander J et al. Pediatr Ann 2004;33:599-606 Lieu TA et al. Med Care 2007;45:S89-95 LaRussa PS et al. Pediatrics 2011;127:S65-73

Summary of VSD Safety Evaluation of HPV Vaccine

Findings from the VSD RCA:

- Among 600,588 doses of quadrivalent vaccine administered to females 9-26 years, no significant increased risk for any of the prespecified adverse events after vaccination:
 - Guillain-Barré syndrome, seizures, syncope, appendicitis, stroke, venous thromboembolism, anaphylaxis and other allergic reactions

Total doses of quadrivalent HPV vaccine administered through January 2013 within VSD:

- > 2.07 million doses
 - ~270K doses of quadrivalent HPV vaccine given to males

Impact on Biologic Outcomes -What is Vaccine-Preventable?

Cancers: 70% of cervical and ~90% of non-cervical HPV associated cancers are potentially preventable by either vaccine

- > ~21,000 cancer cases each year
- Cervical Pap test abnormalities: 30-70% are potentially preventable by either vaccine

~1 million cervical Pap test abnormalities each year

Genital warts: 90% of genital warts preventable by quadrivalent vaccine

> ~ 325,000 genital warts cases each year

Monitoring Impact on Biologic Outcomes: Current Activities

Surveillance and research to monitor different outcomes

- > Early, mid, late measures
- National, regional, state
- General, other populations

Vaccine effectiveness studies

Laboratory evaluations

- HPV type-specific prevalence for various outcomes
- U.S. population, precancers, cancers

Challenges

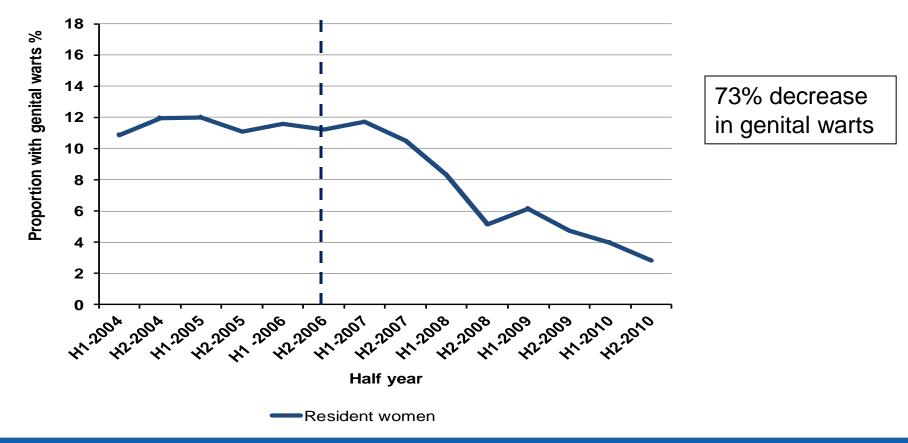
Most outcomes not nationally reportable, many outcomes dependent on cervical cancer screening, varied stakeholder, laboratory testing

Monitoring Impact on Biologic Outcomes: Current Activities

| Timeframe | System/study | Outcome | |
|-----------|--------------------------|---|--|
| Early | NHANES | HPV type specific prevalence | |
| | Administrative data | Genital warts | |
| Mid | Select cancer registries | Cervical precancers | |
| | HPV-IMPACT | | |
| Late | Cancer registries | Cervical and other HPV- associated cancers | |

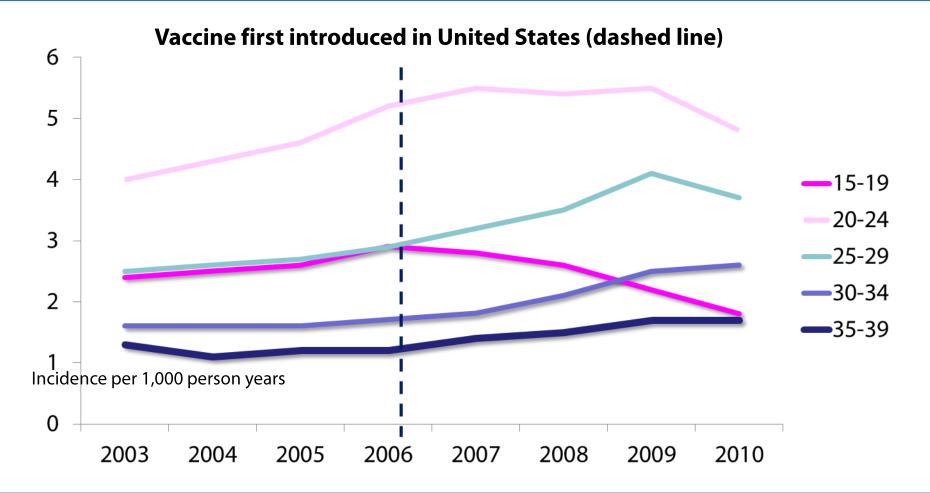
Proportion of Women Aged <26 Years with Genital Warts, 2004-2010, Australia





