Impact and economic analysis

Summary of three models of 9-valent HPV vaccination among adults up to age 45 years in the United States

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Notice of ongoing ACIP health economics review

- ACIP review process is ongoing for all three health economics models presented today
  - Conflict of interest statements appear on slide 12
- A temporary waiver of the ACIP review policy was granted for this update to ACIP on ongoing modeling
  - Results should be considered preliminary

Background

What we know about HPV vaccine cost-effectiveness in US

- Routine vaccination of 11- to 12-year-olds is likely cost-saving
- Vaccination through age 26 years (females) and age 21 years (males) also has a favorable cost-effectiveness profile
- HPV vaccination of adults becomes less cost-effective as the age of vaccination increases

New cost-effectiveness question

- What is the cost-effectiveness of “mid-adult” vaccination?
- Specifically, what is the cost-effectiveness of extending the upper recommended catch-up age of HPV vaccination up to 45 years for males and females?

Outline

- Summary of cost-effectiveness ratios for other vaccines
  - As published in ACIP policy notes and recommendations
- Overview of three US models of 9vHPV
- Results of US HPV-ADVISE model
- Cost-effectiveness results of all models

9vHPV: nonavalent HPV vaccine.

Cost-effectiveness ratios for childhood vaccines

Published in ACIP policy notes and recommendations

Vaccine evaluated (vs. no vaccination unless noted)	Cost per QALY gained
MMR	<$0 (cost-saving)
Varicella, 1-dose	<$0 (cost-saving)
Varicella, 2-dose	<$0 (cost-saving)
Varicella, 2-dose vs. 1-dose	$115,000
Influenza (ages 6 through 23 months)	$15,000
Hepatitis A	$30,000

QALY: quality-adjusted life year.
MMR: Measles, mumps, and rubella.

Cost per QALY gained estimates were obtained from ACIP policy notes and recommendations on ACIP website. Ratios adjusted for inflation to 2017 US dollars and rounded to nearest multiple of $5,000. Base year for inflation adjustment was estimated if not provided in publication.

MMR estimate obtained from MMWR Vol. 47 No. RR-8, which notes a favorable benefit/cost ratio and suggests vaccination is cost-saving. Varicella estimates obtained from MMWR Vol. 56 / No. RR-4. Influenza estimates obtained from MMWR Vol. 58 / No. RR-8. Hepatitis A estimate obtained from MMWR Vol. 55/ No. RR-7. Hepatitis B cost per QALY estimates are provided in MMWR Vol. 67 / No. 1, but not included here because none of the estimates compared vaccination to no vaccination.

Cost-effectiveness ratios for adolescent/adult vaccines

Published in ACIP policy notes and recommendations
(Excludes HPV)

Vaccine evaluated (vs. no vaccination)	Cost per QALY gained
Adolescents	
Tdap	<$0 (cost-saving) to $25,000
Influenza (ages 12 through 17 years)	$150,000
Meningococcal (age 11 years, booster age 16 years)	$235,000
Meningococcal B (age 18 years)	$3.8 million
Meningococcal B (age 18 years)	$9.0 million
Adults	
Influenza (ages 65 years and older)	<$0 (cost-saving)
Zoster (ages 50 years and older)	$30,000

QALY: quality-adjusted life year. Tdap: tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine.
Cost per QALY gained estimates were obtained from ACIP policy notes and recommendations on ACIP website. Ratios adjusted for inflation to 2017 US dollars and rounded to nearest multiple of $5,000 (except Meningococcal B estimates which were rounded to the nearest $0.1 million). Base year for inflation adjustment was estimated if not provided in publication. Tdap estimate obtained from MMWR Vol. 55/No. RR-3. Influenza estimates obtained from MMWR Vol. 58 / No. RR-8. Meningococcal estimate obtained from MMWR Vol. 62 / No. 2. Meningococcal B estimates obtained from MMWR Vol. 64 / No. 41. Zoster estimate obtained from MMWR Vol. 67 / No. 3 and reflects $31,000 estimate for ages ≥ 50 years (CDC model), which is consistent with $30,000 estimate for age 60 years (academic group model, also reported in MMWR Vol. 67 / No. 3) for the recombinant zoster vaccine (see the MMWR for more details, including estimates from 2 other models).

Cost-effectiveness ratios for HPV vaccination strategies

Published in ACIP policy notes and recommendations

Vaccine evaluated (vs. no vaccination unless noted)	Cost per QALY gained
Adolescent females (2vHPV or 4vHPV)	$5,000 to $30,000
Adolescent males (4vHPV), vs. female-only	$25,000 to $45,000 (favorable scenario) $85,000 to >$250,000 (unfavorable scenario)
MSM through age 26 years	<$50,000
9vHPV (vs. 4vHPV)	<$0 (cost-saving)
2-dose 9vHPV (vs. 3-dose 9vHPV)	<$0 (cost-saving)

QALY: quality-adjusted life year. 2vHPV: bivalent HPV vaccine. 4vHPV: quadrivalent HPV vaccine. 9vHPV: nonavalent HPV vaccine.

