

The Advisory Committee on Immunization Practices (ACIP): How it Works and Current Challenges

Mark H. Sawyer, MD

Professor of Clinical Pediatrics

UCSD School of Medicine and Rady Children's Hospital San Diego

Disclosures

- I have no relevant financial relationships with the manufacturer(s) of any commercial product(s) and/or provider of commercial products or services discussed in this CME activity.

Objectives

- Describe the structure of ACIP
- Explain the role of ACIP in vaccine policy making
- Summarize three general challenges that affect the current vaccine policy climate
- List three ACIP recommendations to expect in the coming year

Who makes the decisions about what vaccines we give?

- Vaccine manufacturers
- Federal Drug Administration (FDA)
 - Vaccines and Related Biologics Advisory Committee
- Centers for Disease Control (CDC)
 - Advisory Committee on Immunization Practices
- California State Department of Public Health
- Professional Associations
 - American Academy of Pediatrics (AAP)
 - American Association of Family Physicians (AAFP)
 - American College of Obstetrics and Gynecology (ACOG)
 - American College of Physicians (ACP)



Who makes the decisions about what vaccines we give?

- Individual healthcare organizations
 - Local Health Departments
 - Hospitals
 - Managed care organizations
 - Preferred Provider Organizations (PPO)
- Individual Providers in consultation with patients/parents

Role of ACIP

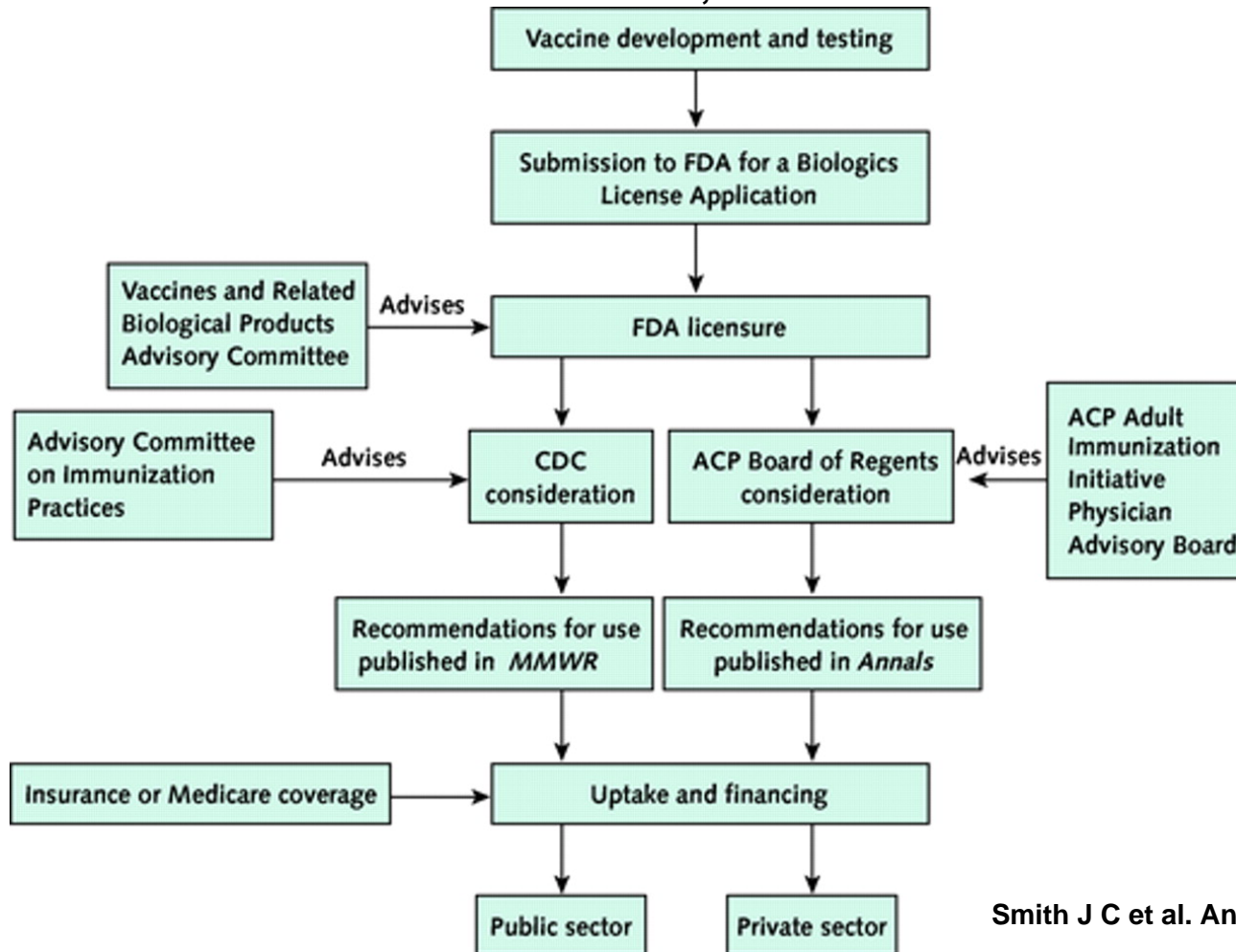
Advisory to CDC and the Secretary of HHS regarding use of vaccines and other interventions for the civilian population to prevent vaccine-preventable disease

