

Human Papillomavirus Vaccine

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Outline



- Background on Human Papillomavirus (HPV)
- HPV Vaccines coverage rates, safety and long-term efficacy
- Patient confidentiality
- HPV vaccine availability

Human Papillomavirus (HPV)

- The most common sexually transmitted infection (STI)
- Double-stranded DNA viruses
- A group of >150 related viruses
 - Can be divided into cutaneous or mucosal categories based upon their tissue tropism
- In most cases, HPV resolved independently
 - But it can cause health problems like genital warts and cancer

HPV Associated Diseases

- HPV is associated with the development of:
 - Anogenital cancer (including cervical, vaginal, vulvar, penile, and anal)
 - Oropharyngeal cancer
 - Genital warts
- Thirteen strains have been shown to cause cervical cancer
- HPV types 16 and 18 account for 66% of cases of cervical cancer
- HPV types 6 and 11 account for 90% of genital warts cases

HPV Associated Diseases

| Disease | % caused by HPV |
|-----------------------|-----------------|
| Cervical Cancer | 91% |
| Anal Cancer | 91% |
| Genital Warts | 90% |
| Oropharyngeal Cancer | 72% |
| Vulvar/Vaginal Cancer | 69-75% |
| Penile Cancer | 63% |

In 2012 there was an estimated 270,000 related deaths and 530,000 new cases worldwide due to Cervical Cancer.

MMWR. Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP).” August 29, 2014.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6305a1.htm>

"Human papillomavirus (HPV) and cervical cancer." *World Health Organization*. N.p., Mar. 2015. Web. 2 May 2016.

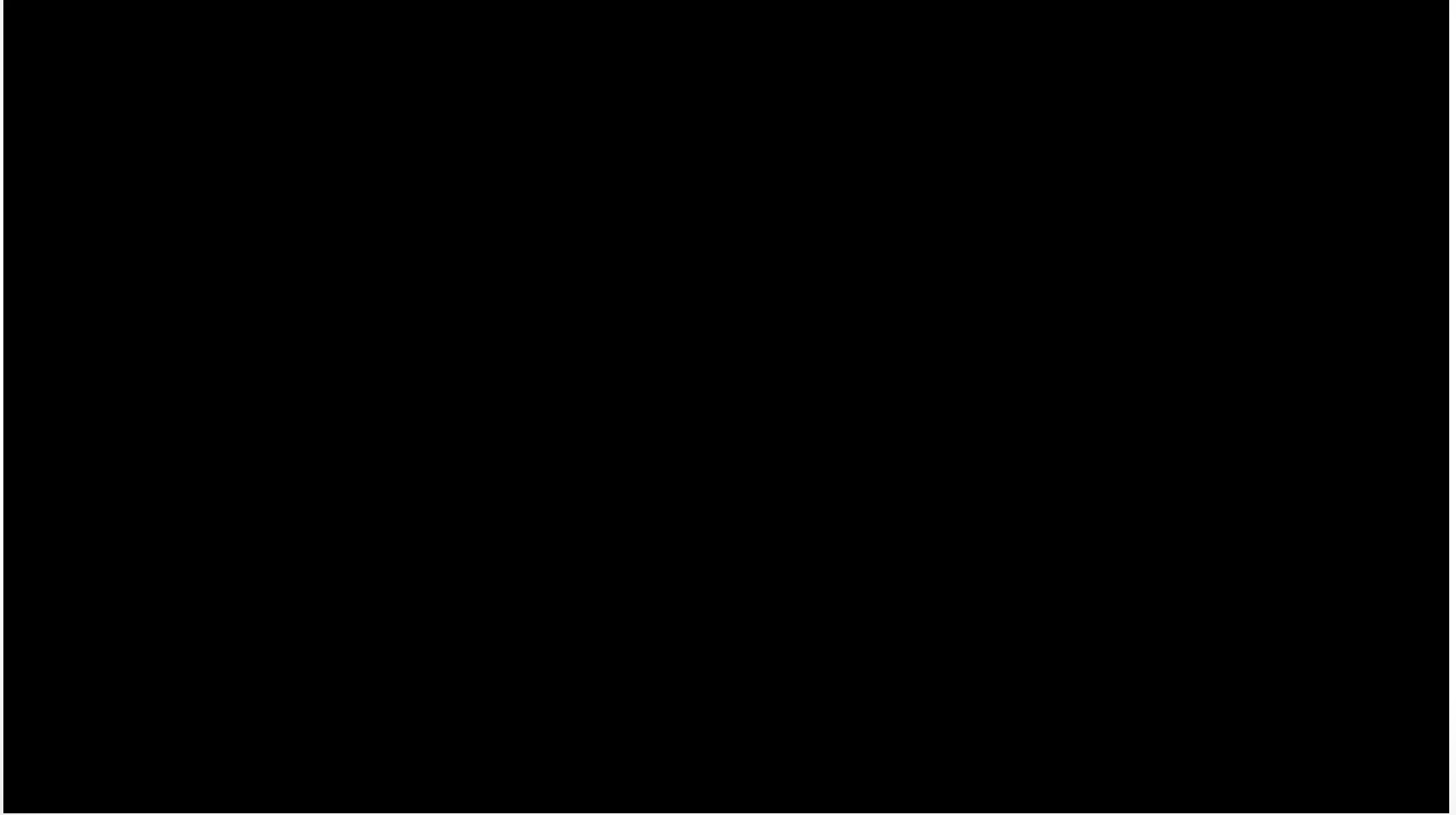
<http://www.who.int/mediacentre/factsheets/fs380/en/>

