

HPV Vaccine Cost-effectiveness Updates and Review

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Centers for Disease Control and Prevention

Advisory Committee on Immunization Practices

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Outline

- Use of QALYs to assess vaccine cost-effectiveness
- HPV vaccine cost-effectiveness: Review
 - Key points
 - Summary of available estimates for male vaccination
- Responses to ACIP queries from February meeting
 - Catch-up of males through age 26 years
 - Details of QALYs gained by male vaccination
 - Impact of duration of protection assumptions

QALY: Quality-adjusted life year

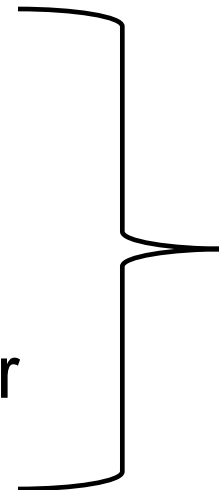
- Cost-effectiveness of vaccines is often assessed in terms of cost per QALY gained
- QALYs account for quality and length of life
 - One year in perfect health = 1 QALY
 - Death = 0 QALY
 - One year of life in less than perfect health is given a value between 0 and 1 QALY

Health outcomes included in recent cost-effectiveness models of HPV vaccination

- Genital warts
- CIN
- Cervical cancer
- Vaginal and vulvar cancer
- Anal cancer
- Oropharyngeal cancer
- Penile cancer
- RRP

Health outcomes included in recent cost-effectiveness models of HPV vaccination

- Genital warts
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- Anal cancer



Indicated outcomes
Outcomes with evidence
of vaccine efficacy

-
- Oropharyngeal cancer
 - Penile cancer
 - RRP

Cost-effectiveness thresholds in the US

- No consensus on appropriate cost-per-QALY threshold for determining cost-effectiveness of public health interventions
- \$50,000 to \$100,000 threshold often cited
 - Described as arbitrary, lacking empirical or theoretical justification

Cost per QALY gained by childhood vaccines in the US

Vaccine	Cost per QALY gained (compared to no vaccine)	Source
DTaP	<\$0 (cost-saving)	Ekwueme (2000); Zhou (2005)
Hib	<\$0 (cost-saving)	Zhou (2005); Cochi (1985)
MMR	<\$0 (cost-saving)	Zhou (2004, 2005); White (1985)
Polio	<\$0 (cost-saving)	Zhou (2005); Thompson (2006)
Varicella	<\$0 (cost-saving)	Zhou (2004,2008); Preblud (1985)
Influenza (LAIV)	≈ \$10,000	Prosser (2006)
Hepatitis A	≈ \$10,000 to \$30,000	Das (1999); Rein (2007)

QALY: quality-adjusted life year. DTaP: Diphtheria and tetanus toxoids and acellular pertussis. Hib: *Haemophilus influenzae* type b. MMR: Measles, mumps, and rubella. LAIV: live, attenuated influenza vaccine.

Updated to 2009 US dollars and rounded. This table shows a collection of point estimates; the ranges shown for hepatitis A reflects base case results of two studies. For each vaccine, the actual range of plausible cost-effectiveness estimates varies (not shown). See the sensitivity analyses in the source studies.

Cost per QALY gained by adolescent vaccines in the US

Vaccine	Target group	Cost per QALY gained (compared to no vaccination)
Hepatitis B	College freshmen	<\$0 (cost-saving) to ≈ \$10,000
Hepatitis A	College freshmen	<\$0 (cost-saving) to ≈ \$15,000
HPV	12-year-old girls	≈ \$3,000 to \$45,000
Influenza	12- to 17-year-olds, high risk	≈ \$10,000
Tdap	All 11-year-olds	≈ \$25,000
Influenza	12- to 17-year-olds, healthy	≈ \$140,000
Meningococcal	2-dose, all 11 & 16-year-olds	≈ \$160,000

Source: Ortega-Sanchez et al. *Pediatrics* (2008), except HPV and Meningococcal (see notes).

