EE12

# Cost-Effectiveness of Bivalent Respiratory Syncytial Virus Prefusion F Maternal Vaccine for Protection of Infants in the United States

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## INTRODUCTION

- Seasonal administration of bivalent respiratory syncytial virus prefusion F vaccine (RSVpreF) was recently recommended by the United States (US) Advisory Committee on Immunization Practices (ACIP) among pregnant persons between 32-36 weeks of gestation to protect their infants against lower respiratory tract illness due to respiratory syncytial virus (RSV-LRTI)
- Cost-effectiveness is a critical part of the evidence to recommendation framework to determine if the RSVpreF is an efficient use of resources

## OBJECTIVES

- **To evaluate the cost-effectiveness of the current recommendation for maternal RSVpreF use compared with no intervention**
- **To evaluate the cost-effectiveness of hypothetical recommendations for maternal RSVpreF use—including expanded seasonal and year-round vaccination—compared with no intervention**

## METHODS

### Model Overview

- A population-based cohort model was used to evaluate clinical outcomes and economic costs of RSV during first year of life, and expected impact of vaccination with RSVpreF compared to no intervention:
  - Clinical outcomes included cases of medically attended RSV by care setting (i.e., hospital [RSV-H], emergency department [RSV-ED], outpatient clinic [RSV-OC]), attributable deaths, and total QALYs
  - Economic costs included direct costs related to medical care and vaccination, as well as indirect costs related to caregiver work loss and future lost earnings associated with premature RSV-related death
- Population was characterized by age, calendar month of birth, and term status defined by gestational age in weeks (wGA) at birth (full-term, ≥37 wGA; late preterm, 32-36 wGA; early preterm, 28-31 wGA; extreme preterm, ≤27 wGA)

### Estimation of Model Inputs

- Number of persons giving birth (N = 3.71 M) and number of infants born in a single year (N = 3.75M) by wGA at birth, were based on CDC WONDER data[1]
- Incidence of RSV was assumed to vary by age, term-status, and calendar month[2,3,4] (Table 1)
- Case-fatality due to RSV-H was invariant by age (full term, 0.8 per 100; preterm, 0.1 per 100)[5,6]
- Age- and term-specific rates of background mortality were obtained from CDC WONDER data[1]
- Effectiveness by care setting was estimated from primary/secondary/exploratory endpoints from MATISSE (Figure 1)[7]
- Cost per RSV episode, by age and care setting (RSV-H: $11,371-177,436; RSV-ED: $1,420-3,157; RSV-OC: $312-907), were based on a recently published study utilizing the MarketScan Commercial Claims and Encounters and Medicaid Multi-State Databases (2016-2018)[8]
- Vaccination costs included drug acquisition ($295) and administration ($24)[9,10]
- Vaccine-related adverse events included injection site reaction which occurred at a rate of 410 per 1,000 based on clinical trial data and was assumed to cost $7.31 per person[11,12]
- Caregiver morbidity costs (RSV-H: $984; RSV-ED: $499; RSV-OC: $382) were estimated using labor force participation rates, average work-loss days and average daily wage[13,14]
- Cost of infant mortality due to premature death from RSV-LRTI ($676,718) was based on expected future earnings[13-15]
- Baseline utility value for healthy infants assumed to be 1; QALY loss was estimated to be 0.0157 for RSV-H and 0.0061 for RSV-ED/OC for all infants[16]; caregiver QALY loss was estimated to be 0.0066 for RSV-H, 0.0068 for RSV-ED, and 0.0041 for RSV-OC[12]