For adolescent males, in the "favorable scenario," female vaccination coverage is lower (e.g., 20%) and all potential health benefits are included in the analysis. In the "unfavorable scenario," female vaccination coverage is higher (e.g., 75%) and only the health outcomes for which the vaccine is indicated are included in the analysis.

Cost per QALY gained estimates were obtained from ACIP policy notes and recommendations on ACIP website. Ratios adjusted for inflation to 2017 US dollars and rounded to nearest multiple of $5,000. This table was previously published (in 2016 dollars) by Markowitz et al., 2018 Acad Pediatr. Because of rounding, the estimates in 2017 dollars are exactly the same as published by Markowitz et al.

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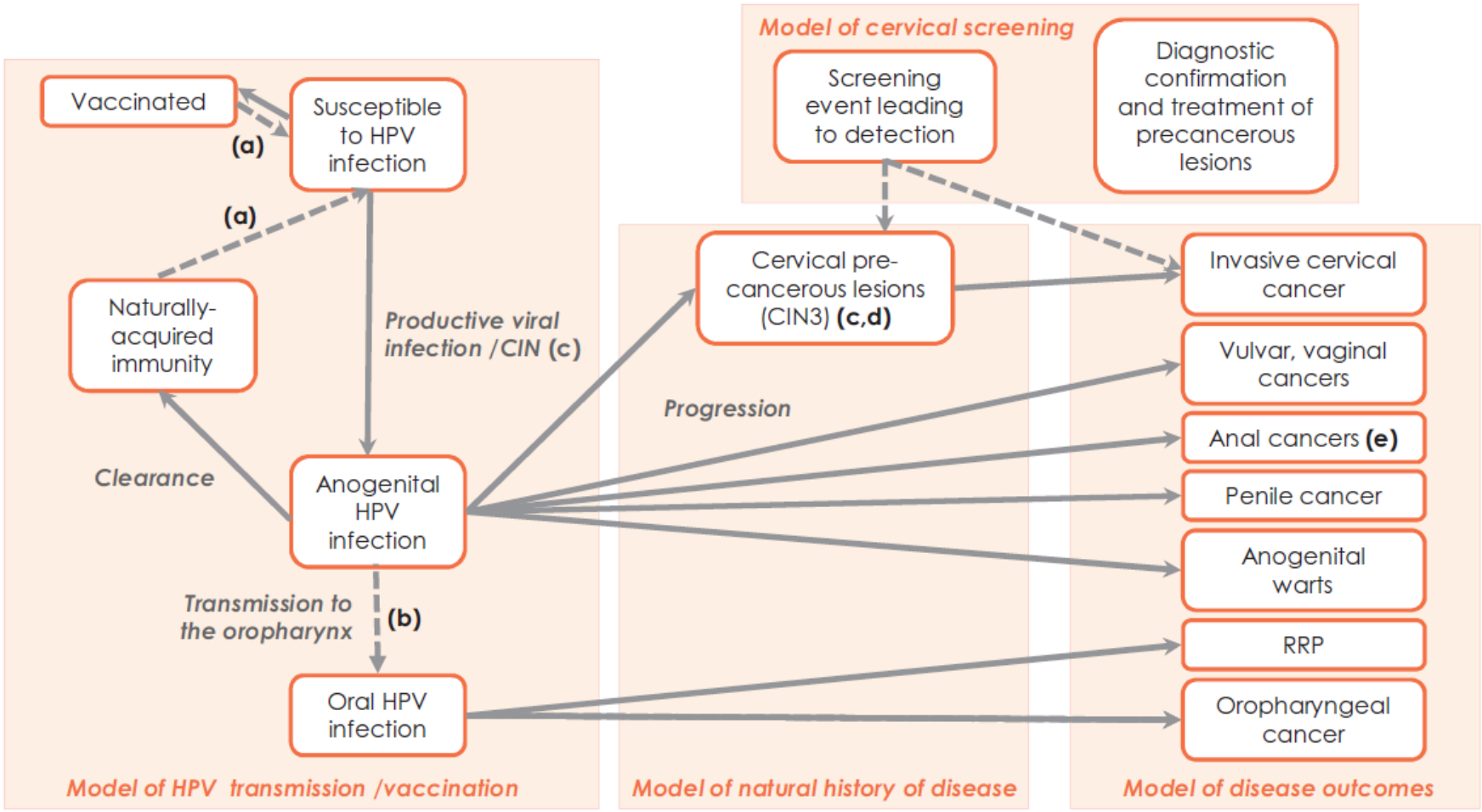
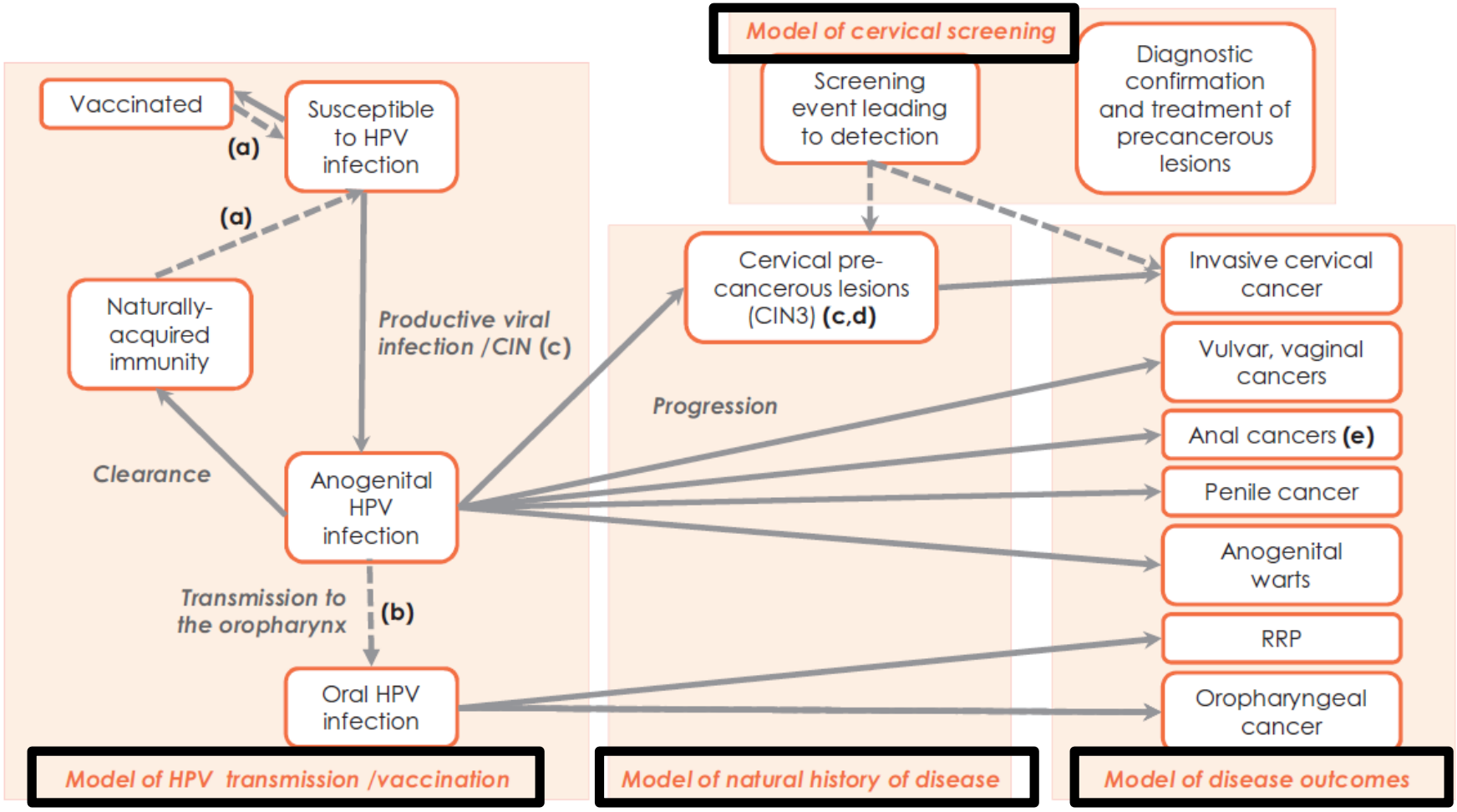
Model of HPV transmission and vaccination, natural history of disease, disease outcomes and cervical screening



