Economic and Clinical Benefits of Bivalent RSVPreF Maternal Vaccine for Prevention of RSV in Infants: A Cost-Effectiveness Analysis for Mexico

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OBJECTIVE

- Respiratory syncytial virus (RSV) is a common respiratory virus that frequently causes mild, cold-like symptoms and is the leading cause of bronchiolitis and pneumonia in children younger than 1 year of age.[1]
- A novel RSV prefusion F (RSVpreF) vaccine for use among pregnant people for the prevention of RSV in infants is expected to be licensed in Mexico.
- The clinical and economic burden of RSV-lower respiratory tract infection (LRTI) among infants in Mexico, with and without a year-round RSVpreF maternal vaccination program, was estimated.

METHODS

Model Overview

- A population-based Markov cohort model was used to project clinical and economic outcomes of RSV from birth to 1 year of age for RSVpreF vaccine compared to no intervention.
- Study population included all infants born during a 1-year period (N = 1.9M)[2,3] followed through age 12 months.
- Clinical outcomes included medically attended RSV stratified by care setting (i.e., hospital [H], emergency department [ED], or physician's office [PO]) and deaths associated with RSV treated in-hospital.
- Economic outcomes included intervention costs (comprised of RSVpreF vaccine and administration) and direct medical costs for infants.

Model Estimation

- Incidence of RSV-H, RSV-ED, and RSV-PO was based on published literature in Mexico;[4,5] incidence rates were allocated by the month of age based on US data.[6]
- Case fatality rate ([CFR]; 1.2 per 100 hospitalizations) for RSV-associated in-hospital mortality was derived from the published literature.[4]
- Vaccine effectiveness was based on data from the MATISSE clinical trial and applied as a year-round program.[7]
- Maternal vaccine uptake was assumed to be 60% among pregnant people year-round based on values reported for maternal tetanus/ diphtheria/ pertussis (Tdap) vaccination in Mexico.[8]
- Treatment costs ranged from MXN$65,292 (infants 6 – 12 months) - MXN$115,206 (infants < 6 months) for RSV-H, MXN$4,203 for RSV-ED, and MXN$1,174 for RSV-PO.[9]
- Administration cost for maternal vaccination (MXN$255.49) was based on Government of Mexico data.[10]
- Healthy infant utility was assumed to be 1.0; for persons aged ≥1 year, utility was based on values from the literature.[11]
- Disutility for infants and quality-adjusted life year (QALY) loss for their caregivers due to RSV were derived from the published literature.[12,13]

Analyses

- Value-based price (VBP) was calculated as the price at which RSVpreF (vs. no intervention) would be cost-effective based on a willingness-to-pay (WTP) range of MXN$247,310 – 741,930 per QALY gained, i.e., 1-3x gross domestic product per capita (GDPpc) in 2023.[14]
- A 5% annual discount rate was applied for costs and outcomes:
  - All costs are reported in 2024 Mexican Pesos (MXN$).
- Analyses were conducted from the healthcare system perspective with a lifetime time horizon.
- Scenario analyses tested the robustness of model settings and key model inputs such as vaccine coverage of 40% and 80%, alternative CFRs (0.7 and 0.4 per 100 hospitalizations for infants < 6 months and 6 – 12 months, respectively, and 1.7 per 100 hospitalizations across all age groups), and inclusion of indirect costs.

LIMITATIONS

- Findings may be conservative as direct effects among vaccinated pregnant people, and potential reductions in upper respiratory tract infections, disease transmission, secondary infections, and long-term sequelae of infant RSV-LRTI were not captured.

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DISCLOSURES

J.L.H., A.W.L., and D.M. are employees of Pfizer and may hold Pfizer stock. R.K. and L.I. are employed by Evidinno Outcomes Research Inc. (Vancouver, BC, Canada), which was contracted by Pfizer Inc to conduct this study.

