

# Preventing Cancer – the HPV Vaccine for *Who Calls the Shots?*

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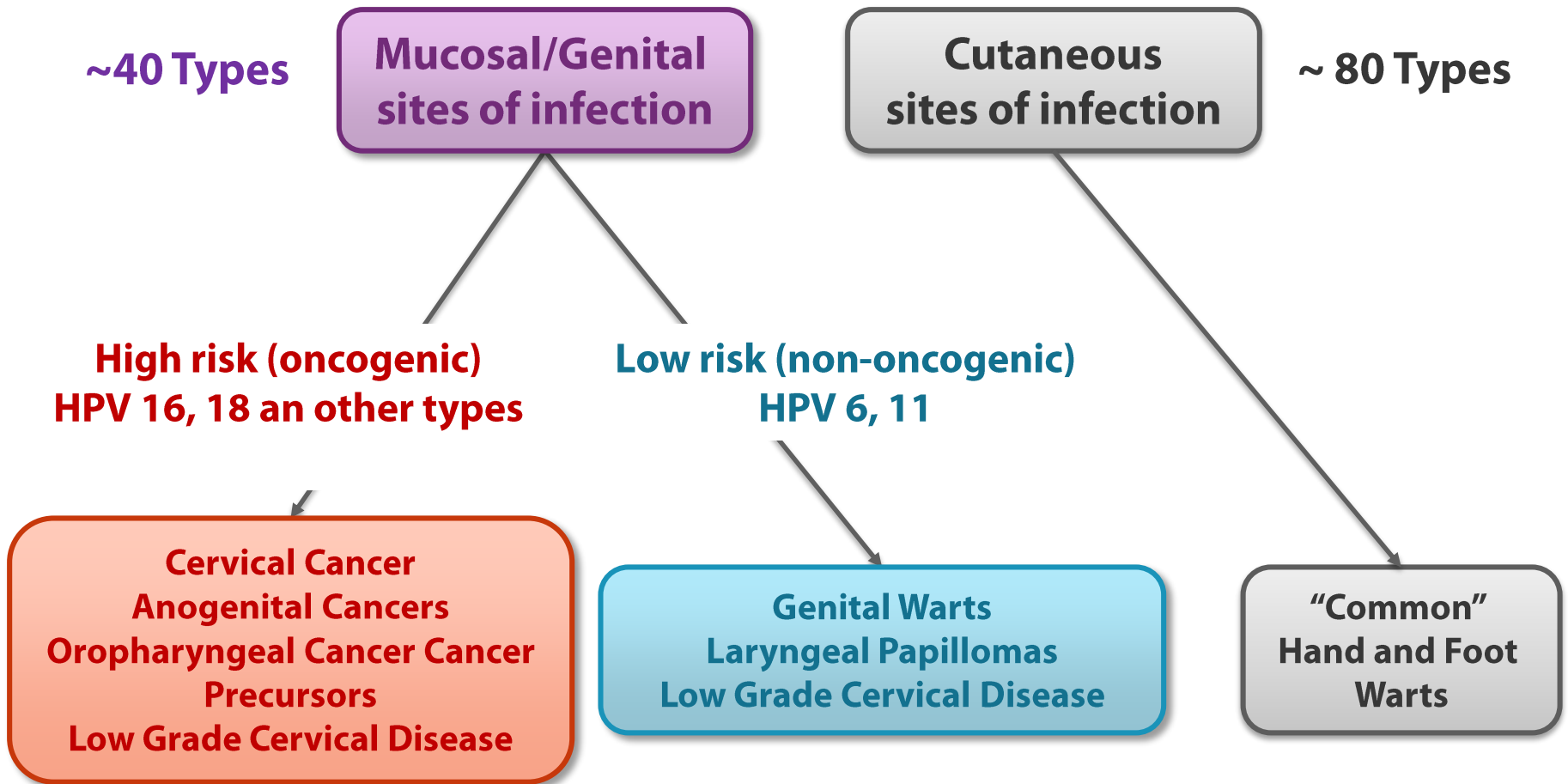
# Potential conflicts of interest

- Dr. Ault was an investigator multiple HPV vaccine trials, including the recently published HPV9 trial. Funding was provided to Dr. Ault's university.
- Dr. Ault represents the American College of Ob-Gyn at the ACIP.
- He also acts as an advisor to NCI and ACOG on vaccine and cancer prevention.