The Full Story

Smith JC, Snider DE, Pickering LK
Immunization Policy Development in the
United States: The Role of the Advisory Committee
on Immunization Practices. *Ann Intern Med*
2009;150:45-49

The Cogs in the Wheel

children, and adolescents.



Smith J C et al. Ann Intern Med 2009;150:45-49

ACIP Composition

- 15 voting members (4 year terms)
- Selected by the Secretary of HHS with input from CDC
- Expertise in Public Health, Infectious Disease, Pediatrics, Family Practice, Internal Medicine, Nursing
- Community Representative

October 2009

PROFESSIONAL AREA BREAKDOWN - ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Authorized Public Positions - 15 (including 1 Lay Member)

Current Members	Term Ending	Expertise	Minority	Sex	Professional	Lay	State
** Baker, Carol	06/30/10	Pediatrics*; Pediatric Infectious Diseases*		F	X		TX
Lett, Susan	06/30/10	Internal Medicine*; Preventive Medicine*		F	X		MA
Neuzil, Kathleen	06/30/10	Internal Medicine*; Infectious Diseases*		F	X		WA
Sumaya, Ciro	06/30/10	Pediatrics*; Pediatric Infectious Diseases*	X	M	X		TX
Chilton, Lance	06/30/11	Pediatrics*; Public Health Practice		M	X		NM
Cieslak, Paul	06/30/11	Internal Medicine*; Infectious Diseases*		M	X		OR
Englund, Janet	06/30/11	Pediatrics*; Pediatric Infectious Diseases*		F	X		WA
Judson, Franklyn	06/30/11	Internal Medicine*; Infectious Diseases*; Preventive Medicine*		M	X		CO
Temte, Jonathan	06/30/12	Family Medicine*		M	X		WI
Sawyer, Mark	06/30/12	Pediatrics*; Pediatric Infectious Diseases*		M	X		CA
Ehresmann, Kris	06/30/12	RN, MPH*; Immunization Program Implementation		F	X		MN
Marcy, Michael	06/30/12	Pediatrics*; Pediatric Infectious Diseases*		M	X		CA
Meissner, Cody	06/30/12	Pediatrics*; Pediatric Infectious Diseases*		M	X		MA
Keitel, Wendy	06/30/13	Internal Medicine*; Infectious Diseases		F			TX
Rosenbaum, Sara	06/30/13	Law; Consumer Representative		F		X	DC

* Board Certification

** Chair

Number of *Ex Officio* Members: 8

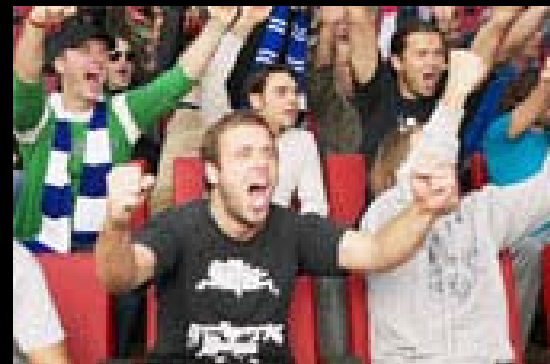
A member may serve up to 180 days after the expiration of that member's term if a successor has not taken office.