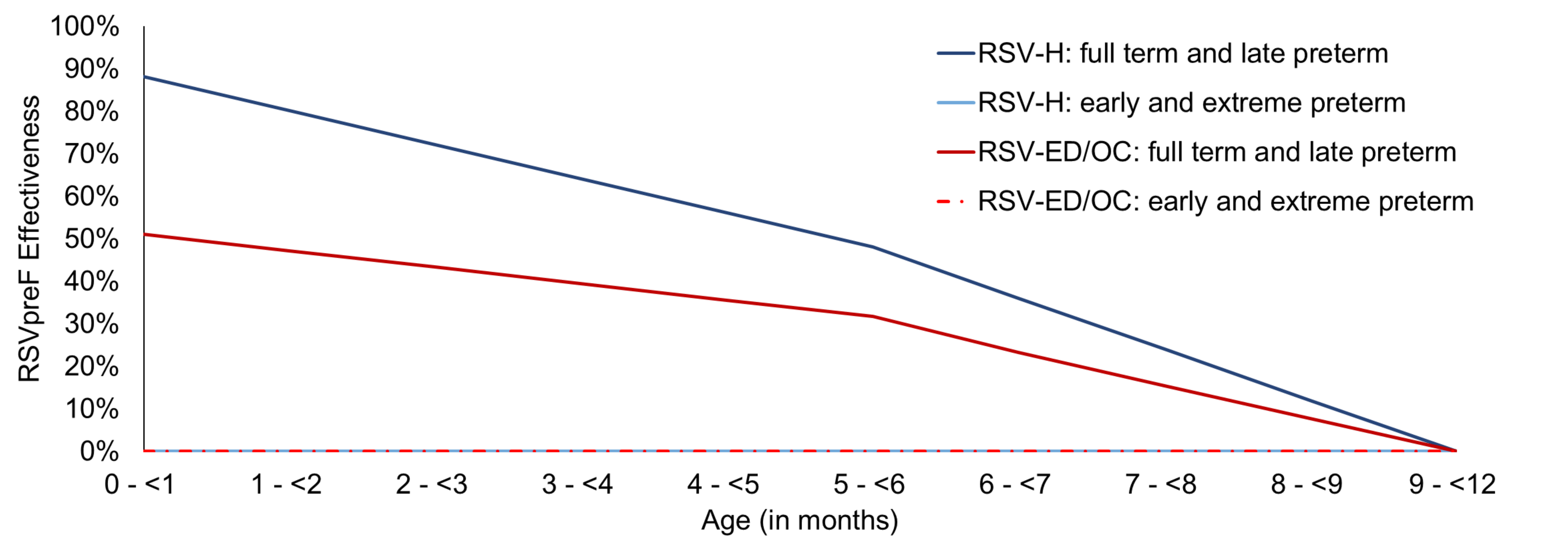
### Analyses

- Cost-effectiveness of RSVpreF versus no intervention was estimated as cost per QALY
- Base case assumes current ACIP recommendation whereby pregnant persons who are 32-36 weeks gestation between September-January are eligible for vaccination
- Scenarios exploring the impact of expanded seasonal administration from August-January, June-February, and May-February, as well as year-round vaccination are reported
- Scenario analyses considering 6- and 12-month duration of protection and an analysis considering the healthcare system perspective also were conducted
- Deterministic sensitivity analyses (DSA) in which vaccine effectiveness and cost of RSV-H were varied by ±20% were conducted
- In all analyses, uptake of RSVpreF was 54.9% during all months in which vaccine was administered[17]
- Costs are reported in 2023 US$; costs and QALYs were discounted 3% annually

**Table 1. Rates of RSV per 1,000 by care setting, age, and term status**

| | Month of Age | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | <1 | 1 - <2 | 2 - <3 | 3 - <4 | 4- <5 | 5 - <6 | 6 - <7 | 7 - <8 | 8 - <9 | 9 - <10 | 10 - <11 | 11 - <12 |
| Hospital | | | | | | | | | | | | |
| Full term | 18 | 31 | 22 | 16 | 14 | 11 | 10 | 8 | 7 | 8 | 6 | 6 |
| Late preterm | 31 | 54 | 39 | 39 | 34 | 27 | 16 | 14 | 12 | 14 | 10 | 10 |
| Early & extr. Preterm | 8 | 15 | 11 | 37 | 32 | 26 | 66 | 55 | 50 | 57 | 41 | 41 |
| Emergency department | | | | | | | | | | | | |
| Full term | 20 | 64 | 72 | 105 | 116 | 71 | 82 | 56 | 56 | 56 | 40 | 56 |
| Late preterm | 34 | 112 | 126 | 260 | 287 | 176 | 140 | 96 | 95 | 95 | 69 | 95 |
| Early & extr. preterm | 9 | 30 | 34 | 250 | 276 | 169 | 559 | 383 | 380 | 380 | 276 | 380 |
| Outpatient clinic | | | | | | | | | | | | |
| Full term | 85 | 188 | 234 | 233 | 265 | 289 | 265 | 207 | 278 | 227 | 242 | 258 |
| Late preterm | 148 | 327 | 408 | 575 | 655 | 715 | 452 | 354 | 474 | 388 | 413 | 441 |
| Early & extr. preterm | 40 | 89 | 111 | 553 | 630 | 687 | 1,807 | 1,415 | 1,897 | 1,551 | 1,650 | 1,762 |