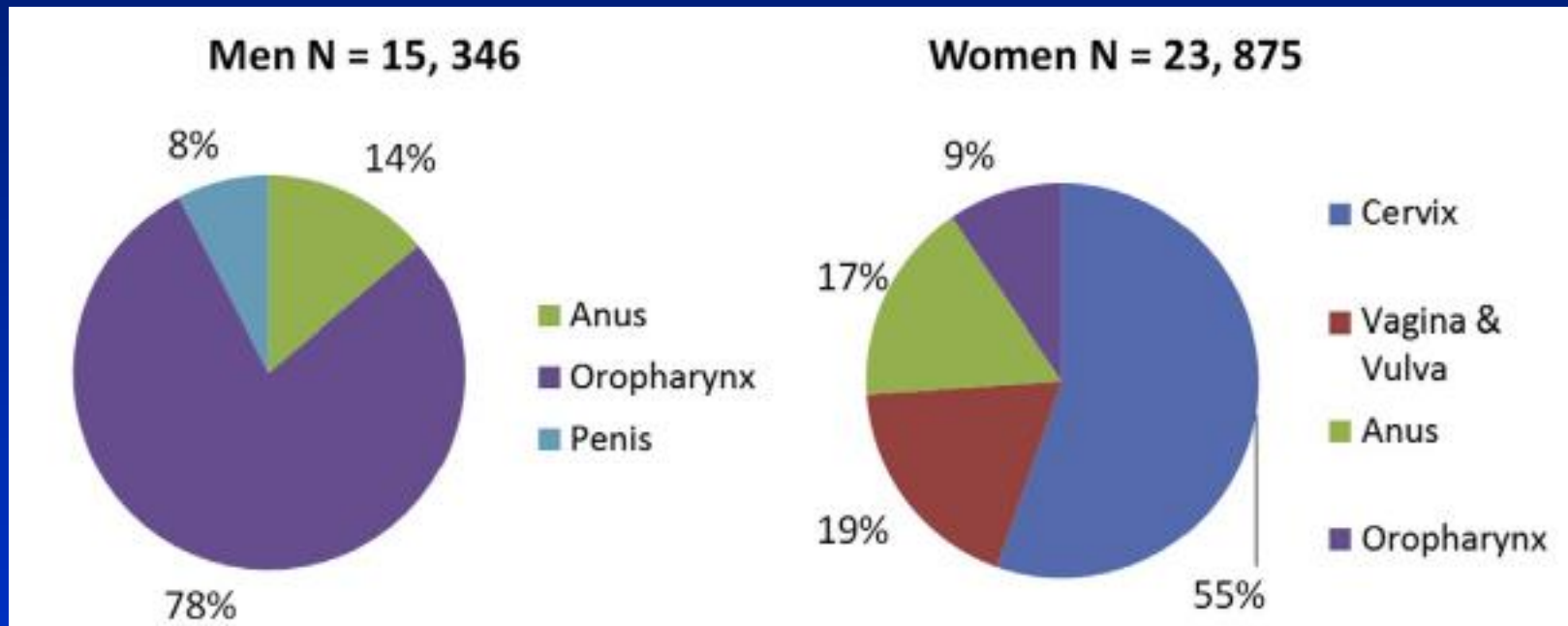
# HPV Vaccine – What's New?