As of October 2009:

Pediatrics	Internal Medicine	Family Medicine	Nurse	Consumer Rep
7	5	1	1	1

ACIP Structure-Liaison Members

- ❑ AAP
- ❑ AAFP
- ❑ ACP
- ❑ AMA
- ❑ ACOG
- ❑ SAM
- ❑ NMA
- ❑ ACHA
- ❑ AGS
- ❑ AHIP
- ❑ AOA
- ❑ APhA
- ❑ APTR
- ❑ SHEA
- ❑ HICPAC
- ❑ BIO
- ❑ PhRMA
- ❑ IHS
- ❑ DOD
- ❑ DVA
- ❑ HRSA
- ❑ CMS
- ❑ NIH
- ❑ FDA
- ❑ NVPO
- ❑ NACCHO
- ❑ NACI
- ❑ DOH, UK
- ❑ NICCHP,
Mexico



Liaison Organization											
	Adult Immunization	Anthrax Vaccine	General Recommendations	Harmonized Schedule	Influenza Vaccine Evidence Based Recommendations	HPV Vaccines	JE Vaccine	Meningococcal Vaccine	Pneumococcal Vaccine	Rotavirus Vaccines	
AAFP	X	X	X	X	X	X		X	X	X	
AAP			X	X	X	X	X		X		
AGS											
AHIP					X						
ACHA	X					X		X			
ACOG	X				X	X					
ACP	X				X	X					
AMA	X				X	X					
AOA			X			X					
APA			X								
ATPM								X			
BIO											
Canadian NACI					X	X			X		
CSTE											
HICPAC					X						
IDSA							X			X	
United Kingdom DOH								X			
NACCHO	X	X			X				X		
NAPNAP											
NFID	X				X	X		X	X		
NICCHP											
NMA						X					
NVAC				X		X		X			
PhRMA											
SAM	X			X	X		X	X			
SHEA	X										
AIM*	X		X	X	X	X	X	X			

The Influence of ACIP

- Determines which vaccines will be included in the Vaccines for Children Program
- Significant impact on recommendations of professional societies
- Many insurance programs tie reimbursement to ACIP recommendations
- Foundation for HEDIS and Pay for Performance measures

ACIP Working Groups

- Include ACIP members and non-ACIP members with expertise in a specific area
- Meet via conference call and occasionally in person to review all relevant material on a particular question
- Makes presentations to full ACIP
- Ultimate policy is determined by vote of the full ACIP

Table 3. Advisory Committee on Immunization Practices Workgroups*

Permanent workgroups

- Adult Immunization Schedule
- Childhood/Adolescent ("Harmonized") Immunization Schedule
- General Recommendations
- Influenza Vaccines

Task-oriented workgroups

- Anthrax Vaccine
- Evidence Based Recommendations
- Hepatitis Vaccines
- Human Papillomavirus Vaccines
- Japanese Encephalitis Vaccines
- Measles–Mumps–Rubella–Varicella Vaccine Safety
- Meningococcal Vaccines
- Pneumococcal Vaccines
- Rabies Vaccine
- Yellow Fever Vaccine

* As of November 2008.

Considerations for Recommending a New Vaccine

- Burden and risk of disease in the community
- Effectiveness of the vaccine
- Safety of the vaccine
- Cost-benefit analysis
- Feasibility/Vaccine Availability
- Cost/reimbursement for providers
- Patient/parental preferences

General Challenges Facing Vaccine Policy Makers

- Shear number and cost of vaccines
- Vaccine shortages
- Determining the role of cost-benefit analyses in vaccine policy
- Expansion of adult vaccines
- Vaccine safety concerns in the community

Immunization Schedules 2009

0-6 years

Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States • 2009
For those who fall behind or start late, see the catch-up schedule