Donovan B et al. Lancet Infect Dis 2011;11:39-44

Genital Warts, Females 2003-2010 by Age Group, U.S. MarketScan® Database



Flagg E et al. AJPH 2013 (in press

Summary

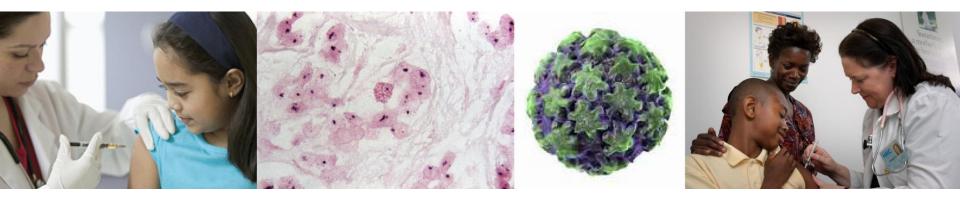
HPV Vaccines

- Bivalent and quadrivalent vaccines are safe and effective
- Potential to prevent large burden of cancers and diseases

Monitoring

- > Ongoing monitoring is important for vaccine program and policy
 - Safety surveillance
 - Biologic outcomes
 - Special evaluations: e.g. effectiveness of less than 3 vaccine doses
- > Early in timeline to measure impact on some biologic outcomes
 - Evidence of impact on genital warts
- Increasing HPV vaccine coverage important to reduce cancers and diseases

U.S. HPV Vaccination Program: Progress and Challenges



Shannon Stokley, MPH

Acting Associate Director of Science Immunization Services Division National Center for Immunization and Respiratory Diseases



U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Overview

- Describe U.S. vaccination program
- Review HPV vaccination coverage levels
- Summarize factors contributing to less than optimal vaccination coverage

U.S. HPV Vaccination Program

HPV is one of several vaccines recommended for the adolescent age group ("adolescent platform")

> Tdap, MCV4, annual influenza

Majority (83%) of vaccines are administered in primary care provider offices and publicly funded clinics (FQHC, RHC)

> Vaccines often administered during preventive healthcare visits

National survey 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

Daley M et al. Pediatrics 2010;126:425-33 Tdap: tetanus, diphtheria, and acellular pertussis vaccine MCV4: quadrivalent meningococcal conjugate vaccine FQHIC: federally qualified health center RHC: rural health clinic

Vaccines For Children (VFC) Program

Federal legislation enacted in 1994 to remove cost as a barrier to vaccination

Provides federally purchased vaccines recommended by ACIP at no cost to eligible children 18 years and younger:

Medicaid eligible

- Uninsured
- American Indian/Alaska Native descent
- > Underinsured (if vaccinated at an FQHC or RHC)

In 2011, 39.4% of adolescents 13-17 years of age were eligible for VFC vaccine

~44,000 immunization providers enrolled in VFC

¹2011 National Immunization Survey-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen ²2010 VFC Program Management Survey available at: http://www2a.cdc.gov/nip/irar/grantee/vfcprovider10.asp ACIP: Advisory Committee on Immunization Practices FQHC: federally qualified health center RHC: rural health clinic

National Immunization Survey-Teen (NIS-Teen)

Annual survey

- Implemented in 2006
- State level estimates available beginning 2008

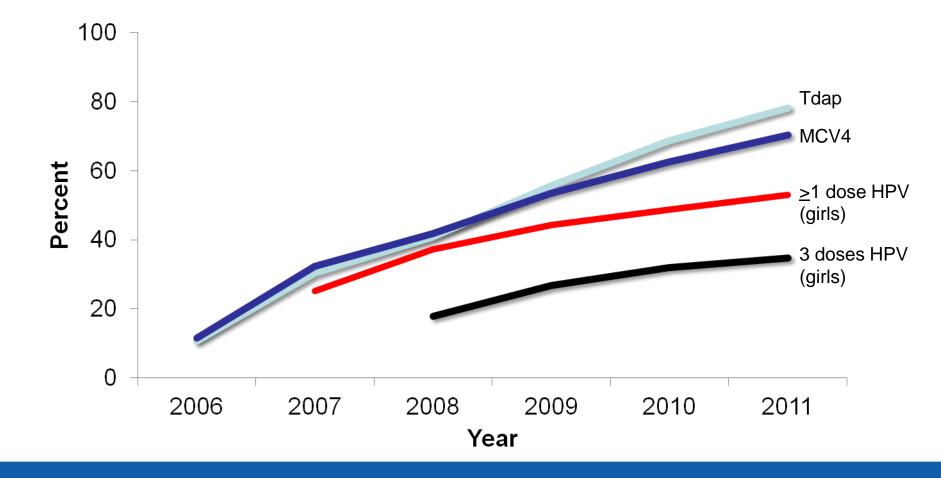
Uses National Immunization Survey (NIS) sample frame methodology