- New Cancer Data
- New Version of Vaccine
- New ACIP Recommendations
- New Uptake Data
- New Data on Importance of Physician Recommendation

# HPV Types Differ in their Disease Associations



# HPV Related Cancers USA 2015



See Pahud & Ault 2015 and Saraiya *et al* 2015

# Available HPV Vaccines in the USA 2015

	<b>Bivalent</b>	<b>Quadrivalent</b>	<b>Nonavalent</b>
<b>Manufacturer</b>	<b>GlaxoSmithKline</b>	<b>Merck</b>	<b>Merck</b>
<b>L1 VLP types</b>	<b>16, 18</b>	<b>6, 11, 16, 18</b>	<b>6, 11, 16, 18, 31, 33, 45, 52, 58</b>
<b>Adjuvant</b>	<b>AS04</b> 500 µg aluminum hydroxide 50 µg 3- <i>O</i> -desacyl-4'- monophosphoryl lipid A	<b>AAHS</b> 225 µg amorphous aluminum hydroxyphosphate sulfate	<b>AAHS</b> 500 µg amorphous aluminum hydroxyphosphate sulfate
<b>Licensed age groups (year)</b>	<b>Females 9-25 years (2009)</b>	<b>Females 9-26 years (2006)</b> <b>Males 9-26 years (2009)</b>	<b>Females 9-26 years and Males 9-15 years (2014)</b>

Source - ACIP meeting Feb 2015

# Recommendations for HPV Vaccine – ACIP 2015

- Routine HPV vaccination recommended for both males and females ages 11-12 years
- If not previously vaccinated, catch-up for males 13-21 years and females 13-26 years
- Vaccine can be given starting at age 9 years
- Recommended schedule of doses at 0, 1-2, 6 months

MMWR March 27, 2015 and 2016 ACIP Vaccination recommendations

# Efficacy of 9-Valent HPV Vaccine

- Clinical trial compared HPV9 and HPV4, not placebo controlled
- Approximately 18,000 women
- 96.7% protection against HPV 31,33,45,52,58 - related outcomes
- “non-inferior” immune responses to original four types in HPV4 in women vaccinated with HPV9