Canfell et al, Vaccine 2012

Model of HPV transmission and vaccination, natural history of disease, disease outcomes and cervical screening



Canfell et al, Vaccine 2012

Three US models of 9vHPV

- US HPV-ADVISE model
  - Brisson et al.
    - Brisson, Boily, Laprise, Drolet, Bénard, Martin, Chesson, Markowitz: No conflicts
- Simplified model
  - Chesson et al.
    - Chesson, Markowitz, Meites, Ekwueme, Saraiya: No conflicts
- Merck model
  - Daniels et al.
    - Daniels, Prabhu, Pillsbury, Kothari, Elbasha
    - Conflicts of interest statement: All authors are employees of Merck & Co, Inc.

9vHPV: nonavalent HPV vaccine.
US HPV-ADVISE based on Canadian HPV-ADVISE model, recalibrated to fit US data. See Drolet et al., Int J Cancer 2014; Brisson et al., Vaccine 2013; Van de Velde et al., JNCI 2012.
Simplified model based on Chesson et al., Vaccine 2011.
Merck model based on Elbasha & Dasbach, Vaccine 2010.

All three 9vHPV models

- Are dynamic (include “herd effects”)
- Include a wide range of health outcomes
  - Cervical precancers and cancer
  - Other HPV-associated cancers
    - Anal, vaginal, vulvar, penile, oropharyngeal
  - Genital warts
  - Recurrent respiratory papillomatosis (RRP)
    - Exception: HPV-ADVISE model does not include RRP
    - Merck model and Simplified model include adult-onset and juvenile-onset RRP
- Apply updated, higher direct medical costs estimates for HPV-associated cancers
- Apply updated vaccine costs

Simplified model

- Model has been used to examine a wide range of HPV vaccination strategies
  - Results often similar to those of more complex HPV models
- Model is useful but not always suitable or sufficient for all analyses due to key simplifications
- Collaboration with HPV-ADVISE modelers to address full range of ACIP needs

HPV-ADVISE model

- Developed initially for Canada
  - Adapted to US data with funding from CDC
  - US version of HPV-ADVISE has been used extensively
    - 9vHPV vs. 4vHPV
    - 2-dose vs. 3-dose
- Model has informed numerous governmental and other organizations
  - WHO
  - ACIP
  - National Advisory Committee on Immunization (Canada)

4vHPV: quadrivalent HPV vaccine.
9vHPV: nonavalent HPV vaccine.

Merck model

- Model has been used to examine a wide range of HPV vaccination strategies
- Model results submitted to all HPV-related ACIP meetings to date
- All model equations are published
- Model has informed numerous governmental and other organizations
  - WHO
  - ACIP
  - Various ministries of health

Description of Merck model provided by Vimalanand Prabhu, 10/23/2018.

Selected model features

Model Feature	HPV-ADVISE model	Simplified model	Merck model
Structure	Individual-based Persons infected can recover and be infected again	Compartmental Persons infected can not be infected again	Compartmental Persons infected can recover and be infected again
Time horizon	100 years	100 years	100 years
Study approach	Examines adding mid-adults to existing 9vHPV vaccine program	Examines HPV vaccine program with mid-adults to program without mid-adults	Examines adding mid-adults to existing 9vHPV vaccine program
Productivity costs included	No	No	No

Selected model features, continued

Model Feature	HPV-ADVISE model	Simplified model	Merck model
Natural immunity after infection and clearance	~10% to 50% of women and 0% to 20% of men develop lifelong immunity	No re-infection; 100% develop lifelong immunity	60% seroconvert; of these, degree of protection is 50% for males and 80% for females
Vaccine efficacy	95% efficacy against infection	95% efficacy against infection	Efficacy against transient infection, persistent infection, disease
Vaccine assumed to protect against re-infection	Yes	No Re-infection is not modeled	Yes

Selected model features, continued

Model Feature	HPV-ADVISE model	Simplified model	Merck model
Data for coverage assumptions ages ≤ 18 years	NIS-Teen	NIS-Teen	NHANES
Probability that unvaccinated adults will be vaccinated	Annual probability: 2.6% women 1.9% men	Annual probability: 2.6% women 1.9% men	2.4% and 1.0% of eligible women and men (total over 100 years)

NIS-Teen: National Immunization Survey-Teen.
NHANES: National Health and Nutrition Examination Survey.

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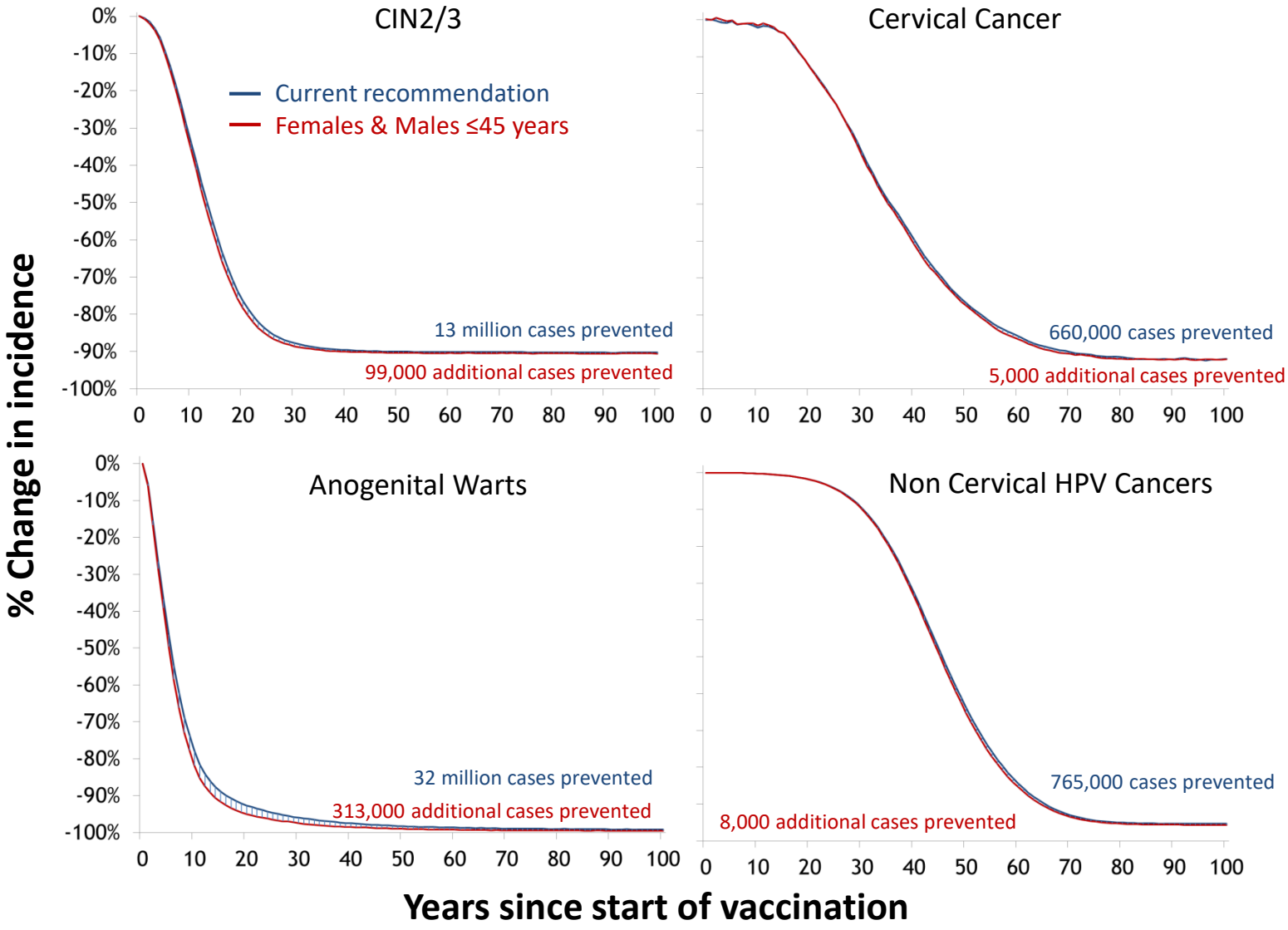
Effectiveness Extended to 45 years vs. Current recommendation