- Random digit dial telephone survey
- > National sample of parents of adolescents aged 13-17 years
- Provider record check for verification of immunizations received

All analyses limited to adolescents with provider reported immunization histories

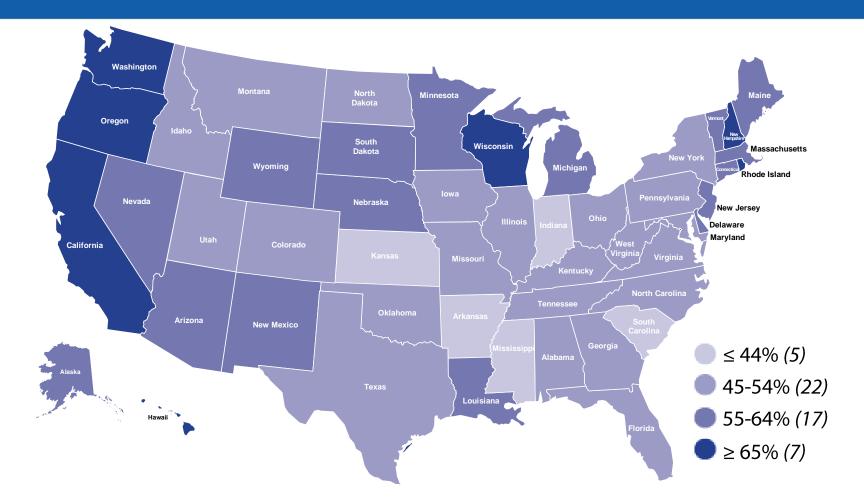
Additional information about the NIS-Teen available at: http://www.cdc.gov/vaccines/stats-surv/nis/default.htm#nisteen

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



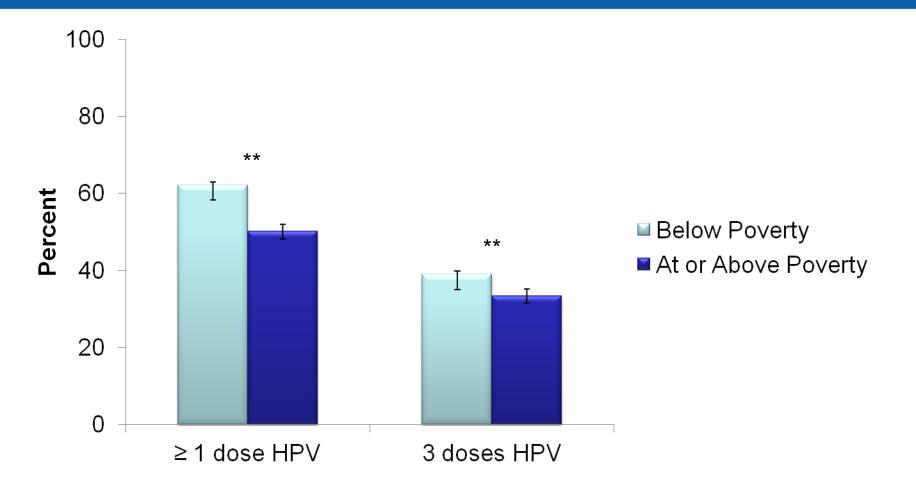
MMWR 2012;61:671-77

Coverage of 1 of More Doses of HPV among Adolescent Girls 13-17 Years by State, NIS-Teen 2011