RESULTS

- Use of RSVpreF vaccine among 1,891,388 pregnant people provided protection to 1,133,336 infants at birth and was projected to avert 15,768 RSV-H cases, 5,505 RSV-ED cases, 5,505 RSV-PO cases, and 171 RSV-related deaths (**Table 1**).
- Considering direct medical care costs, maternal vaccination resulted in a net savings of MXN$1,754M and a gain of 3,666 QALYs.
- In base case analyses, maternal RSVpreF vaccination would be cost saving at up to MXN$1,301 per dose and cost-effective at MXN$2,105 – 3,715 per dose at 1-3x GDPpc per QALY gained. The estimated VBP of MXN$2,105 at 1x GDPpc per QALY gained was used in the base case.

Table 1. Base case results: Maternal vaccine vs. no intervention for RSV prevention

	Maternal RSVpreF	No Intervention	Difference
Clinical outcomes			
No. of cases			
RSV-H	32,437	48,206	-15,768
RSV-ED	18,166	23,671	-5,505
RSV-PO	18,166	23,671	-5,505
No. of RSV-related deaths	383	553	-171
Life years (discounted)	38,060,131	38,056,730	3,402
QALYs (discounted)	35,700,767	35,697,274	3,493
Caregiver QALYs lost	437	610	-173
Economic outcomes (MXN$ millions)			
Medical care	3,132	4,886	-1,754
Maternal vaccination*	2,660	0	2,660
Total	5,792	4,886	906
ICER			
Cost per LY			266,299
Cost per QALY			247,102

* Maternal vaccination costs incl. MXN$255.49 administration fee and assumed VBP of MXN$2,105 per dose.

- In a scenario adopting a societal perspective, the total indirect costs estimated under no intervention were MXN$333.92 million, and the indirect costs saved by RSVPreF were MXN$101.96 million. The resulting ICER would decrease to MXN$219,287 per QALY gained. Under the societal perspective, maternal RSVpreF vaccination would be cost saving at up to MXN$1,392 per dose and cost-effective at MXN$2,196 – 3,805 per dose.
- Clinical outcomes (RSV cases and RSV-related deaths) for base case and vaccine uptake scenario analyses are presented in **Figure 1** and **Figure 2**, respectively.
- RSV cases and RSV-related deaths decreased with higher maternal vaccine uptake.