HPV-ADVISE model, base case

Preliminary



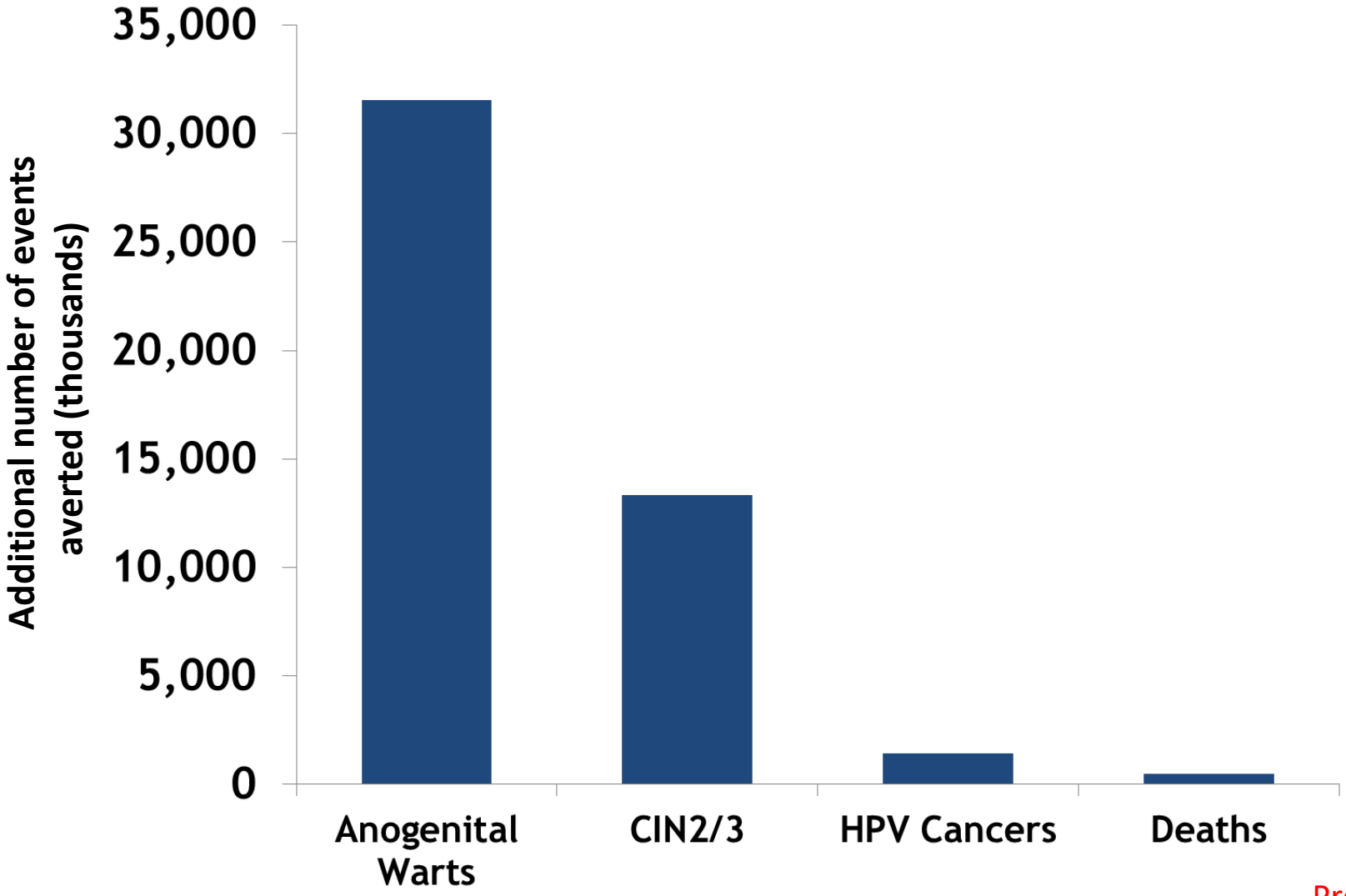
CIN=Cervical intraepithelial neoplasia.