**Figure 1. Effectiveness of RSVpreF by age**




## RESULTS

### Base Case

- **Maternal vaccine versus no intervention is dominant (i.e., more effective and lower cost) under the current recommendation, resulting in 89,908 fewer RSV episodes (hospital: 10,308; ambulatory: 79,601) and total costs lower by $18 million (Table 1)**

### Scenario Analyses

- **Expanding the administration window further reduces RSV cases (vs. the current recommendation) by 20% for August-January, 49% for June-February, 55% for May-February, and 58% for year-round vaccination**
- **Incremental cost-effectiveness of RSVpreF (vs. no intervention) was <$90,000/QALY in all scenarios, including the scenario with year-round administration**

### Deterministic Sensitivity Analyses

- **Even in scenarios with initial VE and RSV-H costs, respectively, 20% lower than base case input values, cost-effectiveness remains <$50,000/QALY**

**Table 2. Clinical outcomes and economic costs among US infants aged <1 year with use of maternal vaccine vs. no intervention for prevention of RSV**

| | | Difference in Outcomes (vs. No Intervention) | | | | |
|---|---|---|---|---|---|---|
| | | Base Case | Scenario Analyses | | | |
| | No Intervention | September-January | August-January | June-February | May-February | Year-Round |
| Clinical outcomes | | | | | | |
| No. RSV cases | | | | | | |
| Hospital | 48,384 | -10,308 | -11,340 | -12,875 | -13,133 | -13,349 |
| ED | 246,118 | -20,538 | -24,875 | -30,669 | -31,786 | -32,414 |
| OC | 854,465 | -59,062 | -71,402 | -90,279 | -94,199 | -96,540 |
| No. RSV-related deaths | 110 | -17 | -19 | -21 | -22 | -22 |
| QALYs* | 101,563,275 | 1,544 | 1,790 | 2,150 | 2,218 | 2,264 |
| Economic costs (millions) | | | | | | |
| Direct costs | | | | | | |
| Medical care | $1,660.3 | -$282.3 | -$310.4 | -$353.5 | -$360.1 | -$366.3 |
| Maternal vaccination | $0.0 | $315.4 | $372.2 | $537.2 | $590.0 | $643.1 |
| AEs | $0.0 | $3.0 | $3.5 | $5.0 | $5.5 | $6.0 |
| Subtotal direct | $1,660.3 | $36.1 | $65.3 | $188.8 | $235.4 | $282.8 |
| Indirect costs | $556.6 | -$53.7 | -$62.6 | -$75.5 | -$78.0 | -$79.6 |
| Total costs | $2,216.9 | -$17.7 | $2.7 | $113.3 | $157.4 | $203.2 |