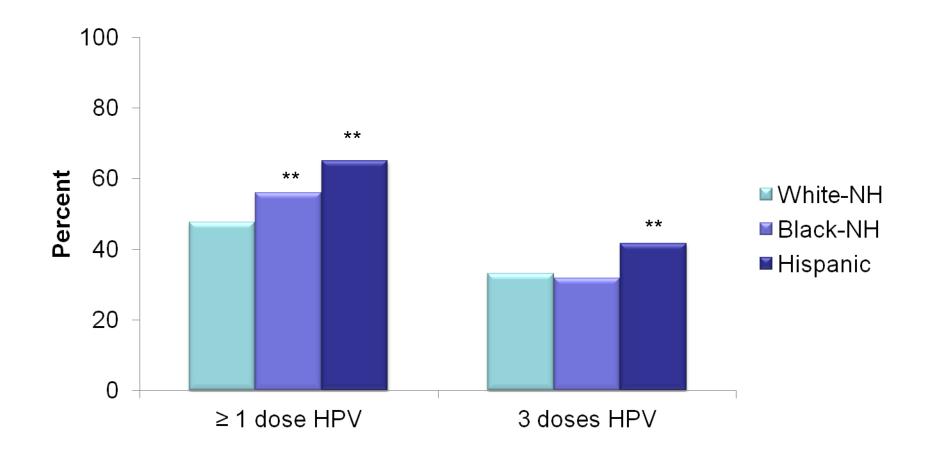
Note 1: Human Papillomavirus Vaccine, either quadrivalent or bivalent. Note 2: Includes female adolescents born between January 1993 and February 1999 2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

Vaccination Estimates among Adolescent Girls 13-17 Years by Poverty Status, NIS-Teen 2011



** statistically significant (p<0.05) 2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

Vaccination Estimates among Adolescent Girls 13-17 Years by Race/Ethnicity, NIS-Teen 2011

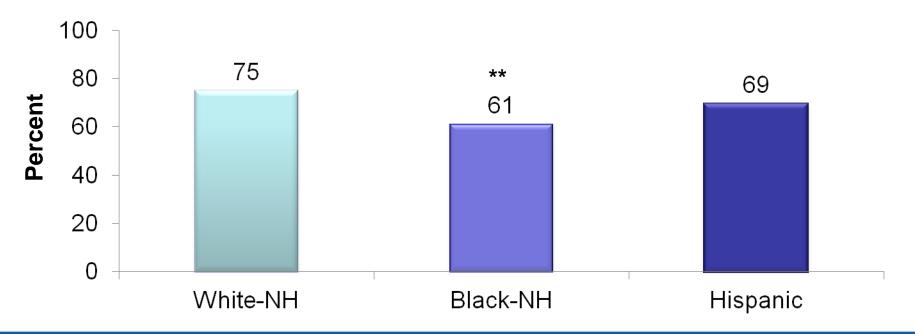


** statistically significant (p<0.05) 2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

Completion of the HPV Series among Adolescent Girls 13-17 Years by Race/Ethnicity, NIS-Teen 2011

Completion: among the girls who started the series, the proportion that received all 3 doses

- Nationally, 71% of girls that start the HPV series, complete the series.
- In contrast, population-wide 3-dose coverage was 35% in 2011



^{**} Statistically different (P<0.05) from White-NH.

NH: non-Hispanic

2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

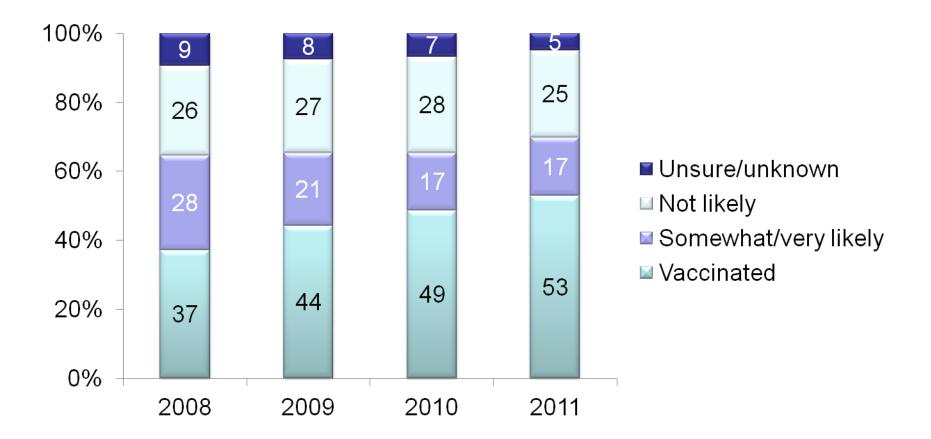
HPV Vaccination Uptake among Adolescent Boys

- Available data represents vaccination activities prior to implementation of routine recommendation approved in October, 2011
- 8.3% of boys 13-17 years of age have initiated the series
- So far vaccine uptake (coverage) follows the same pattern as observed for girls
 - > Higher coverage among boys living below the poverty level
 - Higher coverage among Black and Hispanic boys
 - Based on only one year of data

Challenges in Achieving High Levels of HPV vaccination

- Parental attitudes and vaccine intentions
- Provider attitudes and practices

HPV Vaccine Intentions (in the Next 12 Months) among Parents of Adolescent Girls 13-17 Years of Age, NIS-Teen



NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/default.htm#nisteen

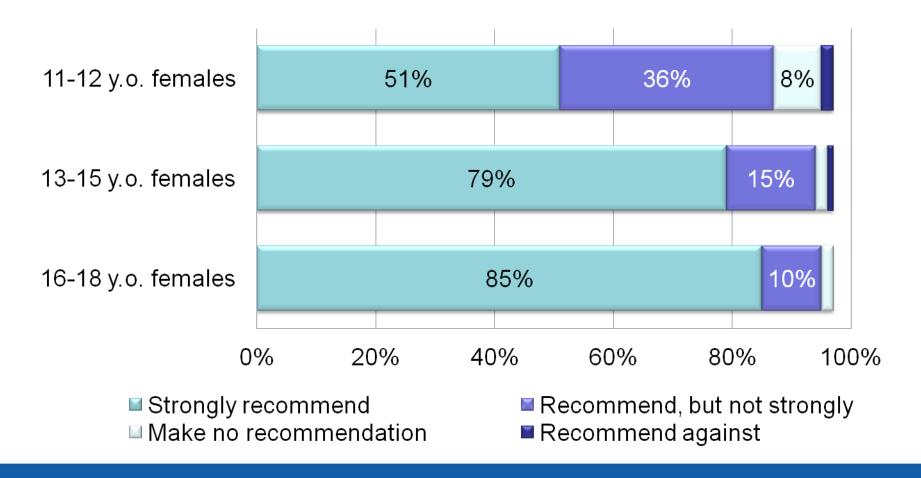
Most Common Reasons for Not Vaccinating Daughter, among Parents with No Intention to Vaccinate in the Next 12 Months, NIS-Teen 2011

| Not needed or necessary | 23.2% |
|-------------------------------|-------|
| Not sexually active | 19.5% |
| Safety concern/side effects | 19.3% |
| Lack of knowledge | 15.2% |
| No recommendation by provider | 9.6% |

Response categories are not mutually exclusive

2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

Strength of HPV Vaccine Recommendation for Female Patients, Pediatricians and Family Physicians (N=609)

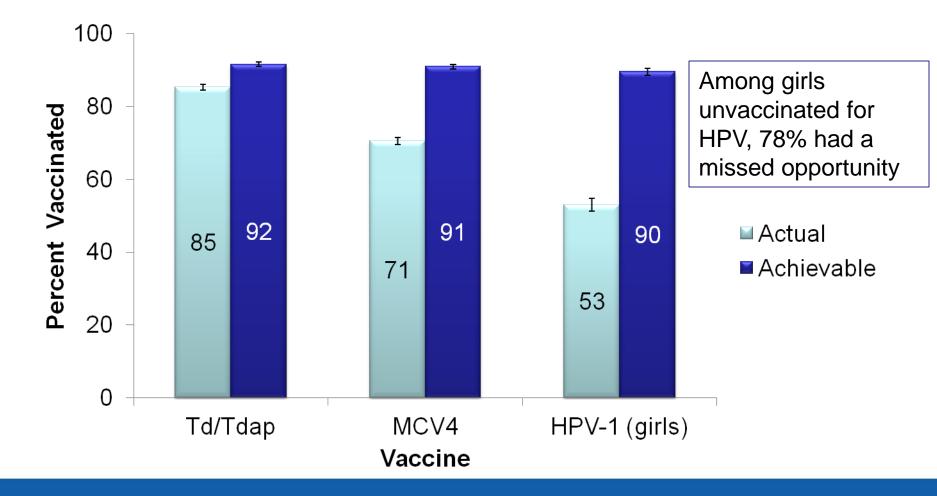


Allison et al. https://cdc.confex.com/cdc/nic2011/webprogram/Paper25181.html

HPV Vaccine Communications During the Healthcare Encounter

- HPV vaccine is often presented as 'optional' whereas other adolescent vaccines are recommended
- Some expressed mixed or negative opinions about the 'new vaccine' and concerns over safety/efficacy
- When parents expressed reluctance, providers were hesitant to engage in discussion
- Some providers shared parents' views that teen was not at risk for HPV and could delay vaccination until older

Actual and Achievable Vaccination Coverage if Missed Opportunities were Eliminated: Adolescents 13-17 Years, NIS-Teen 2011



Missed opportunity: encounter when some but not all ACIP-recommended vaccines are given HPV-1: receipt of at least one dose of HPV