HPV Statistics



- Nearly 80 million Americans are currently infected with HPV
 - 1 in 4 affected with HPV
 - 14 million new HPV infections each year
 - Estimated to cause 1 out of every 20 cancers worldwide
- Lifetime probability of contracting HPV is 85% in women and 90% in men
 - HPV affects ALL people even those in responsible, monogamous relationships
 - >80% of sexually active men and women will have been exposed by age 45

HPV Vaccines



Vaccination Rates in the U.S.

- HPV vaccination rates in the United States are **unacceptably low**
 - 60% of girls and 41.7% of boys aged 13–17 years in the United States have received at least one vaccine dose
 - Only 40% of girls and 21.6% of boys in the same age group have received all three doses.
- In California:
 - About 48% of girls in the same age group and 31 % of boys were estimated to have received three doses of the vaccine

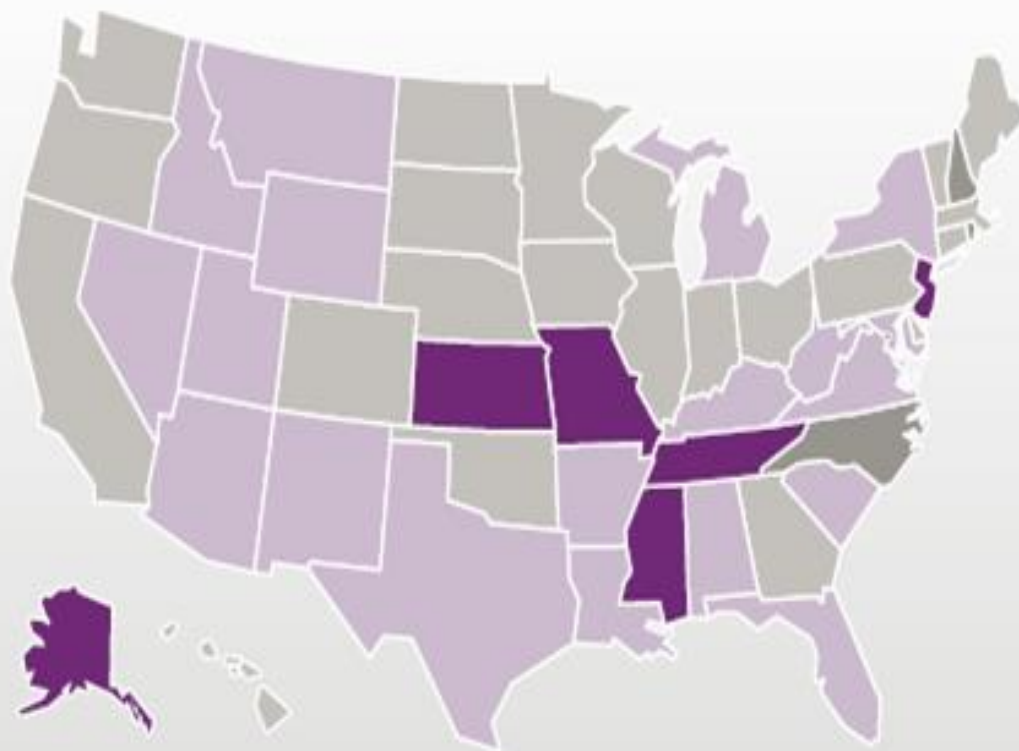
Vaccination Rates in the U.S.