Vaccine ▼	Age ►	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19-23 months	2-3 years	4-6 years
Hepatitis B ¹		HepB	HepB	see footnote 1	HepB							
Rotavirus ²			RV	RV	RV ²							
Diphtheria, Tetanus, Pertussis ³			DTaP	DTaP	DTaP	see footnote 3	DTaP					DTaP
Haemophilus influenzae type b ⁴			Hib	Hib	Hib ⁴	Hib						
Pneumococcal ⁵			PCV	PCV	PCV	PCV					PPSV	
Inactivated Poliovirus			IPV	IPV		IPV						IPV
Influenza ⁶						Influenza (Yearly)						
Measles, Mumps, Rubella ⁷						MMR		see footnote 7				MMR
Varicella ⁸						Varicella		see footnote 8				Varicella
Hepatitis A ⁹						HepA (2 doses)						HepA Series
Meningococcal ¹⁰												MCV

Range of recommended ages
Certain high-risk groups

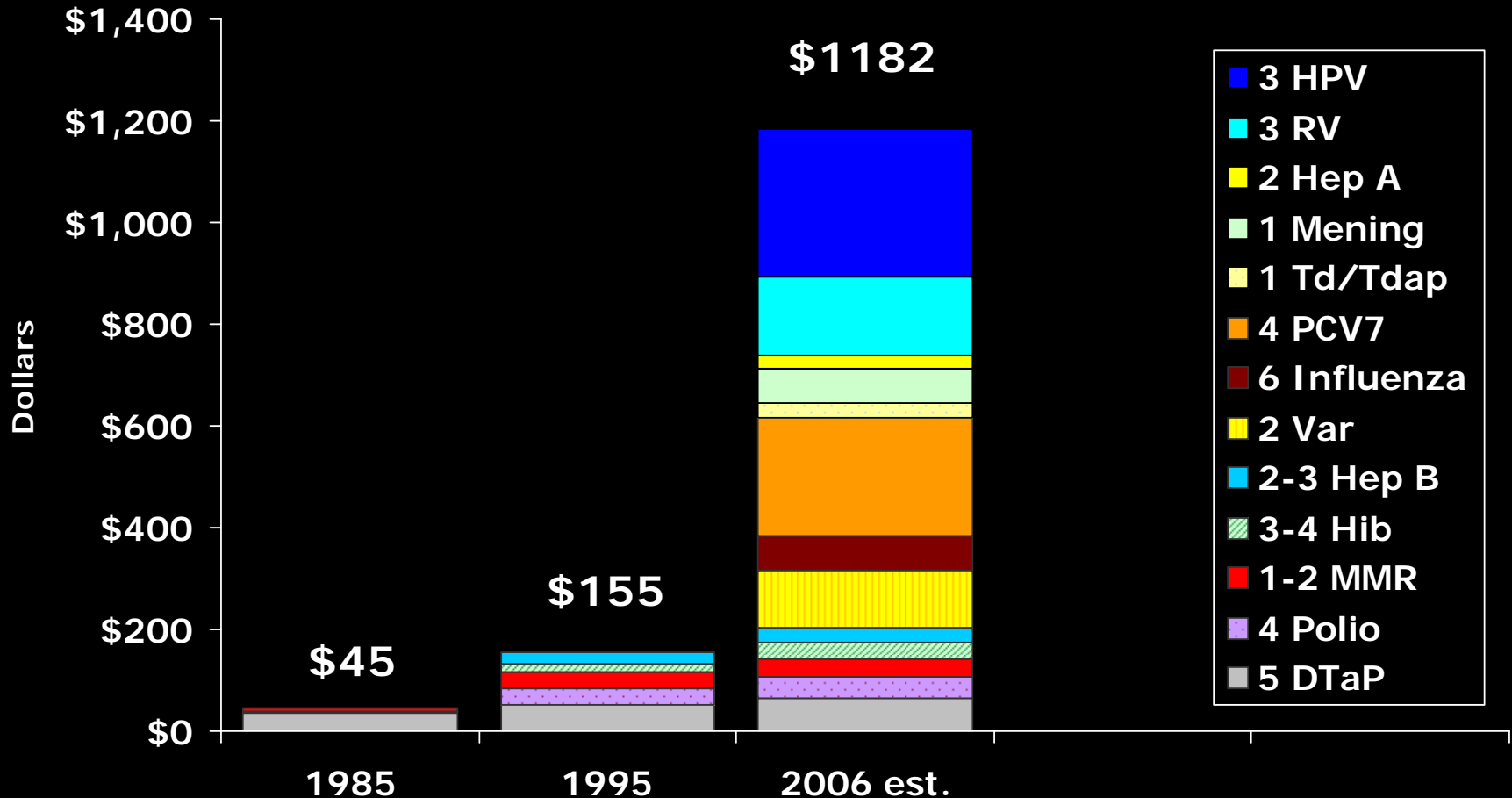
Adult

VACCINE ▼	AGE GROUP ►	19-26 years	27-49 years	50-59 years	60-64 years	≥65 years
Tetanus, diphtheria, pertussis (Td/Tdap) ¹		Substitute 1-time dose of Tdap for Td booster; then boost with Td every 10 yrs				Td booster every 10 yrs
Human papillomavirus (HPV) ²		3 doses (females)				
Varicella ³		2 doses				
Zoster ⁴					1 dose	
Measles, mumps, rubella (MMR) ⁵		1 or 2 doses		1 dose		
Influenza ⁶		1 dose annually				
Pneumococcal (polysaccharide) ⁷		1 or 2 doses				1 dose
Hepatitis A ⁸		2 doses				
Hepatitis B ⁹		3 doses				
Meningococcal ¹⁰		1 or more doses				

7-17 years

Vaccine ▼	Age ►	7-10 years	11-12 years	13-18 years
Tetanus, Diphtheria, Pertussis ¹		see footnote 1	Tdap	Tdap
Human Papillomavirus ²		see footnote 2	HPV (3 doses)	HPV Series
Meningococcal ³		MCV	MCV	MCV
Influenza ⁴		Influenza (Yearly)		
Pneumococcal ⁵		PPSV		
Hepatitis A ⁶		HepA Series		
Hepatitis B ⁷		HepB Series		
Inactivated Poliovirus ⁸		IPV Series		
Measles, Mumps, Rubella ⁹		MMR Series		
Varicella ¹⁰		Varicella Series		

Federal Contract Prices for Vaccines 1985, 1995, 2006