2011 NIS-Teen available at http://www.cdc.gov/vaccines/stats-surv/nis/nis-2011-released.htm#nisteen

Summary

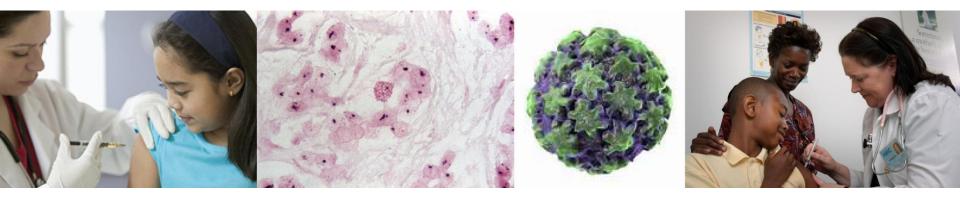
HPV vaccination coverage among U.S. adolescent girls is increasing, but slowly

Vaccination uptake varies by state

Efforts are needed to achieve high HPV coverage and subsequent HPV disease prevention:

- Address provider and parent attitudes towards HPV vaccination
- Improve communication skills among primary care providers
- Implement evidence based strategies (e.g. reminder/recall, coverage assessment and feedback) to reduce missed opportunities

What Is Needed to Increase HPV Vaccine Coverage?



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U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Disclosure

Dr. Middleman's institution receives grants from Novartis and the Society for Adolescent Health and Medicine

Increasing HPV Vaccine Coverage

Adolescent platform

A specific time period during which there is an expectation of vaccine completion

Public policy strategies

Provider strategies

- Practice strategies
- Provider communication

ACIP Adolescent Immunization Schedule ("Adolescent Platform")

| Vaccines | 11-12 yrs | 13-15 yrs | 16-18 yrs |
|-----------|----------------------|-----------|-----------|
| HPV | 3-dose series | | |
| Tdap | 1 dose | | |
| MCV4 | 1 st dose | | booster |
| Influenza | Annual immunization | | |



Range of recommended ages for all children

Range of recommended ages for catch-up immunization

Tdap: tetanus, diphtheria, and acellular pertussis vaccine MCV4: meningococcal conjugate vaccine ACIP: Advisory Committee on Immunization Practices

Building an Adolescent Immunization Platform

- Focuses on disease prevention and health promotion among this age group
- Presents opportunities for improved comprehensive care that includes other health issues (e.g., screening and prevention of risk behaviors)
- Creates parental and provider expectation of adherence to established adolescent vaccine recommendations



Increasing HPV Vaccine Coverage

- Adolescent platform
- Public policy strategies
 - **Provider strategies**
 - Practice strategies
 - Provider communication

Policy Approaches to Support Adolescent Immunization

- State legislative efforts for school requirements and education
- Utilization of alternative immunization sites
- Health insurance reform

Current State Legislation

Middle School requirements

- Vaccination: Td/Tdap: 41 states; MCV4: 13 states;
- HPV (vaccination: 2 (DC, VA)
- > HPV (education): 7 states (WA, LA, NC, MI, IA, TX, IN)

General state legislation related to HPV vaccine:

Education of parents/general public (n=14 states)

Study of state requirements and coverage

- School requirements: For Tdap and MCV4 significantly higher coverage compared with states no requirements
- Education requirements: for HPV and MCV4, no difference compared with states with no requirements

Alternative Immunization Sites and Potential Benefits

Sites

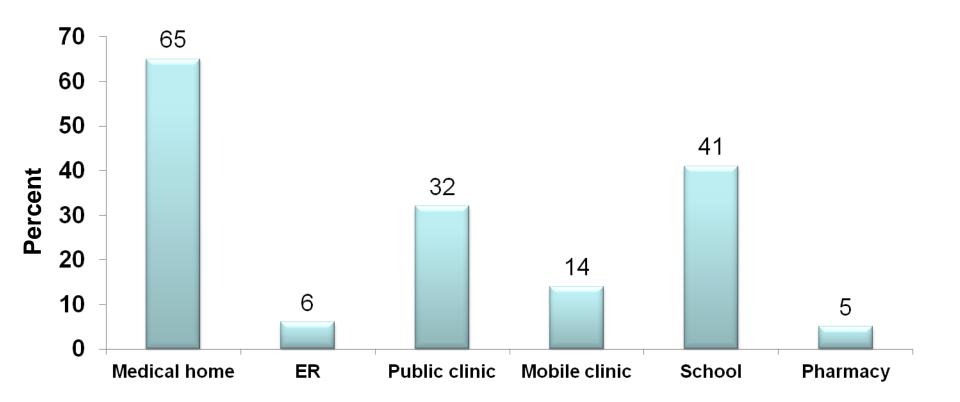
Pharmacies, school-located clinics, city/county clinics, family planning clinics, Ob/Gyn offices and clinics, emergency departments

Potential Benefits

- Immunize adolescents who lack a medical home AND provide a list of nearby adolescent medical homes
- Complete multiple-dose regimens
- Provide access (e.g., expanded hours and closer to home)
- Safety of vaccination at alternate sites documented
- Share information with patient's medical home using IIS