NATIONWIDE
4 OUT OF 10
GIRLS ARE UNVACCINATED

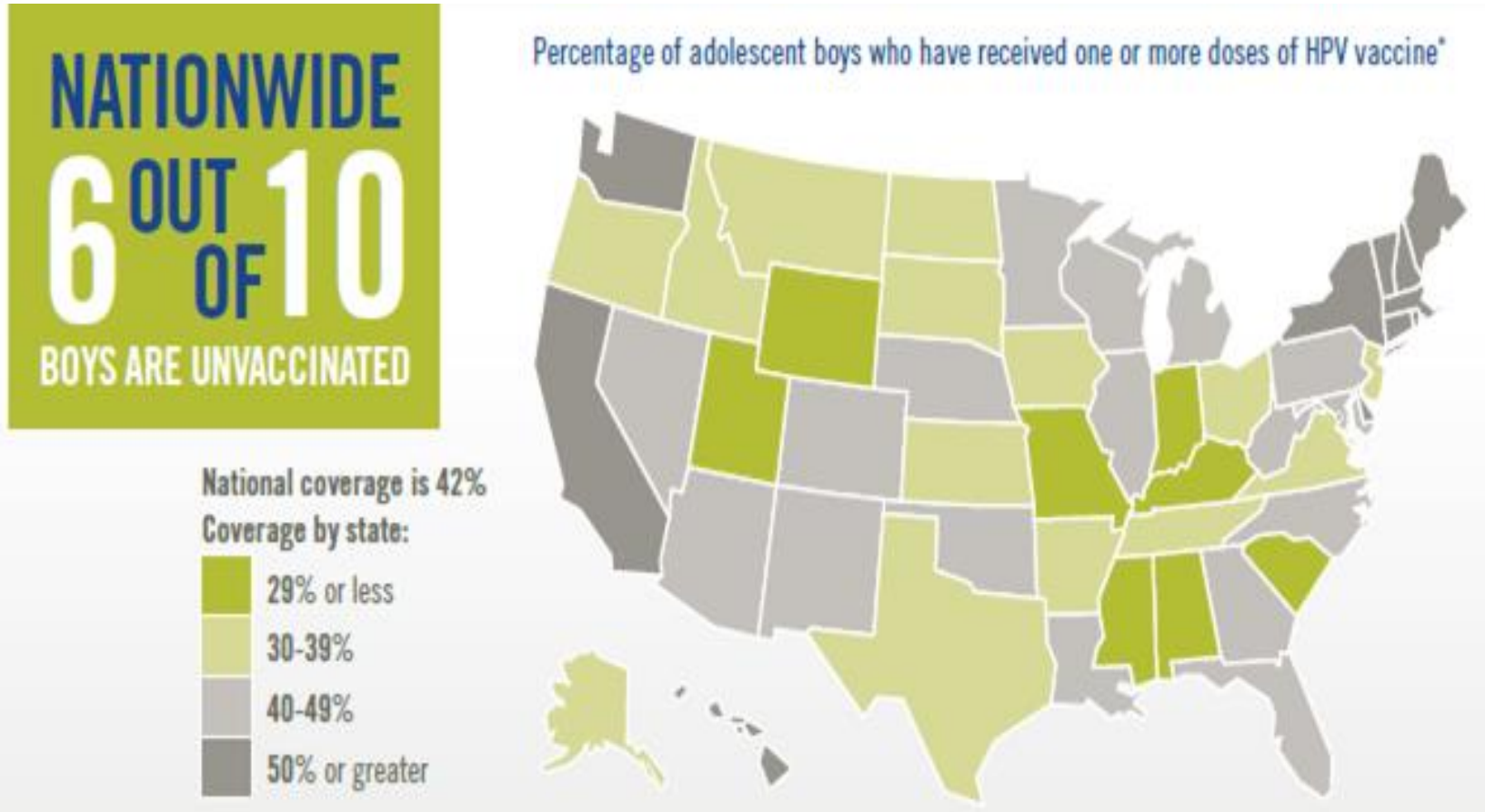
Percentage of adolescent girls who have received one or more doses of HPV vaccine*

National coverage is 60%

Coverage by state:



Vaccination Rates in the U.S.