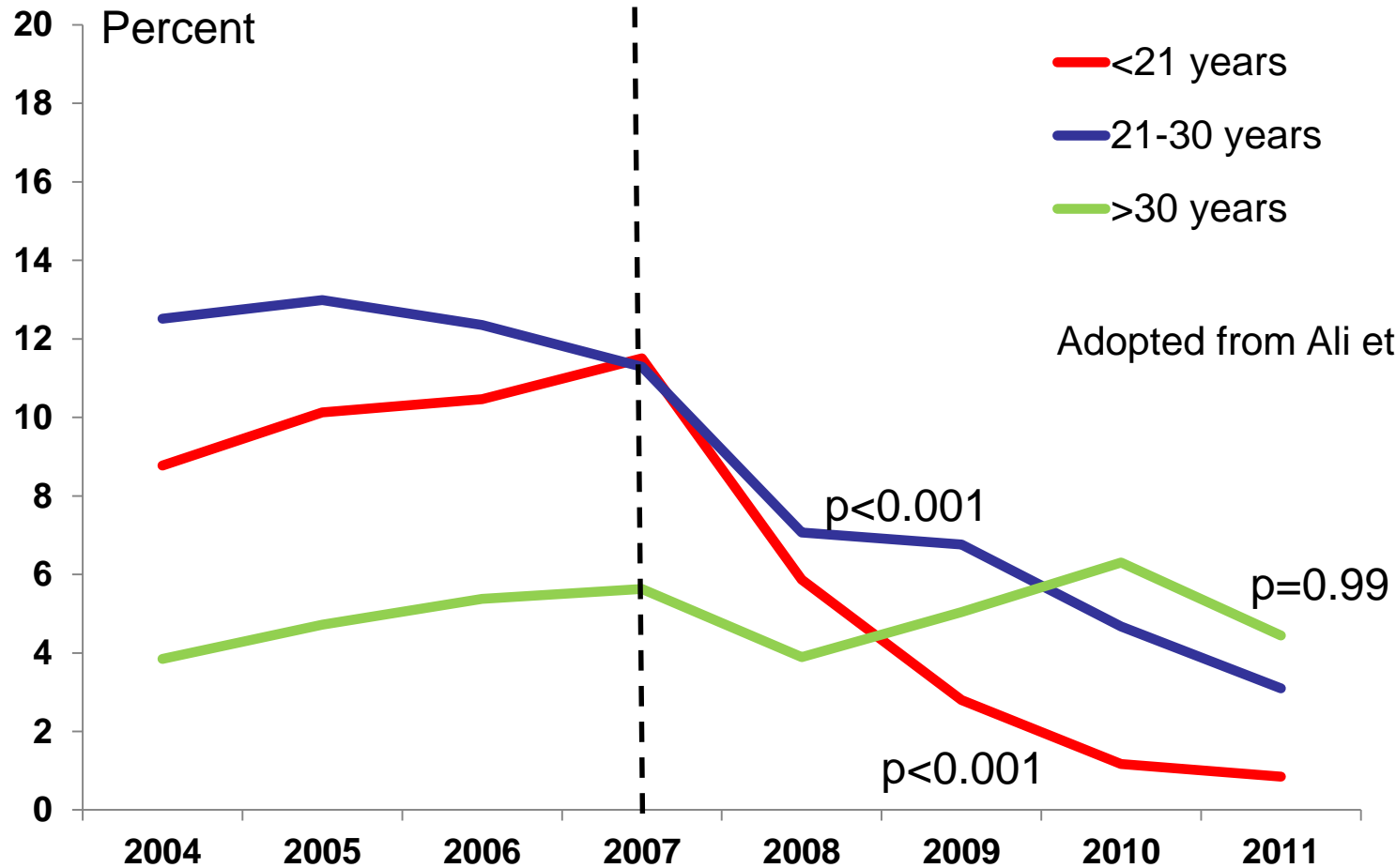


# Safety and Tolerability of a 9-Valent HPV Vaccine in Boys and Girls 9-15 Years Old

- Many recent publications concerning vaccine for all versions of the HPV vaccine
- HPV9 vaccine was generally well tolerated in women age 16-26 and boys/girls age 9-15
- Vaccine AEs largely attributable to injection-site AEs
  - Most of were of mild or moderate intensity
  - Vaccine-related serious adverse experiences rare

