



# *Prevalence of hrHPV*

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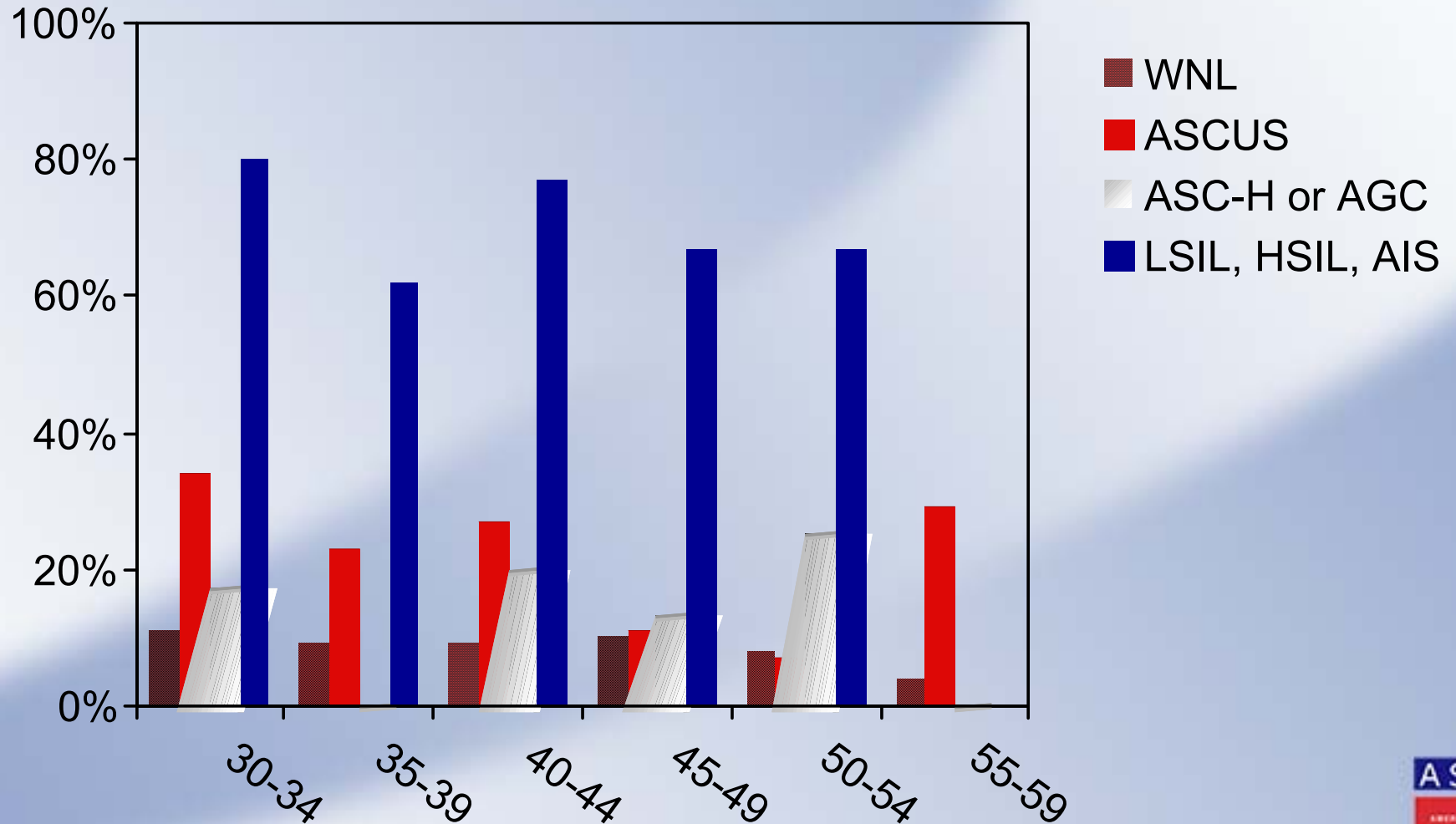
## *CDC - HSS Project:*