Federal contract price shown for 1985 and 1995 are averages that account for price changes within that year.

The 2006 estimated contract prices do not include HPV vaccine, because there is not a federal contract at this time. The catalog price for HPV vaccine is \$360 for the 3-dose series.

Adapted from CDC, Unpublished Data
Current as of November 20, 2006

Current Vaccine Shortages

- Haemophilus influenzae, type B
- Hepatitis B
- Hepatitis A
- Rabies



<http://www.cdc.gov/vaccines/vac-gen/shortages/default.htm>

Cost-Benefit

- HPV for women
- HPV for men
- Rotavirus vaccine
- PCV 13 catch up

Adult Immunizations

- Lack of adequate reimbursement
- No coverage for uninsured
- Hesitancy among key groups (e.g. seniors, healthcare workers)
- Lack of systems to assure vaccine delivery in offices and clinics

New Vaccine Products

- Bivalent HPV vaccine (GlaxoSmithKline)
 - Contains HPV 16 and HPV 18
 - Good protection for cervical cancer
 - No significant protection for genital warts
- Second meningococcal conjugate vaccine – MCV (Novartis)
 - Same 4 serotypes
 - Same recommendations likely
- PCV 13-conjugated pneumococcal vaccine

New Vaccine Recommendations

- HPV vaccines-no preference between the two products but know the differences between them
- HPV vaccine in males-permissive recommendation but not recommended routinely for all boys
- Replace PCV7 with PCV 13 for young children and give one dose to all children ≤ 59 months of age who have already completed the PCV7 series

New Vaccine Recommendations

- Universal influenza vaccination for all persons 6 months of age or older
- Polio vaccine-final dose should be on or after 4th birthday with a minimum interval of 6 months since the last dose
- Second dose of MCV₄ for high-risk individuals (e.g. asplenia, complement deficiency) 3-5 years after first dose

What is a QALY?!?