See Van Damme et al 2015

# Proportion of Australian-born Women with Genital Warts by Age Group, 2004-2011



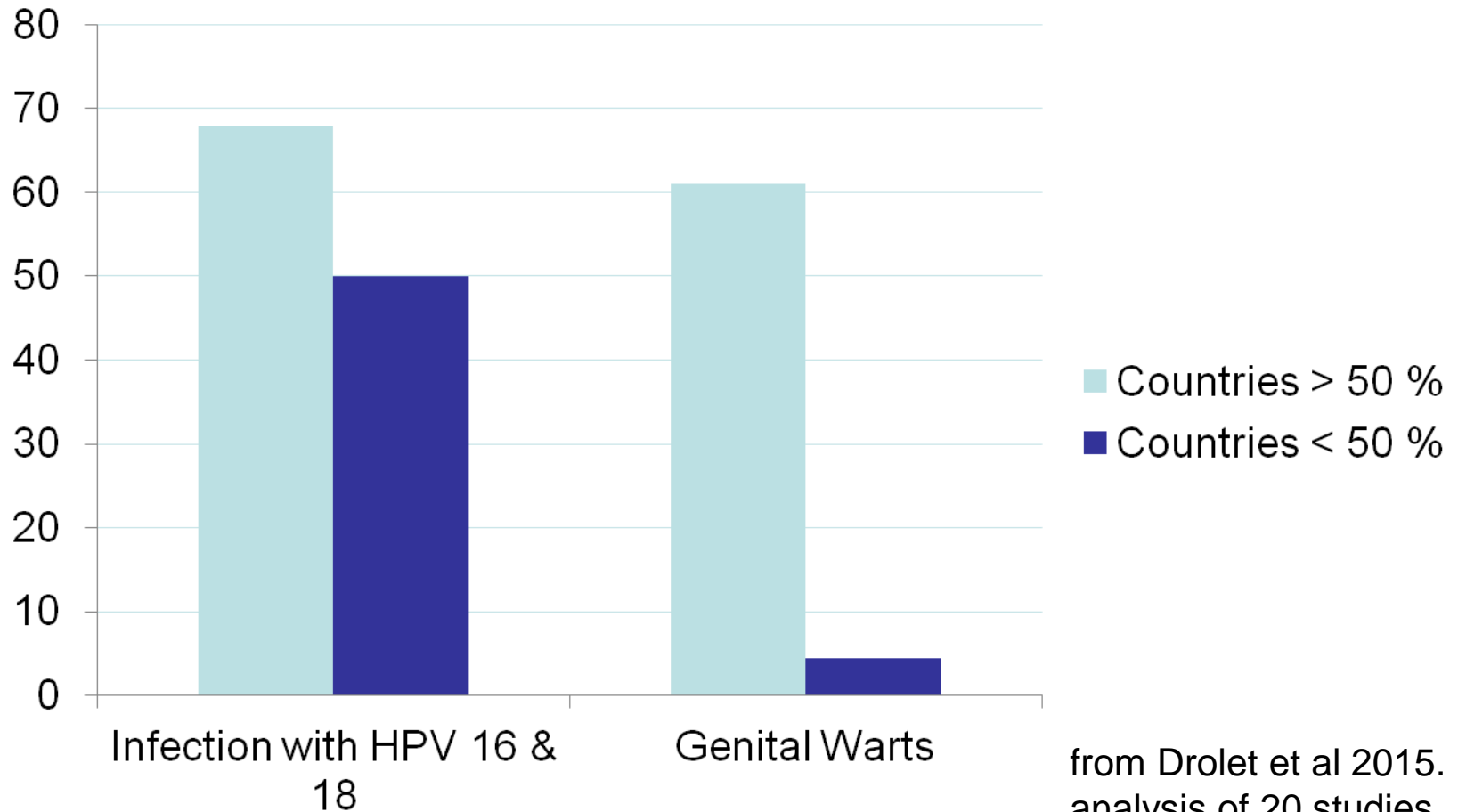
# Meta analysis of Population Effects of HPV Vaccination

- Twenty studies were summarized
- In countries where there was 50 % or greater vaccine coverage
  - 68 % reduction in HPV 16 and 18 infections
  - 61 % reduction in genital warts