NEWS: Teenager who died after having HPV vaccine



- Natalie Morton a 14 y/o teenager from Great Britain received the HPV vaccine (Cervarix) in 2009
- She died 2 hours after being vaccinated
- Immediate suspicion?
 - The HPV vaccine
 - Vaccination programs around the country were disrupted
- Cause of death?
 - Tumor of unknown origin in her heart and lungs
 - The vaccine was not a contributory factor
 - “Condition was so severe that that death could have arisen at any point”

Anti-vaccine Propaganda

- HPV vaccines affect fertility
 - Also thought to be related to the chemical stabilizer polysorbate 80
- Infertility is actually indirectly protected by the HPV vaccine
 - High-risk HPV infection in women leads to cervical cancer
 - Cervical cancer treatments (hysterectomy, chemotherapy, or radiation) could leave a women unable to have children

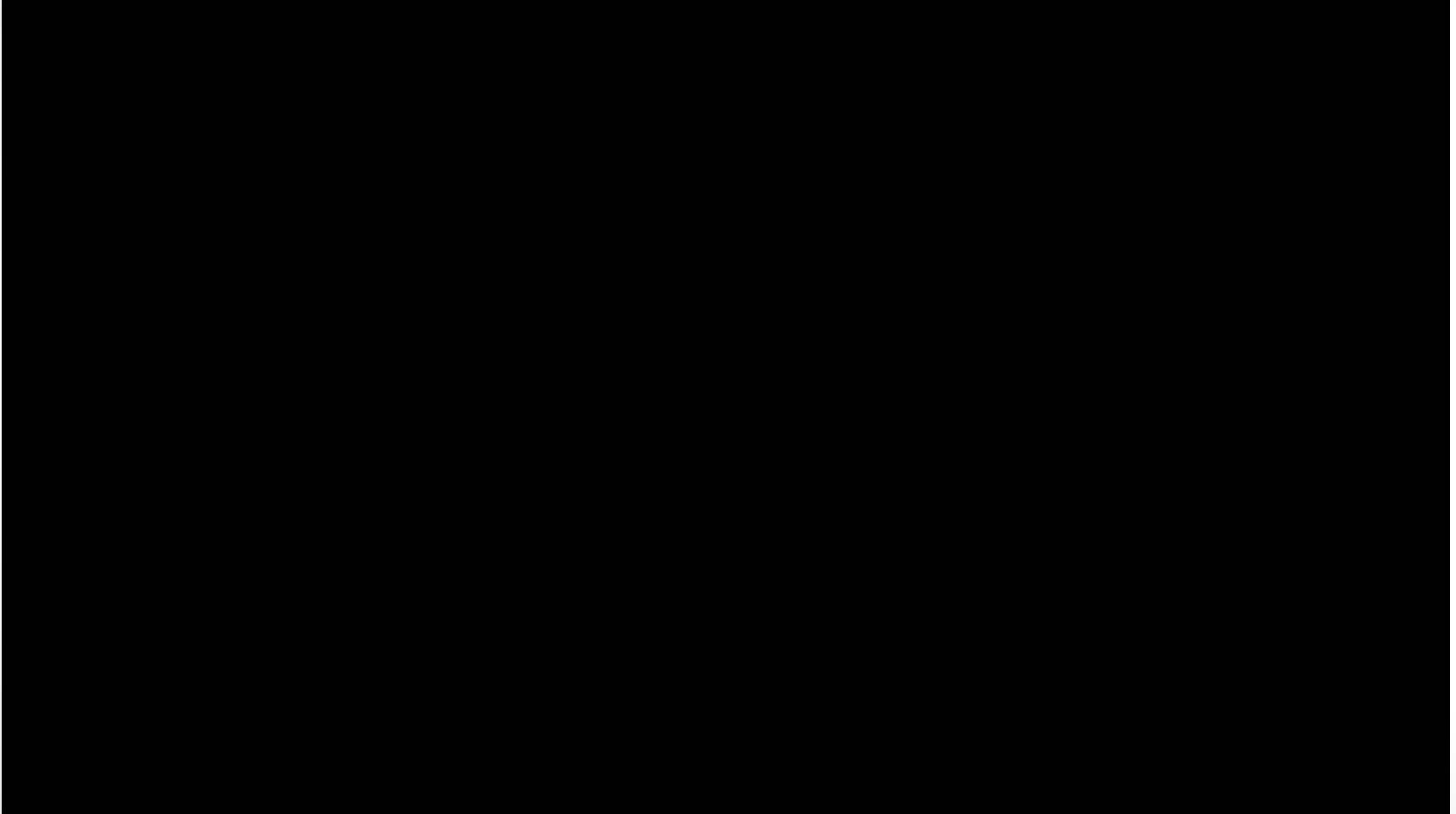
Anti-vaccine Propaganda

- Premature ovarian failure (POF) or premature menopause
 - POF: Loss of normal ovarian function before age 40
 - Mechanism of action: Proposed autoimmune associations with aluminum adjuvant used and polysorbate 80
 - From 2006 – 2015, VAERS received 26 reports of POF or related conditions following receipt of Gardasil in the United States
 - No patterns were determined with POF reports
 - Gardasil® clinical trials did not show an association between POF or infertility and the HPV vaccination