QALY: Quality-adjusted life year

- 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

Chesson presentation, ACIP February 2010

<http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-feb10/02-4-hpv.pdf>

Cost per outcome gained for selected childhood vaccines in the US

Vaccine	Cost per outcome gained (compared to no vaccine)	Source
DTaP, Hib, MMR, Polio, Varicella	<\$0 per QALY (cost-saving) Individually and as a group	Ekwueme (2000), Zhou (2004, 2005, 2008), Cochi (1985), White (1985), Thompson (2006), Preblud (1985)
Influenza (LAIV)	≈ \$10,000 per QALY	Prosser (2006)
Hepatitis A	≈ \$10,000 to \$30,000 per QALY	Das (1999), Rein (2007)
Meningococcal	≈ \$120,000 per QALY	Shepard (2005)
Pneumococcal	≈ \$10,000 to \$105,000 per LYS	Ray (2006, 2009) and Lieu (2000)
Rotavirus	≈ \$135,000 to \$225,000 per LYS	Cortese (2009) and Widdowson (2007)

QALY: quality-adjusted life year. LYS: life-year saved.

Updated to 2009 US dollars. Meningococcal estimate is for vaccination at age 1 year. This table shows a collection of point estimates; the ranges shown for hepatitis A, pneumococcal, and rotavirus vaccination reflect base case results of more than one study. For each vaccine, the actual range of plausible cost-effectiveness estimates varies (not shown). See source studies for details.

Cost per QALY of male vaccination

Incremental cost per QALY gained by adding male vaccination to female-only program

	Including only cervical outcomes	Including all health outcomes	Vaccine coverage of females	Ages vaccinated
Kim/Goldie model*	\$180,000*	\$78,000 - \$170,000* (depending on vaccine efficacy in males)	75%	12-yr-olds
Merck model	\$219,000	\$25,000	≈ 38%**	9- to 26-yr-olds

QALY: Quality-adjusted life year

*Not for citation

**Adjusted for adherence

Incremental cost-effectiveness ratios by HPV disease prevented

Merck model results: Base case cost per QALY estimates

HPV Diseases	Female-only 9–26	+ 27–34 females	+ 35–44 females
Cervical	\$17,500	\$84,000	\$224,000
+ Vulvar and vaginal	\$16,000	\$77,000	\$205,200
+ Genital warts	\$7,800	\$51,900	\$142,000
+ Anal	\$6,200	\$41,600	\$113,400
+ Head & neck	\$4,300	\$31,700	\$87,800
+ Penile	\$4,200	\$30,900	\$85,700
+ RRP	\$2,300	\$28,900	\$83,300