- HPV Sentinel Surveillance Project
- 10, 208 women 14-65 years of age
- 6 cities - family planning, STI primary care clinics
- Cytology and HPV testing (Hybrid Capture 2)

*Datta et al. (2008) Ann Intern Med.*



# *hrHPV by Cytology Result in HSS Project*





# *Prevalence of hrHPV*

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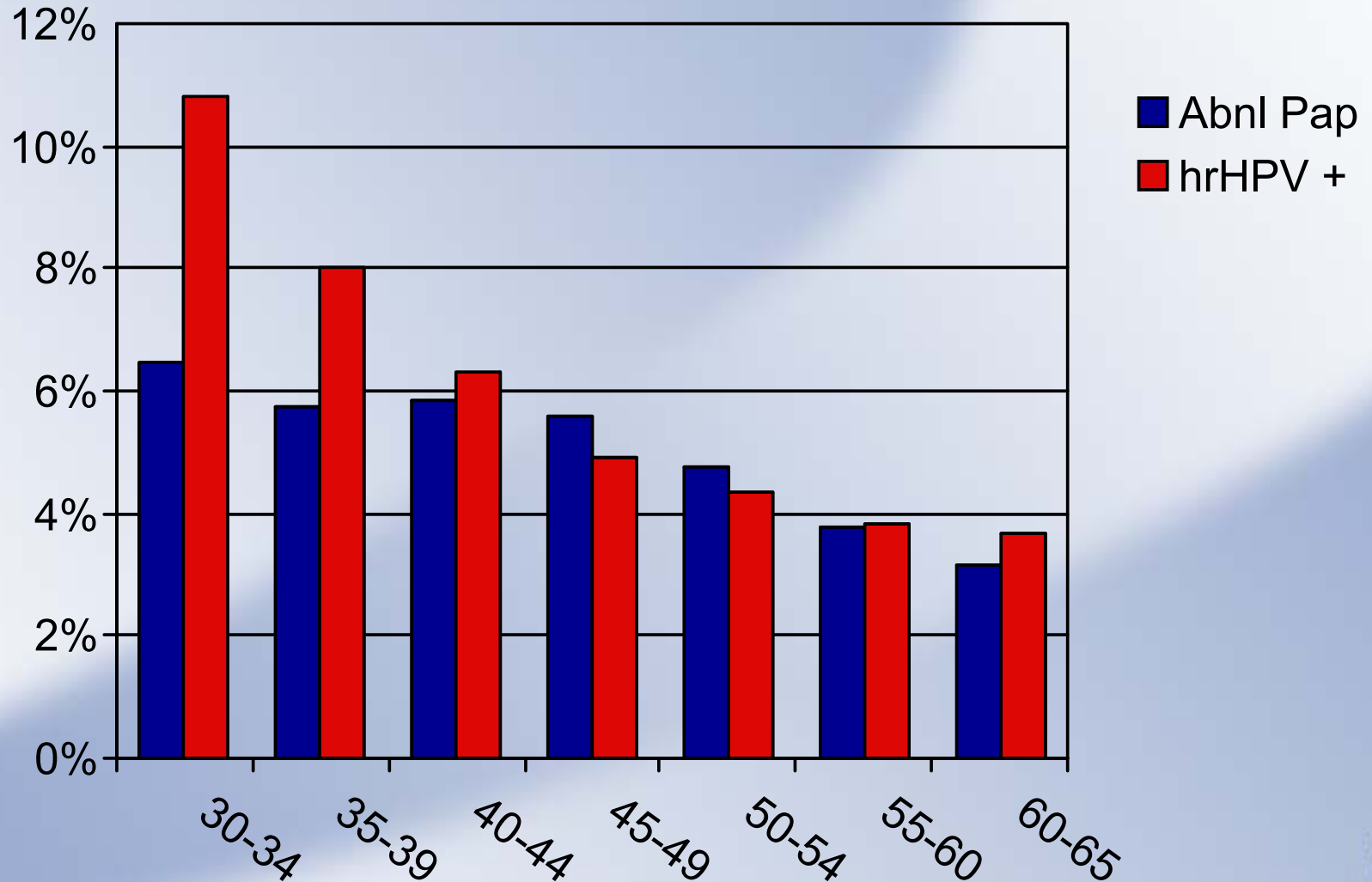
## *Kaiser Northern California:*