Drolet et al 2015

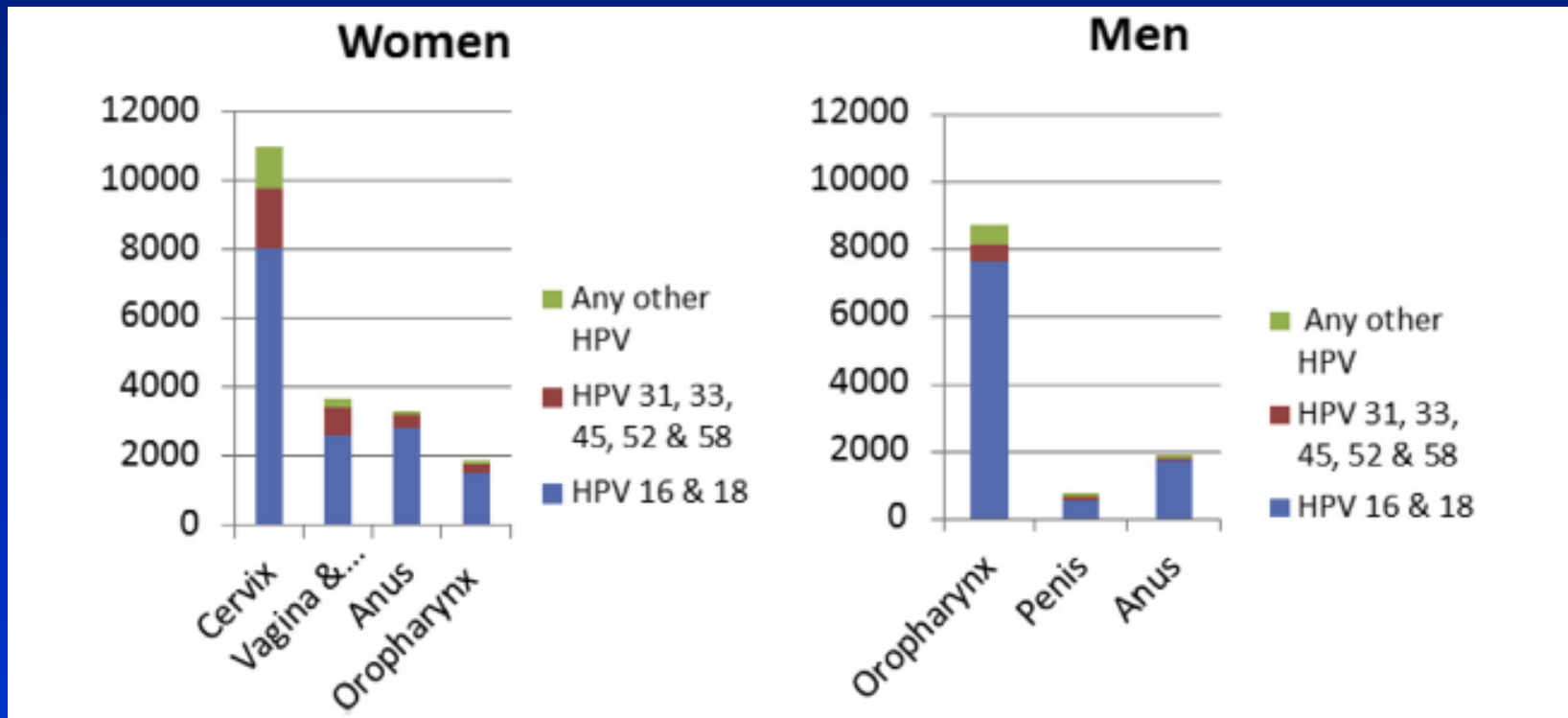
# Population Effects of HPV Vaccination

% reduction in disease