IIS: Immunization Information Systems D'Heilly SJ et al. Vaccine 2006;24:4024-27

Middle School Parents' Willingness to Use Alternative Sites



Houston, Texas; 1838 respondents Middleman AB et al. Vaccine 2010; 28:2674-78

School-Located Vaccination

Benefits

- Majority of adolescents attend school
- Potential to vaccinate a large number of adolescents
- Reach many adolescents who may not have regular access to healthcare

Challenges

- > Adolescent participation may be limited to specific sub-groups
- Cost to provide vaccination in schools can be quite high
- Billing different health plans for immunization services
- Obtaining parental consent

Preliminary Data From A School-located Immunization Program Targeting VFC-eligible Students in Houston, Fall, 2012

Approximately 6% of all students returned consent forms
Among 8 middle schools, 522 eligible students were immunized:

| Vaccine | Number Administered |
|-------------------------------|---------------------|
| Flu (inactivated and LAIV) | 475 |
| Тдар | 328 |
| MCV4 | 327 |
| HPV | 410 |
| Other (HepB, varicella, etc.) | 82 |

Middleman AB, Short MB, Auslander BA. Unpublished data. VFC: Vaccines for Children

Insurance Reforms that Might Impact Vaccine Uptake (Affordable Care Act)

First dollar coverage under private insurance

- No out of pocket costs for all ACIP routinely recommended vaccines when given by in-network provider
- In effect September 2010
- Plans have one year following CDC adoption of <u>new</u> ACIP recommendations to implement

Increase in Medicaid reimbursement for vaccine administration fee - time limited

- Time period: 2013-2014
- Before 2013 range: \$2.00 \$17.85
- Proposed fees range: \$19.54 \$27.44

Increasing HPV Vaccine Coverage

Adolescent platform

Public policy strategies

Provider strategies

- Practice strategies
- Provider communication

Strengthening Immunization in the Medical Home: What Can Providers Do?

Increase their own knowledge regarding vaccine recommendations and safety of recommended vaccines

Improve communication with parents

- Importance of provider recommendation
- Overall messages
- Responses to specific concerns

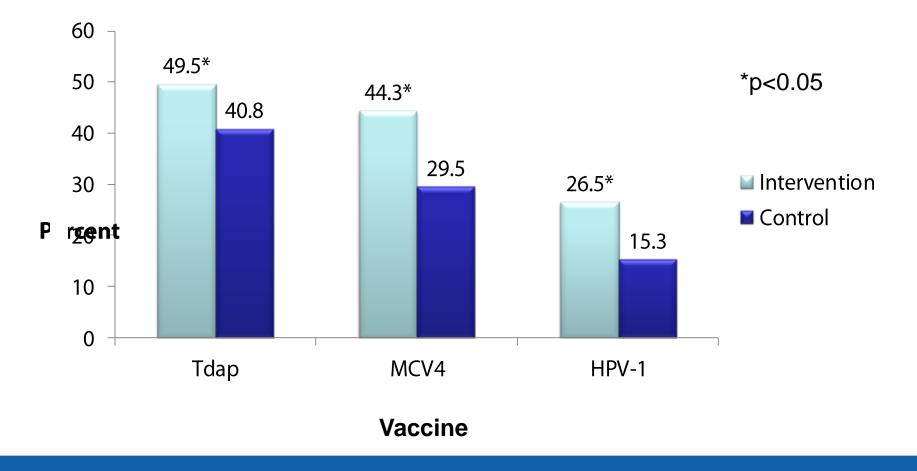
Initiate practice changes to increase immunization

- Recall systems
- Screening tools and standing orders
- Use of Immunization Information Systems (IIS)
- Vaccination "quick visits"



Guide to Community Preventive Services at http://www.thecommunityguide.org/vaccines/universally/index.html

Impact of Reminder and Recall on Vaccination Rates among Adolescents



Key Messages for Parents

- This is a vaccine to prevent CANCER
- The vaccine is SAFE and EFFECTIVE
- The time to give the vaccine is before exposure
- Vaccine is recommended for boys and girls

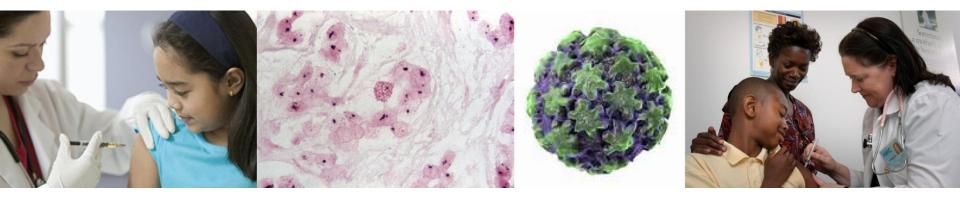
Guidance for Providers: Improving the "Discussion"