HPV Vaccine Safety Data

- More than 80 million doses of HPV vaccine have been distributed from June 2006 to September 2014
- According to the VAERS, there are no data linking the HPV vaccination to any severe adverse effects or adverse reactions
 - 92% of Gardasil reports were classified as non-serious
 - 7.6% classified as serious included serious nausea, vomiting, headache, and fever
- The 4vHPV and 9vHPV had similar safety profiles
 - 9vHPV had a higher rate of injection site swelling and erythema than 4vHPV

Addressing Vaccine Safety Concerns



Long-term Efficacy

- Australian HPV Vaccination Program
 - Initiated in April 2007
 - Used quadrivalent vaccine (4vHPV)
 - 4vHPV is included as a routine vaccination for girls (aged 12-13 years)
 - Catch-up strategy, from Apr 2007 to Dec 2009, included women up to age 26
 - Boys (aged 12-13 years) were included in the program in 2013

Australian HPV Vaccination Program Study

- Included 2 groups of women aged 18-24 years
 - Prevaccine-implementation sample: Between Oct 2005 – Jul 2007
 - Postvaccine-implementation sample: Between Aug 2010 – Nov 2012
- Results
 - Crude prevalence of 4vHPV targeted genotypes:
 - Prevaccine sample 29% (n=202)
 - Postvaccine sample 7% (n=1058) $p < 0.0001$
 - Adjusted prevalence ratio for unvaccinated women was 0.65
 - Suggests herd immunity

Long-term Efficacy

- National Health and Nutrition Examination Study (NHANES)
 - Surveys conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention (CDC)
- HPV DNA prevalence analyzed in cervicovaginal specimens in NHANES
 - Include females aged 14 to 34 years in prevaccine era (2003-2006) and vaccine era (2009-2012)
 - Compared prevalence of 4vHPV types and other HPV types between eras

Long-term Efficacy

- Results:

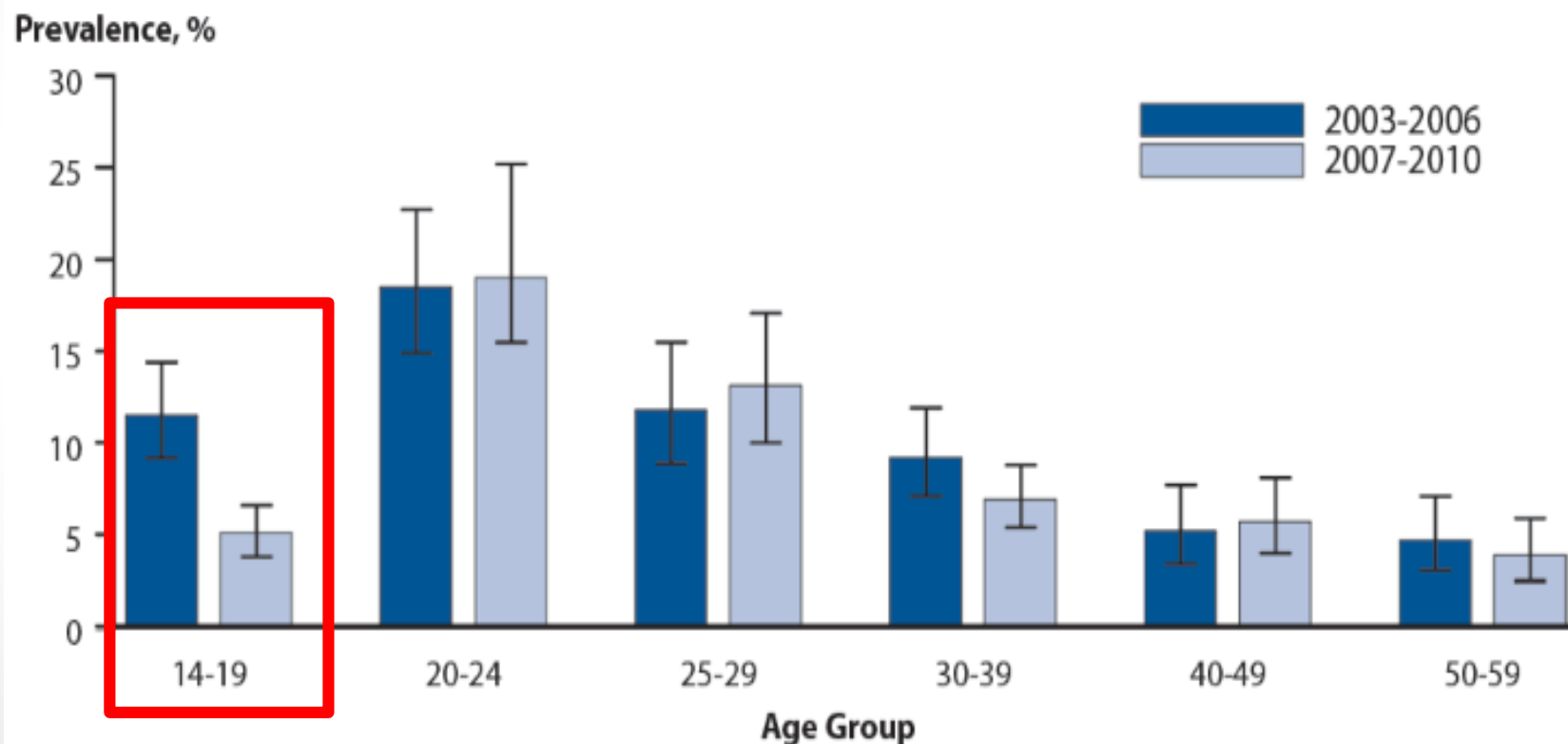
| Age Group | Prevaccine Era 2003-2006 % (95% CI) | Vaccine Era 2009-2012 % (95% CI) |
|-----------------|---|--|
| 14-19 Years old | 11.5 (9.2-14.4) | 4.3 (2.7-6.8) |
| 20-24 Years old | 18.5 (14.9-22.7) | 12.1 (9.1-16) |

- Conclusion

- 64% decrease in 4vHPV type prevalence among females aged 14 to 19 years and 34% decrease in females 20 to 24 years old