- Kaiser began co-testing for HPV (Hybrid Capture 2) with conventional Pap tests in 2003
- Reported on 580,000 women  $\geq 30$  years with both test results

*Castle et al. (2009) Obst. Gynecol.*



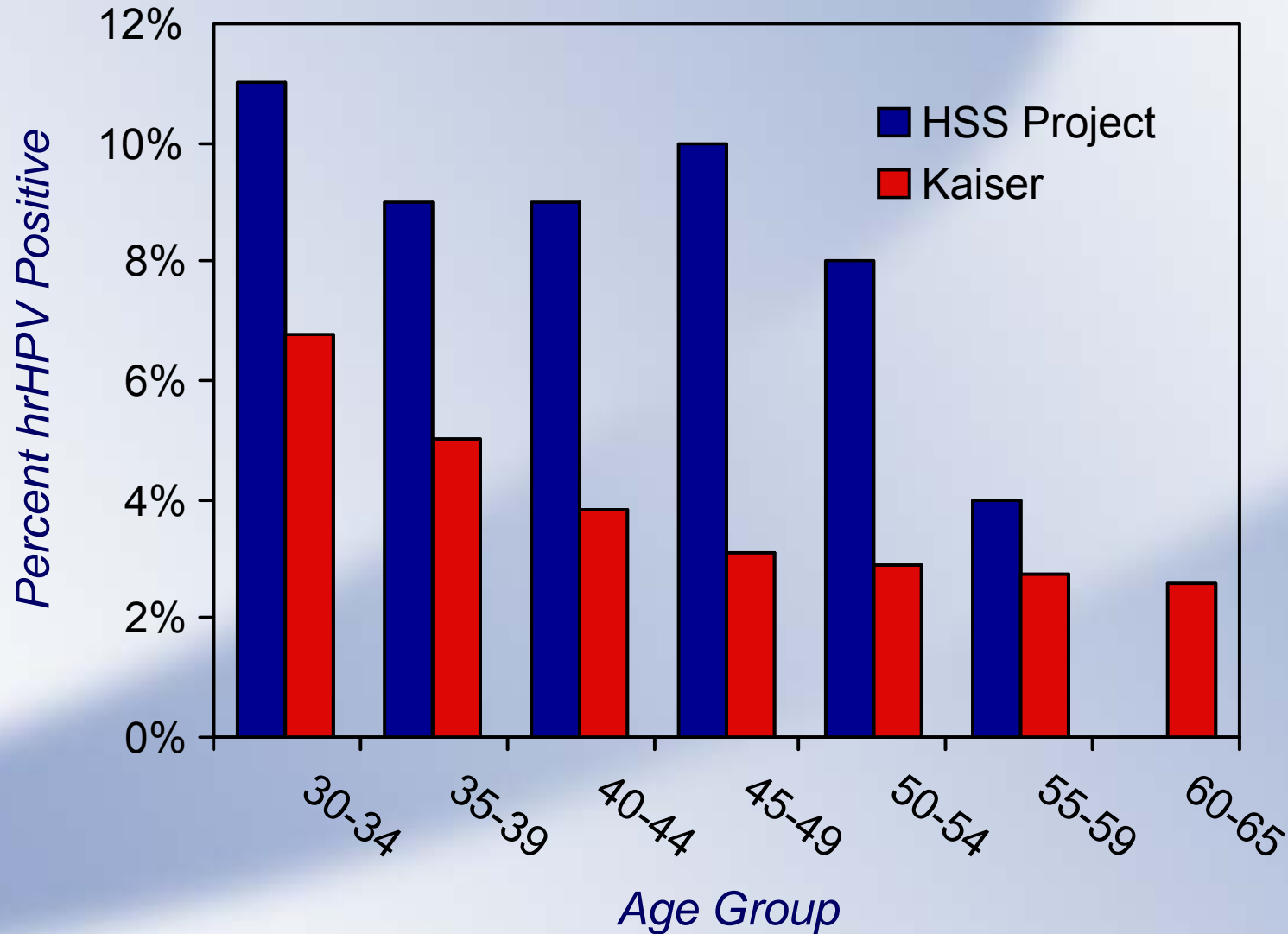
# Prevalence of Abnormal Cytology or hrHPV