*QALYs estimated based on infant QALYs minus caregiver QALY loss

**Figure 2. Incremental cost-effectiveness ratios ($/QALY) for base case and scenario analyses**

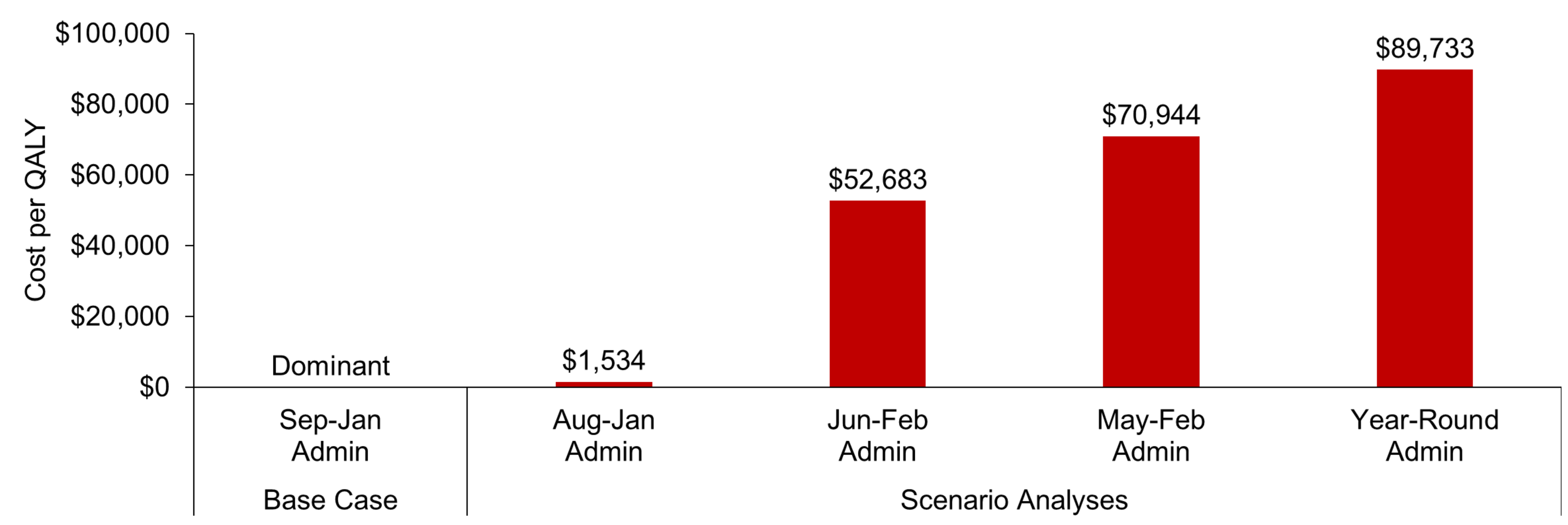



**Table 3. Results from sensitivity and scenario analyses**

| | Difference in Outcomes for RSVpreF vs. No Intervention | | | | | |
|---|---|---|---|---|---|---|
| | RSV-H Cases | RSV-Amb Cases | QALYs | Direct Costs (millions) | Indirect Costs (millions) | ICER (per QALY) |
| Sensitivity | | | | | | |
| VE 80% of base case | -8,246 | -63,680 | 1,235 | $93 | -$43 | $40,093 |
| VE 120% of base case | -11,701 | -95,521 | 1,808 | -$6 | -$63 | Dominant |
| RSV-H cost 80% of base case | -10,308 | -79,601 | 1,544 | $80 | -$54 | $17,120 |
| RSV-H cost 120% of base case | -10,308 | -79,601 | 1,544 | -$8 | -$54 | Dominant |
| Scenario | | | | | | |
| 6 mo. duration of protection | -10,213 | -77,434 | 1,514 | $38 | -$53 | Dominant |
| 12 mo. duration of protection | -10,476 | -84,117 | 1,601 | $32 | -$56 | Dominant |
| Healthcare system perspective | -10,308 | -79,601 | 1,544 | $36 | --- | $23,349 |

## LIMITATIONS

- Several potential benefits of vaccination are not captured in the model (e.g., direct impacts of vaccination on pregnant people or indirect impact on other populations)
- Lacking clinical trial data beyond age 6 months, waning of RSVpreF effectiveness from age 6-<10 months was informed by evidence on kinetics and decay of maternal transferred antibodies following natural infection and vaccination[18-20]
- Outcomes in model do not necessarily align with prespecified endpoints in MATISSE
- Cost of RSV based on a single database which may not be nationally representative; costs may also be somewhat overestimated because they are based on episodes of RSV-LRTI

## CONCLUSIONS

- **Under current US ACIP recommendation, seasonal administration of maternal RSVpreF is a cost saving intervention for reducing RSV among infants**
- **Expanding maternal RSVpreF recommendations to include year-round administration would remain highly cost-effective and should be considered by policymakers to maximize protection against RSV, especially for infants born in regions where RSV season extends beyond October-March**

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**This study was sponsored by Pfizer Inc.**