US HPV-ADVISE Model results (mean estimate generated by the 50 best fitting parameter sets) .

Health Outcomes Prevented over 100 years

HPV-ADVISE model, base case

Current recommendation (vs. no vaccination)



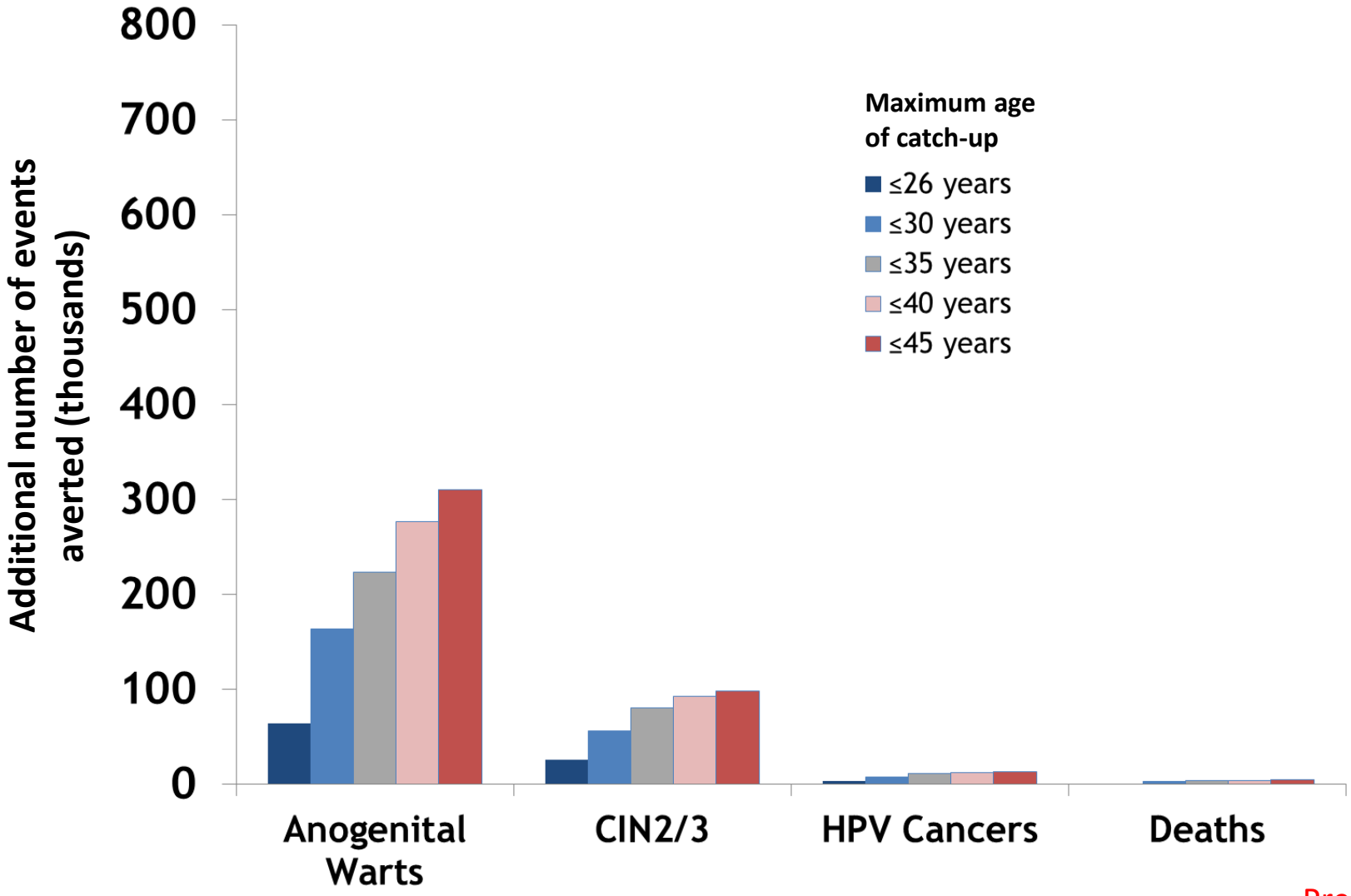
Preliminary

CIN=Cervical intraepithelial neoplasia. US HPV-ADVISE model results: Mean estimate generated by the 50 best fitting parameter sets.