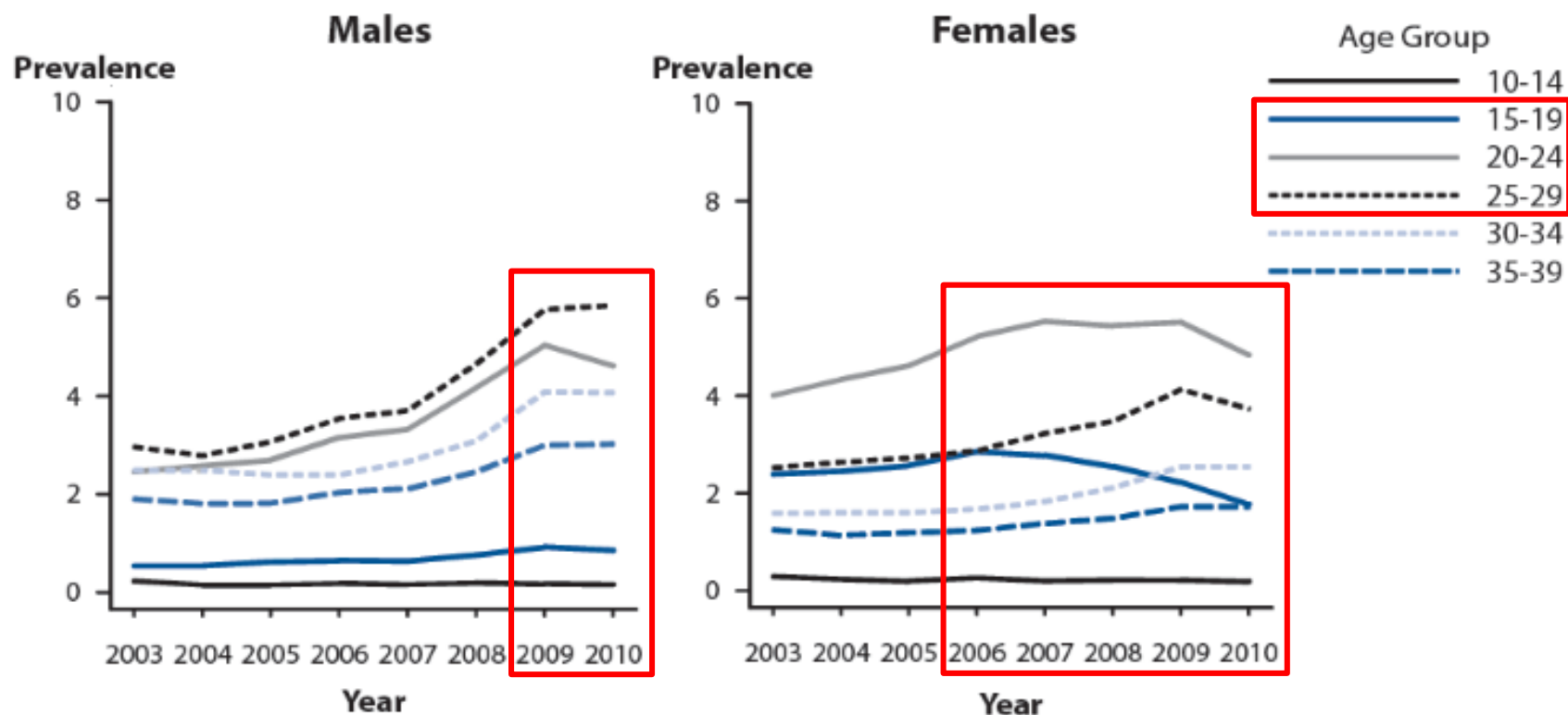
Long-term Efficacy

Cervicovaginal Prevalence of Types 6, 11, 16, and 18 Among Women Aged 14-59 Years by Age Group and Time Period, 2003-2006 and 2007-2010



Long-term Efficacy

Genital Warts Prevalence Among Aged 10-39 Years by Sex, Age Group and Year, 2003-2010