- The discussion regarding mode of HPV transmission should be age appropriate
- Discussion of HPV vaccine might provide an opportunity to discuss sexual health issues, if appropriate
- Vaccination not found to result in increase sexual risk behavior

Take Home Points

- New immunization recommendations provide enhanced primary prevention opportunities for adolescents
- Public health policies at state and federal levels can be implemented to support adolescent immunization
- Providers can implement communication and quality improvement strategies in the office to improve adolescent immunization rates

Prevention of HPV-associated Disease Global and Domestic Overview



Lauri Markowitz, MD

Team Lead Division of STD Prevention National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention

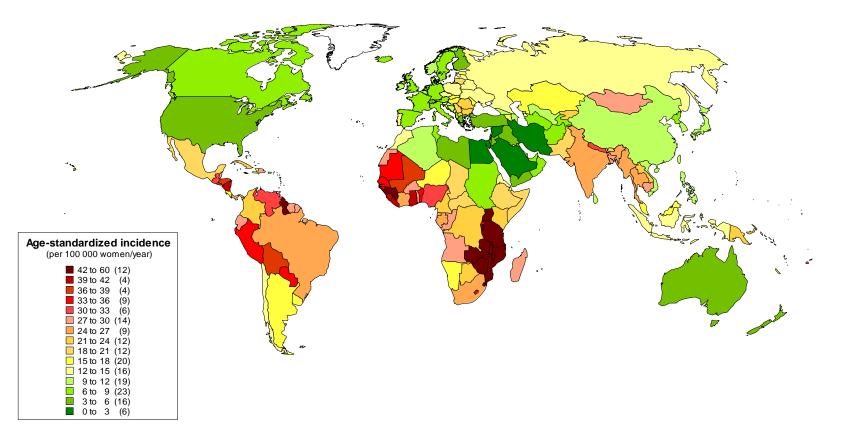


U.S. Department of Health and Human Services Centers for Disease Control and Prevention

Global Burden of Cervical Cancer

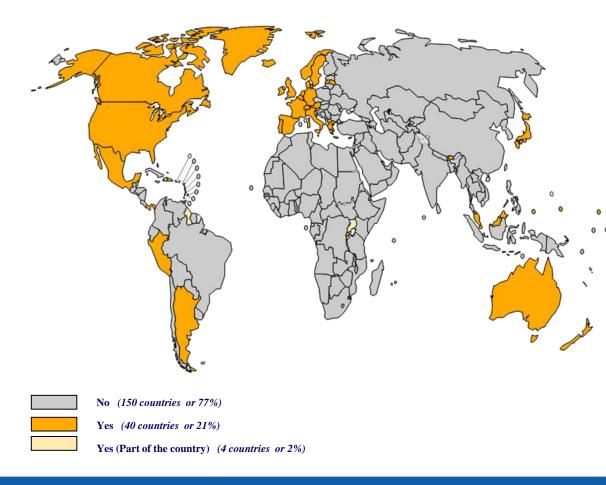
Incidence of cervical cancer per 100,000 females (all ages), age-standardized 2008

80% of cervical cancer deaths occur in developing countries



Arbyn M et al. Ann Oncol 2011;22:2675-86

Countries with HPV Vaccine in their National Immunization Schedules, 2011



- HPV vaccination programs have been introduced into more than 40 countries
- Most are developed countries
- Challenges:
 - Expense of vaccine
 - Competing priorities with other new vaccine introduction
 - Adolescent target age group

WHO/IVB database, 194 WHO Member States. Data as of October 2012

International Cervical Cancer Prevention Efforts

WHO recommends introduction of HPV vaccination

Part of a comprehensive strategy for cervical cancer prevention

Vaccine financing will allow increased HPV vaccine introductions in low resource countries

- The Global Alliance on Vaccines and Immunizations (GAVI) will fund HPV vaccine for eligible countries starting in 2013
- Cervical cancer prevention through other public-private partnerships focusing on cervical cancer screening
 - Pink Ribbon Red Ribbon[®]

(Partners include Susan G. Komen for the Cure, PEPFAR, George W. Bush Foundation, UNAIDS)

WHO. WER No.15, 2009;84:117-32 http://www.gavialliance.org/

Summary

- The substantial burden of HPV-associated disease can be decreased by use of two available safe and effective prophylactic HPV vaccines
- In the United States, vaccine coverage is below target goals
 - Programs are in place to monitor coverage, safety and impact of vaccination
 - > Measures can be implemented to improve vaccine uptake
- Progress being made to introduce vaccine in low income countries where most cervical cancer cases and deaths occur