Tdap: Tetanus and diphtheria toxoids and acellular pertussis. Influenza estimates are for inactivated vaccine. For HPV, the lower and upper bound estimates [Elbasha (2007) and Kim (2008), respectively] were published after the cutoff date for inclusion in the Ortega-Sanchez review. Estimate for Meningococcal was presented by Ortega-Sanchez, October 2010 ACIP. All estimates updated to 2009 US dollars and rounded. This table shows a collection of point estimates; the range shown for HPV reflects base case results of two studies; and the ranges shown for hepatitis A & B reflect base case results from two perspectives. For each vaccine, the actual range of plausible cost-effectiveness estimates varies (not shown). For more details, see the sensitivity analyses in the source studies.

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Cost-effectiveness of HPV vaccination

Review of key points

- Routine vaccination of 12-yr-old girls cost-effective
 - Consistent finding across models, provided sufficient duration of protection
- More uncertainty in cost-effectiveness estimates for:
 - Vaccination of adult women
 - Feb 2010, June 2008, Feb 2008 ACIP meetings
 - Vaccination of males
 - Feb 2011, Oct 2010, Oct 2009, June 2009 ACIP meetings

Cost-effectiveness of HPV vaccination

Review of key points II

- Cost-effectiveness of male vaccination depends on vaccine coverage of females
 - Most favorable scenario for male vaccination is when coverage of females is low
 - Male vaccination likely not cost-effective when female coverage is high
 - With higher female coverage:
 - Less impact of male vaccination on disease in females
 - More males are protected indirectly through female vaccination

Cost-effectiveness of HPV vaccination

Review of key points III

- Depends on health outcomes included
 - Most favorable scenario is when all potential health outcomes are included
- Depends on vaccine costs
 - Vaccine costs are important factor in affordability and cost-effectiveness of male vaccination
 - With lower cost, male vaccination more likely to be cost-effective over a wide range of scenarios
 - (e.g., higher female coverage)

Cost-effectiveness of HPV vaccination

Review of key points IV

- HPV vaccination of MSM appears cost-effective
 - Kim (2010) found cost per QALY < \$50,000 over range of assumptions about age at vaccination and prior exposure to HPV
- Additional data needed
 - e.g., type-specific HPV acquisition by age among MSM

Cost-effectiveness of HPV vaccination

Review of key points V

- Accounting for recent trends in cancer incidence does not have major impact on male vaccination cost-effectiveness
 - Impact of accounting for decreasing trends in some cancers (e.g., cervical) is offset by impact of accounting for increasing trends in other cancers (e.g., oropharyngeal, anal)
 - Possible exceptions
 - If recent trends are assumed to continue for 50 to 100 years before leveling off
 - If future annual changes in cancer incidence are assumed to be greater than in recent years

Cost-effectiveness of HPV vaccination

Review of key points VI

- Routine male HPV vaccination could be cost-effective, particularly if coverage of females is low ($\leq 50\%$)
 - \$24,000 to \$62,000 per QALY in published studies
- Routine male HPV vaccination might not be cost-effective, even if coverage of females is low
 - In certain scenarios when key assumptions are varied
 - Compared to strategy of increased female coverage
 - If males vaccinated have mostly vaccinated partners

*\$24,000 per QALY is from Merck model (Elbasha & Dasbach, 2010) with effective coverage (all 3 doses) by age 18 of $\approx 40\%$ and $\approx 25\%$ for females and males, respectively. \$62,000 per QALY is from Kim et al. (2009) with 50% 3-dose coverage of girls and boys by age 12.

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Estimated cost per QALY of male vaccination

Outcomes included	Study	Vaccine cost per series	Female coverage (3-dose) by age 12 years			
			≈ 10% to 30%	≈ 50%	≈ 70% to 75%	≈ 80% to 90%
Cervical outcomes	Taira 2004*	\$300 +\$100 booster	\$41,000	-	\$442,000	-
Cervical outcomes	Elbasha 2007*	\$360	-	\$24,000*	\$42,000*	\$128,000*
Genital warts (male & female)	Jit (UK) 2008*	\$440	-	-	-	\$1,000,000
Cervical outcomes	Kim 2009*	\$500	-	\$62,000	\$91,000	-
Genital warts (male & female)						
Non-cervical cancers (male & female)	Elbasha 2010†	\$400	\$24,000†	-	-	-
RRP (male & female)	Chesson† Preliminary	\$500	\$41,000†	\$81,000†	\$184,000†	-

* Elbasha (2007) includes a temporary (5-year) catch-up program through age 26 years. † These studies include a permanent catch-up program through age 26 years. Shaded studies include catch-up through age 26, and in these studies 3-dose coverage by age 26 will be higher than the 3-dose coverage levels indicated for 12-year-old girls.