Additional Health Outcomes Prevented over 100 years

HPV-ADVISE model, base case

Extended catch-up scenarios vs. Current recommendation



Preliminary

CIN=Cervical intraepithelial neoplasia. US HPV-ADVISE model results: Mean estimate generated by the 50 best fitting parameter sets.

Number needed to vaccinate to prevent one outcome

HPV-ADVISE model

Vaccine strategy	Number needed to vaccinate to prevent one case			
	Anogenital warts	CIN 2/3	Cancer	Death
Current recommendation	9	22	198	605
Ages ≤ 30 years	82	241	1,681	5,231
Ages ≤ 35 years	108	299	2,080	6,456
Ages ≤ 40 years	127	378	2,831	8,418
Ages ≤ 45 years	149	472	3,533	10,498

Current recommendation is compared to no vaccination.
Mid-adult vaccination scenarios are compared to current recommendation.

Preliminary

CIN=Cervical intraepithelial neoplasia. Number needed to vaccinate (NNV) calculated as (Additional # vaccinated)÷(Additional events prevented by vaccinating).

Number needed to vaccinate to prevent one outcome

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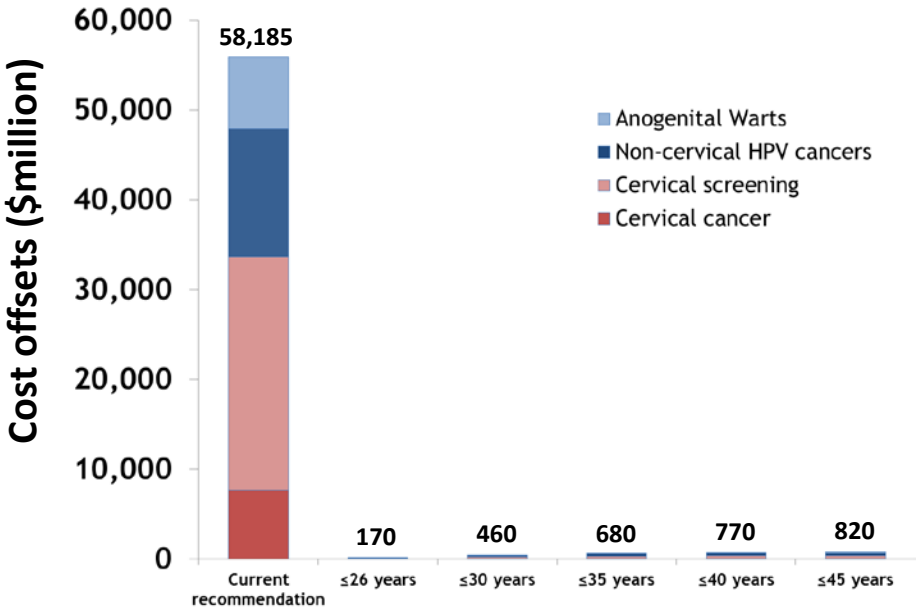
Incremental costs and health benefits

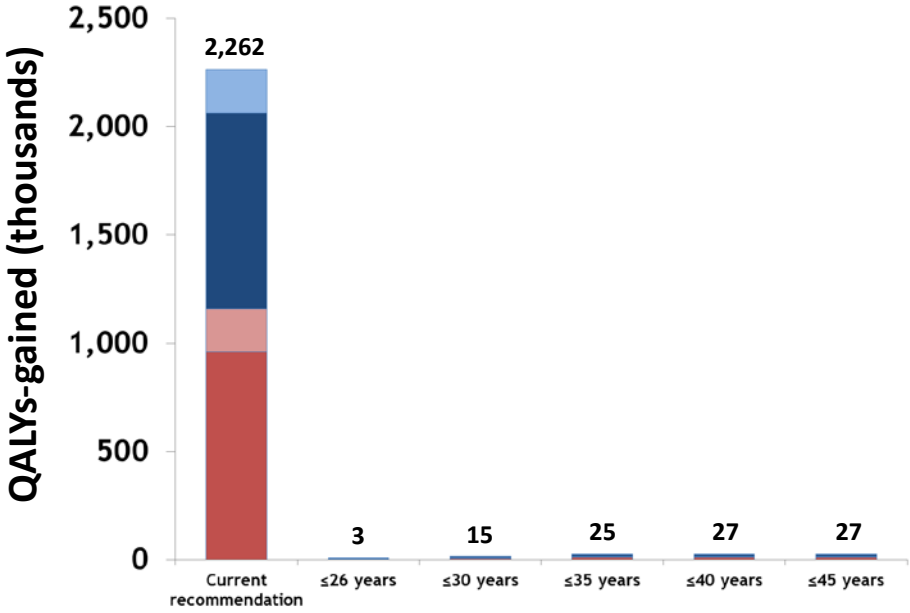
HPV-ADVISE model, base case, 100 years

Preliminary

Incremental health care costs saved



Incremental QALYs gained



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QALY=quality-adjusted life year.
Results are discounted at 3% annual rate..