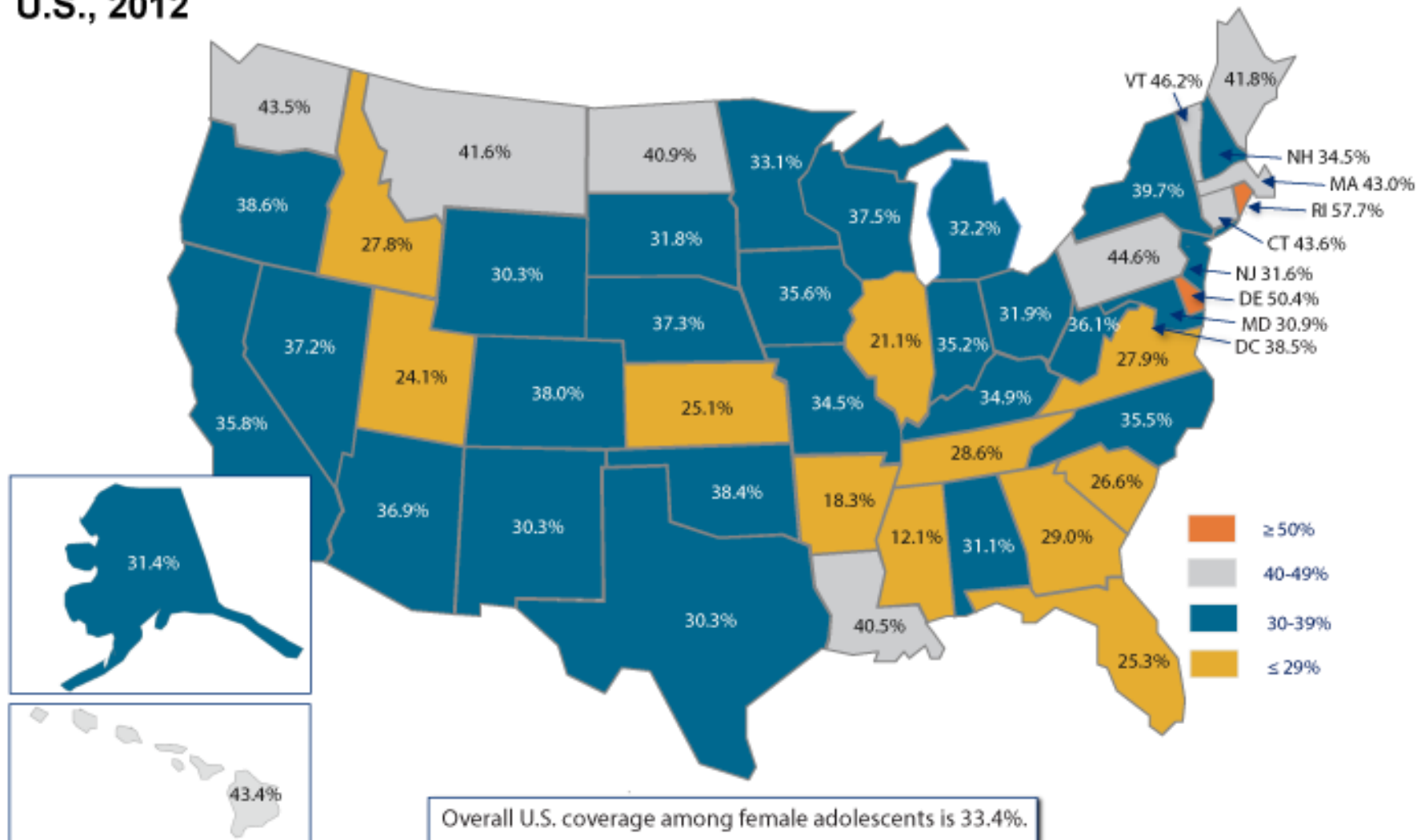
from Drolet et al 2015. Meta analysis of 20 studies