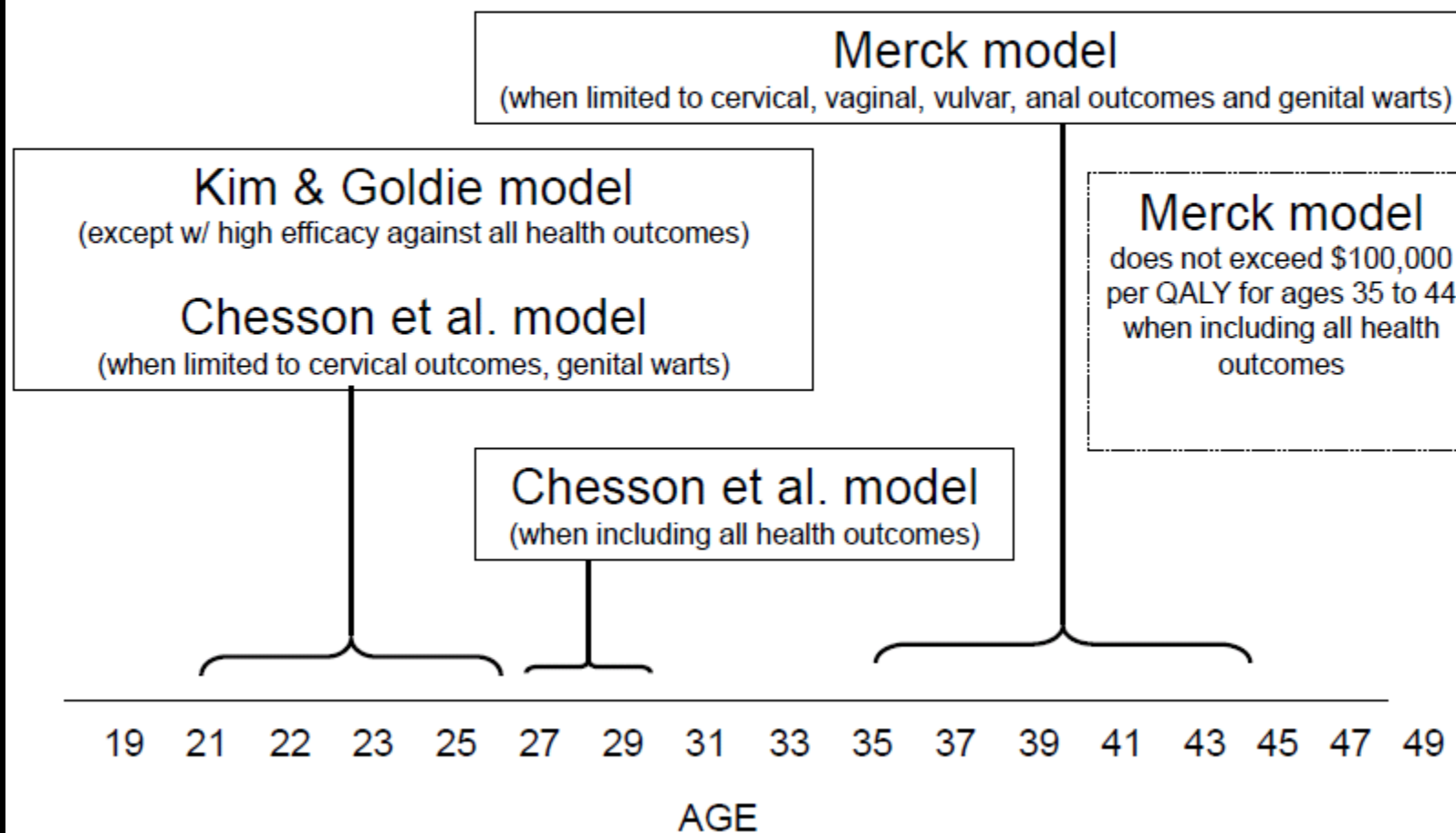
QALY: quality-adjusted life year

Chesson et al. model results: Cost-effectiveness of female vaccination by age

Ages vaccinated	Incremental ages added	Cost per QALY	
		Cervical, warts	All outcomes
12	12	\$8,000	\$3,000
12-18	13-18	\$26,000	\$17,000
12-21	19-21	\$55,000	\$38,000
12-26	21-26	\$119,000	\$85,000
12-29	27-29	\$254,000	\$179,000
12-34	30-34	\$449,000	\$305,000

Cost per QALY (quality-adjusted life year) of each strategy is the incremental cost-effectiveness ratio of the strategy compared to the preceding strategy. Cost per QALY of vaccinating 12-year-olds is as compared to no vaccination (screening only). All strategies include cervical cancer screening. Results preliminary.

Age group at which female vaccination exceeds \$100,000 per QALY



Chesson presentation, ACIP February 2010

<http://www.cdc.gov/vaccines/recs/acip/downloads/mtg-slides-feb10/o2-4-hpv.pdf>

Next year's influenza vaccine

- A/California/7/2009 (H₁N₁)-like virus
- A/Perth/16/2009 (H₃N₂)-like virus
- B/Brisbane/60/2008-like virus.

Upcoming Recommendations from ACIP

- HPV vaccine for older women
- Annual Influenza statement
- Hep B vaccine for diabetics
- Updated pertussis recommendations
 - Tdap interval
 - Tdap in healthcare workers
 - Tdap in pregnancy
- PCV₁₃ in older populations
- Meningococcal vaccine for infants

Discussion