Figure 1. Total number of RSV cases with different vaccine uptake

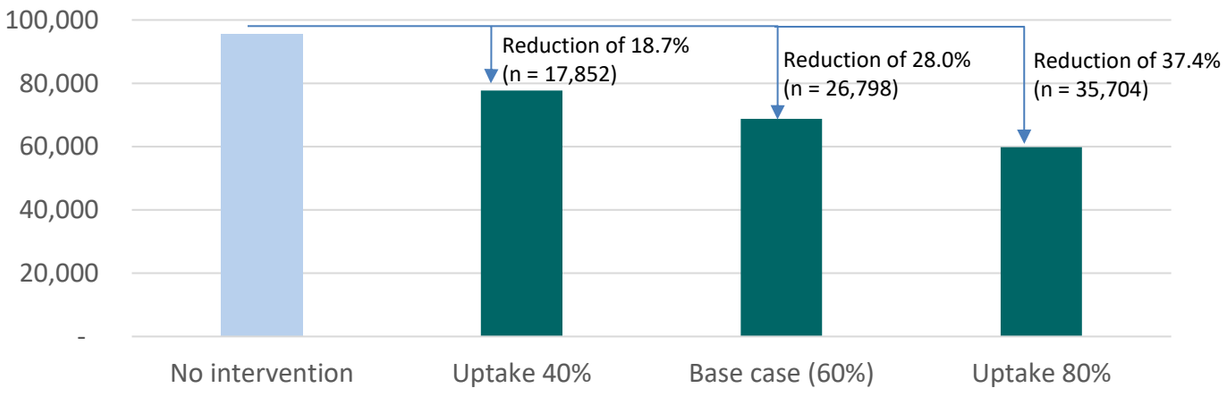
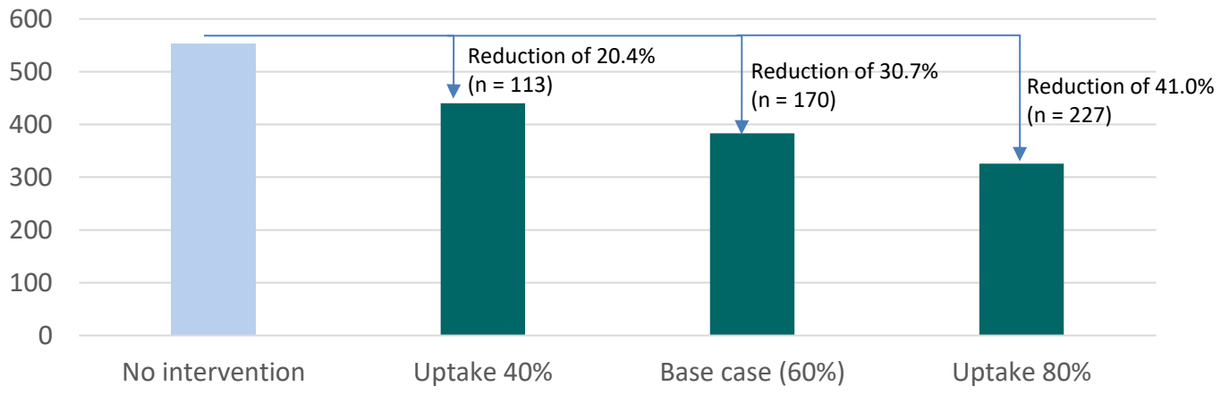
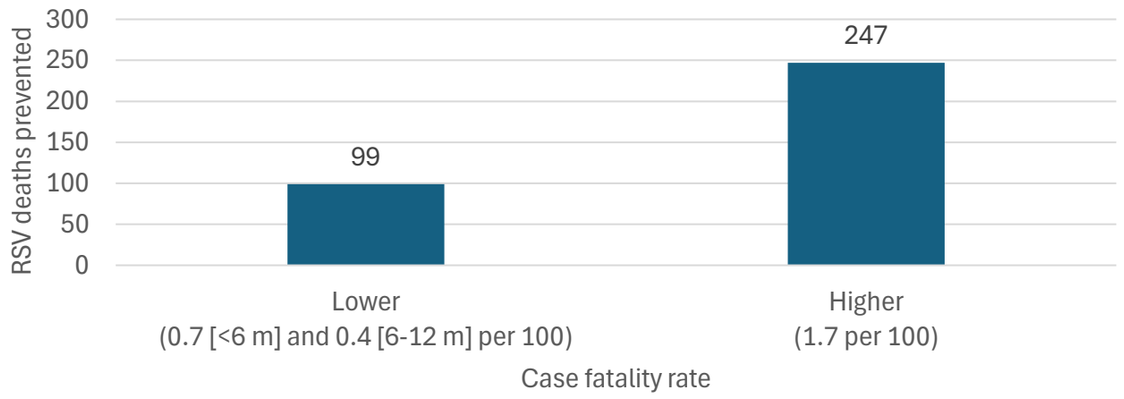


Figure 2. Number of RSV-related deaths with different vaccine uptake



- Results on the number of RSV-related deaths prevented from alternative CFR scenarios are shown in **Figure 3**.

Figure 3. RSV-related deaths prevented annually with alternative CFRs



CONCLUSION

- **Year-round RSVpreF maternal vaccination would substantially reduce RSV's clinical and economic burden among infants in Mexico.**
- **Maternal RSVpreF is likely a cost-effective and potentially cost-saving program compared to no vaccination in Mexico.**