Castle et al. (2009) *Obst. Gynecol.*



# *hrHPV if Normal Cytology in Kaiser & HSS*





# ***Phase III - Bivalent Vaccine***

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## ***Study Characteristics:***

- Women 15-25 years of age (n=18,644)
- Double-blind, placebo controlled trial vaccinated at 0, 1, and 6 months
- Mean follow-up of 34.9 months

*Paavonen et al. (2009) Lancet*



# *HPV Bivalent Vaccine*

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## *Safety of the vaccine*

Prevalence of:

*Serious adverse events*

*Medically significant conditions*

*New onset chronic disease*

*New onset autoimmune disease*

*Pregnancies and pregnancy outcomes*

Similar in vaccine and placebo recipients



# ***Bivalent Phase III Trial***

## ***Pre-defined endpoint:***

- According to protocol-efficacy (ATP-E) for CIN 2+ associated HPV 16 or 18
- Normal or low grade cytology and HPV DNA and serology negative (for given HPV type)
- Received all three doses of vaccine

*Paavonen et al. (2009) Lancet*



# ***Phase III - Bivalent Vaccine HPV***

***HPV 16/18 associated CIN 2,3 or AIS***

## ***No. Cases***

<b><i>Outcome</i></b>	<b>Vaccine</b>	<b>Placebo</b>	<b><i>Efficacy</i></b>
<b><i>CIN 2 (+)</i></b>	4	56	93%
<b><i>CIN 3 (+)</i></b>	2	10	80%

*Paavonen et al. (2009) Lancet*



# ***Cumulative Incidence of CIN 2+ in the TVC Group***

**QuickTime™ and a  
decompressor  
are needed to see this picture.**

*Figure A includes only CIN 2+ lesions associated with HPV 16 or 18  
Figure B includes all CIN 2+ lesions, irrespective of associated HPV type.*

*Paavonen et al. (2009) Lancet*



# Vaccine Efficacy in Naïve Women

Group	Type	No. of Cases		Efficacy <sup>^</sup>
		Vaccine	Placebo	
<i>ATP-E #</i>				
	HPV 16	2	46	95.7% (82.9 - 99.6)
	HPV 18	2	15	86.7% (39.7 - 98.7)
<i>TVC-E *</i>				
	HPV 16	3	73	95.9% (87.0 - 99.3)
	HPV 18	2	24	91.6% (64.6 - 99.2)

<sup>^</sup> For CIN 2+ lesions associated with HPV 16 or HPV 18.

<sup>#</sup> According to Protocol-Efficacy (HPV DNA and serology negative at enrollment and 6 mos)

<sup>\*</sup> Total Vaccinated Cohort-Efficacy (HPV DNA and serology negative at enrollment and 6 mos)

Modified from Pavonen et al. (2009) Lancet



# Reductions in Colposcopy and LEEP

Group	No. of Cases		Efficacy
	Vaccine	Placebo	
<i>TVC ^</i>			
Colposcopy	1107	1235	10.4% (2.3 - 17.8)
Excisions	182	240	24.7% (7.4 - 38.9)
<i>TVC-Naive *</i>			
Colposcopy	354	476	26.3% (14.7 - 36.4)
Excisions	26	83	68.8% (50.0 - 81.2)

*^ Total Vaccinated Cohort*

*\* Both DNA negative and serologically negative for specific HPV type*

*Modified from Paavonen et al. (2009) Lancet*