# Potential Impact of a 9 Valent HPV Vaccine



See Pahud & Ault 2015

# Percentage of 13- to 17-Year-Old Girls Completing HPV Vaccine Series, U.S., 2012



Source: The President's Cancer Panel



# HPV Vaccine Coverage in Female Adolescents in Managed Care Plans 2013

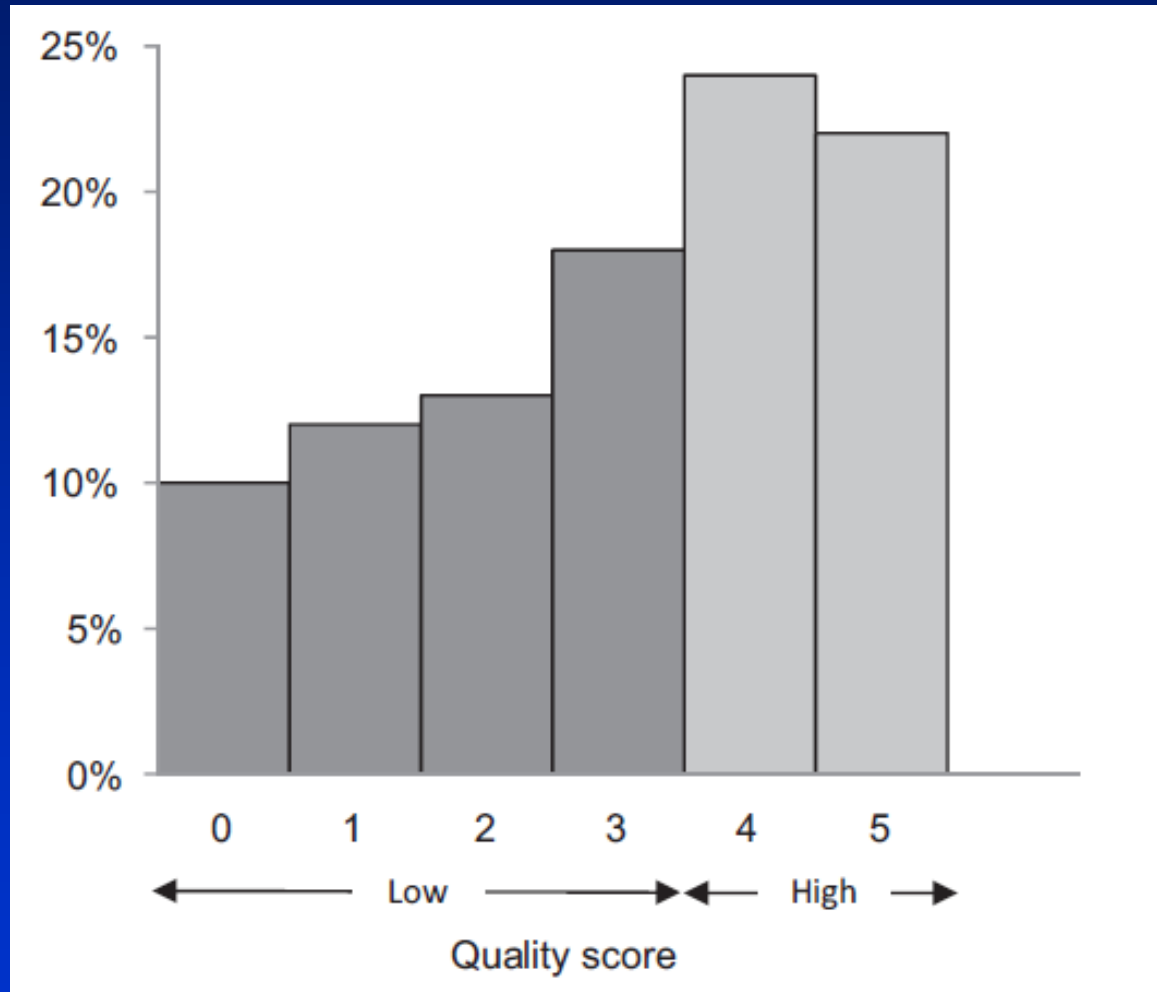
- HEDIS measures “access quality of care in health plans”
- HEDIS measure - % of 13 yo females who have received three doses of HPV vaccine
- 367 commercial & 153 Medicaid plans representing 31 % of the US population
- Median commercial rate – 11.7 %
- Median Medicaid – 19.2 %
- Best performing plan – 52.3 %

# Importance of Provider Recommendation

- Survey of 2,368 pediatricians and family physicians
- Quality score concerning HPV vaccination practice – age range for both genders, routine (vs risk based) urgency (same day), importance (optional vs. very important)
- Scale – zero to 5



# Quality of Provider Recommendation



# Major Weaknesses of Provider Recommendations

- “Risk based” strategies
- Lack of urgency (delayed to future visit)
- Weaker recommendation for males
- Correlation of high quality recommendation
  - a) child is due for adolescent vaccines b) strong recommendation c) prevents multiple cancers and d) elicit questions

“Thank you ever so much”  
Any questions?



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