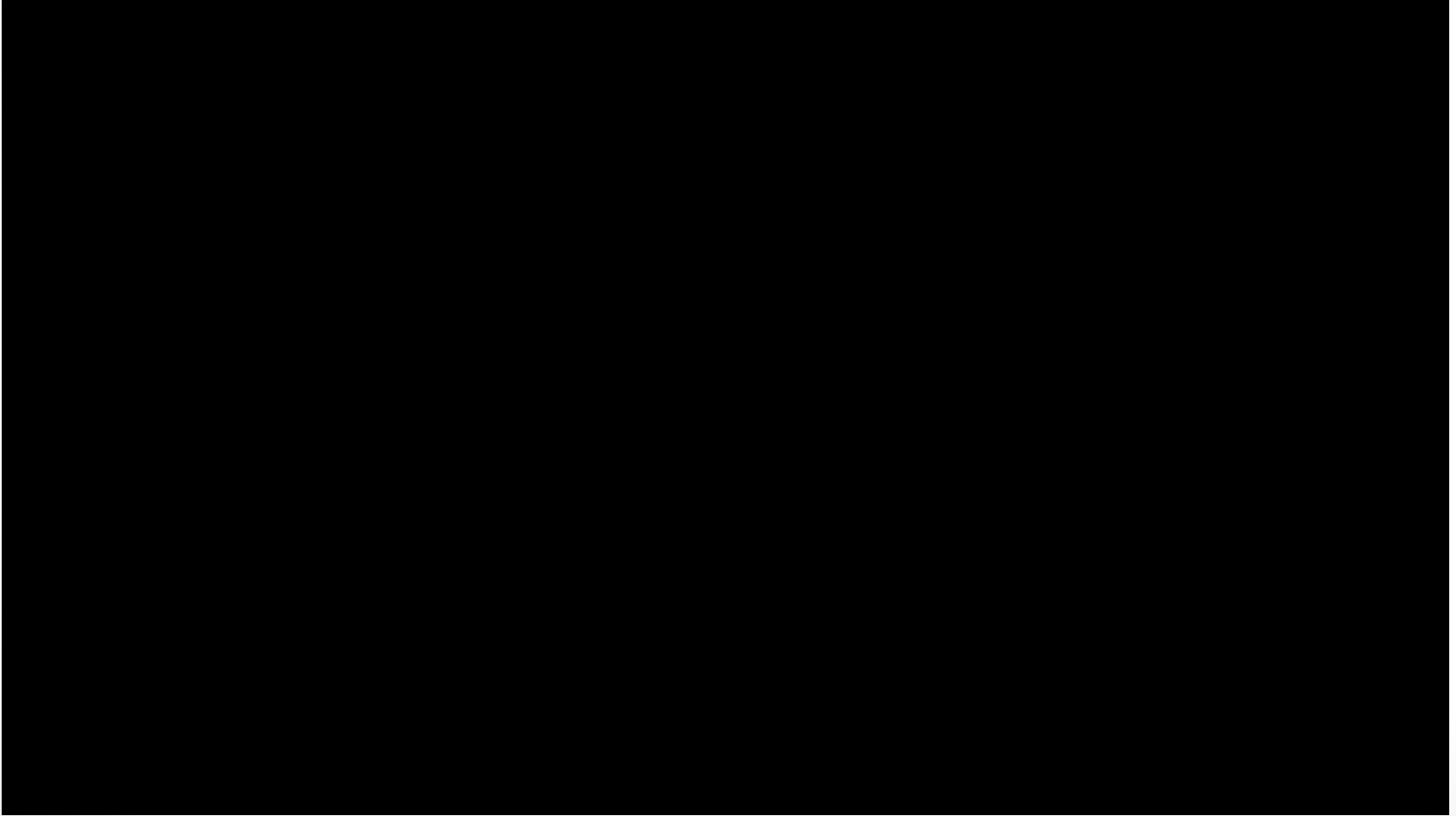


Addressing Vaccine Refusal

- Crucial role of physicians in HPV vaccine parental acceptance
- With an increase in HPV vaccination coverage to 80%, it is estimated to prevent 53,000 cases of cervical cancer during the lifetime of those < 12 years old
- 3 vaccinations recommended for preteens (ages 11 or 12) in a single visit
 - Protect me with 3+ Program
 - Quadrivalent meningococcal conjugate vaccine
 - HPV vaccine
 - Tdap vaccine



HPV, Tdap, and MCV Vaccines



Top 5 reasons adolescents are not receiving the HPV vaccine

| Parents of girls | | Parents of boys | |
|-----------------------------|------|------------------------------|------|
| Reason | % | Reason | % |
| Lack of knowledge | 15.5 | Not recommended | 22.8 |
| Not needed or necessary | 14.7 | Not needed or necessary | 17.9 |
| Safety concern/side effects | 14.2 | Lack of knowledge | 15.5 |
| Not recommended | 13.0 | Not sexually active | 7.7 |
| Not sexually active | 11.3 | Safety concerns/side effects | 6.9 |

Addressing Vaccine Refusal

Target education – It's about cancer prevention not sex

Vaccination is most effective prior to onset of sexual activity

Vaccination is not associated with an earlier onset of sexual activity or increased incidence of STI

Use presumptive language – “She or he is due for a shot today.”

Address fears of immediate and long-term side effects

Keep a positive, non-confrontational dialogue open

CA Law AB 499 (Effective 1/1/12)

- Minors ≥ 12 years of age may request for confidential medical services for the prevention of sexually transmitted diseases (STDs) without their parents' consent
 - Includes:
 - HPV and Hepatitis B Vaccines
 - Medications to prevent STDs and HIV infection



Minors' Confidentiality

- The medical information of a minor ≥ 12 years of age cannot be shared with parents unless consent is given by the minor (Cal. Health & Safety Code §§ 123110(a), 123115(a)(1); Cal. Civ. Code §§ 56.10, 56.11)
- Insurance companies may share claims information about STD prevention services with primary policy holders, such as parents
- Immunization data about minors in CAIR and other record systems may be accessible to parents.

HPV Vaccine Availability

| Pharmacy | HPV Vaccine Offered |
|------------------|---------------------------|
| Ralphs | Yes |
| Walgreens | Yes |
| CVS | Yes (Minute Clinic Only) |
| Rite-Aid | Yes (Varies by location) |
| Costco | Yes |
| Walmart | Yes |
| Vons | Yes |
| Albertsons/Savon | Yes (By appointment only) |

Summary

- Diseases associated with HPV can be prevented
- HPV vaccine coverage rates remain low in California and throughout the United States
- It is important to address and resolve parental and patient concerns regarding the safety and efficacy of the HPV vaccine
- The HPV vaccine is about preventative health and is readily available in many locations, including pharmacies

References

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3. Human Papillomavirus – Teen Vaccination Coverage. (July 2015). Retrieved March 25, 2016. <http://vaccines/who/teens/vaccination-coverage.html>
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6. O’Dowd A. Teenager who died after having HPV vaccine had a malignant chest tumour. BMJ. 2009 October 1; 339:b4032.

Questions?

*Thank
You*