QALY: quality-adjusted life year. RRP: recurrent respiratory papillomatosis. Estimates show incremental cost per QALY of adding males to female-only vaccination program. Vaccine costs are per person fully vaccinated in Kim (2009) and Chesson (preliminary). See source studies for additional details and results under alternate assumptions, as estimates vary when model assumptions are changed. The \$128,000 estimate from Elbasha (2007) was not in published study but obtained from Erik Dasbach, personal communication, 10/16/2009. Results are approximations and are not updated for inflation.

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Estimated cost per QALY gained including different outcomes (Chesson et al. model)

HPV disease included	Lower coverage scenario 30% 3-dose coverage at age 12 50% 3-dose coverage by age 26		Higher coverage scenario 50% 3-dose coverage at age 12 70% 3-dose coverage by age 26	
	Female (Ages 12-26)	Male (Age 12)	Female (Ages 12-26)	Male (Age 12)
Cervical disease only	\$21,300	\$121,700	\$23,700	\$253,900
+ vulvar and vaginal cancer	\$19,600	\$113,700	\$21,800	\$237,300
+ genital warts	\$15,200	\$84,400	\$16,900	\$167,500
+ anal cancer	\$12,200	\$68,200	\$13,600	\$134,800
+ RRP	\$10,900	\$66,500	\$12,300	\$132,400
+ oropharyngeal	\$7,300	\$41,800	\$8,300	\$81,800
+ penile cancer	\$7,200	\$41,400	\$8,200	\$80,900

QALY: quality-adjusted life year. RRP: recurrent respiratory papillomatosis. Cost-effectiveness ratios for female-only vaccination are as compared to no vaccination (screening only). Cost-effectiveness ratios for male vaccination show the incremental cost per QALY gained by adding vaccination of 12-year-old boys to the female-only vaccination strategy, with coverage of 12-year-old boys assumed to be the same as coverage of 12-year-old girls. Cost-effectiveness ratios include all diseases in the preceding rows (if applicable).

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Male vaccination vs. increased female coverage

- Published studies typically report cost-effectiveness of adding male vaccination to female-only vaccination
- Another strategy to reduce HPV burden in both sexes is to increase vaccine coverage of females
 - What is the cost-effectiveness of male vaccination compared to a strategy of increased vaccine coverage of females?

Male vaccination vs. increased female coverage

(Chesson et al. model)

- Incremental cost per QALY of male vaccination (all outcomes included):
 - \$103,500 when compared to strategy of increased female coverage
 - \$25,000 when compared to status-quo female coverage
- Increased female coverage strategy could incur costs of \$350 per additional woman vaccinated and still be as cost-effective as male vaccination

Coverage assumptions used in example

Vaccination strategy	3-dose coverage of 12-year-olds	
	Girls	Boys
Strategy A: Female-only vaccination: Base case coverage	30%	0%
Strategy B: Female-only vaccination: Increased coverage	45%	0%
Strategy C: Male and female vaccination: Base case coverage	30%	30%

\$25,000 cost per QALY calculated when comparing Strategy C to Strategy A
 \$103,500 cost per QALY calculated when comparing Strategy C to Strategy B

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Cost-effectiveness of male catch-up vaccination

(Chesson et al. model)