Incremental cost-effectiveness ratios, HPV-ADVISE

HPV vaccination strategy	Incremental cost ($ million)	Incremental QALYs gained (1,000)	Incremental cost per QALY gained
Both sexes ≤ age 17 years (vs. no vaccination)			< $0 (cost-saving)
Current recommendation* (vs. both sexes ≤ age 17 years)	3,700	113	$33,000
Both sexes ≤ age 26 years (vs. current recommendation)	1,100	3	Dominated**
Both sexes ≤ age 30 years (vs. current recommendation)	3,100	15	$204,000
Both sexes ≤ age 35 years (vs. ≤ age 30 years)	3,100	10	$310,000
Both sexes ≤ age 40 years (vs. ≤ age 35 years)	3,600	2	$1,671,000
Both sexes ≤ age 45 years (vs. ≤ age 40 years)	4,000	0**	Dominated***

QALY: quality-adjusted life year. Base case results shown here assume $225 per dose for adult vaccination.

Preliminary

*"Current recommendation" was modeled as vaccination of females ≤ age 26 years and males ≤ age 21 years.

**The strategy "Both sexes ≤ age 26 years" was weakly dominated by the strategy "Both sexes ≤ age 30 years", which had a lower cost per QALY gained.

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Summary of HPV-ADVISE results

Cost-effectiveness predictions

- Current U.S. HPV vaccination program offers good value for the cost
  - Vaccination of adolescents is cost-saving
- Extending HPV vaccination above 26 years of age results in a substantially higher cost per QALY gained

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Incremental cost-effectiveness ratios, 3 models

Cost per quality-adjusted life year (QALY) gained

HPV vaccination strategy	HPV-ADVISE model	Simplified model	Merck model
Vaccination through age 30 years (vs. current recommendation)	$204,400	$306,000	$53,000
Vaccination through age 35 years (vs. 30)	$310,000	$499,000	$89,000
Vaccination through age 40 years (vs. 35)	$1,671,000	$639,000	$145,000
Vaccination through age 45 years (vs. 40)	Dominated*	$849,000	$252,000

Preliminary

*In the HPV-ADVISE model, for the strategy "Both sexes through age 45 years" no significant population gains in QALYs could be measured compared to vaccination through age 40 years.

Differences in results across models

- No single factor accounts for different cost-effectiveness estimates
- Important factors identified so far include
  - Natural immunity assumptions
  - Historic vaccination coverage assumptions

Natural immunity assumptions

- Cost per QALY gained generally decreases as degree of natural immunity decreases
  - Lower natural immunity, lower cost per QALY
  - Higher natural immunity, higher cost per QALY
- Simplified model assumes 100% natural immunity
- HPV-ADVISE model assumptions may result in a higher effective degree of natural immunity than the Merck model

Cost-effectiveness ratios under different natural immunity assumptions

Cost per quality-adjusted life year (QALY) gained

Vaccine strategy	Merck model base case	HPV-ADVISE base case	HPV-ADVISE lower natural immunity	HPV-ADVISE higher natural immunity
Vaccination through age 30 years vs. current recommendation	$53,000	$204,000	$146,000	$228,000
Vaccination through age 40 years vs. current recommendation	$72,000	$358,000	$253,000	$404,000

Preliminary

Vaccination coverage assumptions

- Preliminary results suggest HPV-ADVISE results and Simplified model results are not particularly sensitive to moderate changes in coverage
- In Merck model, cost per QALY gained by mid-adult vaccination increases with higher historic coverage assumptions
  - Cost per QALY gained by vaccination of both sexes through age 45 years vs. current recommendation (preliminary):
    - $85,000 when using base case coverage assumptions (NHANES)
    - $171,000 when using NIS-Teen coverage assumptions

Next steps

- ACIP review of models ongoing
  - Results should be considered preliminary
- Modelers will continue working
  - To document the main differences in model structures and assumptions
  - To understand the implications of these differences in the models
    - Example: median age at which causal HPV infection acquired for cervical cancer
  - To address feedback from ACIP review
  - To provide more details to the Work Group

Plans for February ACIP meeting

- More details of health economic models
  - Assumptions
  - Limitations
- Response to ACIP health economics reviews
- Response to ACIP feedback from October meeting

Acknowledgements

- US HPV-ADVISE model
  - Marc Brisson, Jean-François Laprise, Mélanie Drolet, Élodie Bénard, Dave Martin, Lauri Markowitz
- Simplified model
  - Lauri Markowitz, Elissa Meites, Donatus Ekwueme, Mona Saraiya
- Merck model
  - Vince Daniels, Vimalanand Prabhu, Matthew Pillsbury, Smita Kothari, and Elamin Elbasha
- Andrew Leidner
- ACIP health economics reviewers (anonymous)

Comments from modelers?