Cost per QALY gained

	Lower coverage scenario 30% 3-dose coverage at age 12 50% 3-dose coverage by age 26		Higher coverage scenario 50% 3-dose coverage at age 12 70% 3-dose coverage by age 26	
Vaccine strategy	Indicated outcomes only	All outcomes included	Indicated outcomes only	All outcomes included
Females aged 12 to 26	\$12,200	\$7,200	\$13,600	\$8,200
+ 12 year old males	\$68,200	\$41,400	\$134,800	\$80,900
+ males aged 13 to 18	\$117,700	\$67,900	\$185,200	\$102,800
+ males aged 19 to 21	\$207,300	\$102,900	\$244,300	\$117,000
+ males aged 22 to 26	\$424,300	\$177,800	\$458,300	\$185,800

Indicated outcomes include cervical outcomes, vaginal, vulvar, and anal cancers, and genital warts. All outcomes include indicated outcomes plus oropharyngeal cancer, penile cancer, and recurrent respiratory papillomatosis. The same coverage rates were applied to males and females (although coverage by age 26 will be lower in males than females in scenarios where male vaccination is not extended through age 26 years).

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QALYs gained by vaccination

- Additional health benefits accrue
 - When females are vaccinated
 - When males are added to female-only vaccination
- Models assess the gain in QALYs:
 - Reductions in morbidity
 - CIN, genital warts, cervical and other cancers, RRP
 - Reductions in mortality
 - Cervical and other cancers, RRP

Percent of QALY benefit attributable to HPV disease prevented (Chesson et al. model)

All outcomes

HPV disease	Percent of benefit attributable	
	Female-only vaccination	Male vaccination (incremental gain in QALYs when male vaccination is added to female vaccination)
Cervical	57%	37%
Oropharyngeal	21%	36%
Anal	10%	12%
Genital warts	7%	11%
Vulvar	3%	2%
Vaginal	1%	1%
RRP	1%	<1%
Penile	<1%	1%

QALY: quality-adjusted life year. RRP: recurrent respiratory papillomatosis. Vaccination strategies (both sexes as well as female-only) include ages 9 to 26 years.

Percent of QALY benefit attributable to HPV disease prevented (Chesson et al. model)

All outcomes

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Penile	<1%	1%

QALY: quality-adjusted life year. RRP: recurrent respiratory papillomatosis. Vaccination strategies (both sexes as well as female-only) include ages 9 to 26 years.

Percent of QALY benefit attributable to HPV disease prevented (Chesson et al. model)

Indicated outcomes

HPV disease	Percent of benefit attributable	
	Female-only vaccination	Male vaccination (incremental gain in QALYs when male vaccination is added to female vaccination)
Cervical	73%	59%
Anal	13%	19%
Genital warts	9%	18%
Vulvar	4%	3%
Vaginal	1%	1%

Vaccination strategies (both sexes as well as female-only) include ages 9 to 26 years.

Impact of duration of vaccine protection assumptions

- Assuming a shorter duration of protection:
 - Would make female-only vaccination less cost-effective
 - Could make male vaccination:
 - Less cost-effective
 - Reduced impact on vaccinated males
 - » Kim *BMJ* (2009)
 - More cost-effective
 - Reduced impact on vaccinated females could leave a greater HPV burden to be averted by male vaccination
 - » Jit *BMJ* (2008)

Conclusions

- Male vaccination potentially not cost-effective
 - Particularly at high female coverage levels
 - Even at current coverage levels
 - In certain scenarios when key assumptions are varied
 - When compared to strategy of increased female coverage
 - If males vaccinated have mostly vaccinated partners
- Male vaccination potentially cost-effective
 - Particularly at current female coverage levels
 - All available models suggest potentially favorable cost-per-QALY estimates when female coverage is $\leq 50\%$
 - With lower vaccine cost
 - Male vaccination more likely to be cost-effective across a range of scenarios

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 - Erik Dasbach, Elamin Elbasha (Merck)

- ACIP health economics review:
 - Conflict of interest statement:
 - Chesson: No known conflicts of interest
 - For this presentation, no new models were developed
 - New results (updates and sensitivity analyses) obtained from models reviewed for previous ACIP presentations
 - Existing model structures, underlying assumptions not changed
 - Only parameter values and ranges were changed

The findings and conclusions in this presentation have not been formally disseminated by the Centers for Disease Control and Prevention and should not be construed to represent any agency determination or policy.

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