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Cost Effectiveness of Nirsevimab and Maternal RSVpreF Vaccine for Prevention of Respiratory Syncytial Virus Disease Among Infants in the United States

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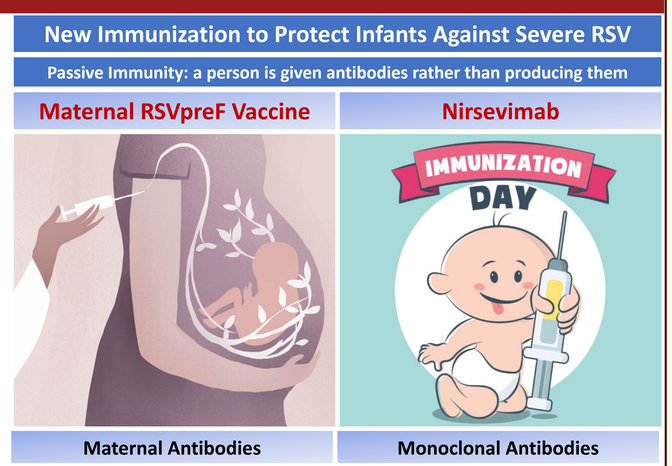
INTRODUCTION

- **Significant Burden of RSV among Children:** RSV causes substantial clinical and economic impact in the U.S., with annual rates of 1.5 million outpatient visits, 58,000 hospitalizations, and 150 deaths among children under five.
- **Vulnerability of Infants:** Infants under six months represent 45% of RSV-related hospitalizations and deaths, with potential for long-term respiratory issues.



- **New Immunization Products:** Both approved by the FDA in 2023 to prevent RSV in infants, the RSVpreF maternal vaccine is administered to pregnant women to transfer protective antibodies, while nirsevimab, a monoclonal antibody, provides a single-dose option directly for infants.

OBJECTIVE

- To evaluate the cost-effectiveness of year-round RSV immunization strategies with nirsevimab and RSVpreF for the U.S. infant population from a healthcare perspective.

METHODS

Model Overview

- **Model Structure:** Hybrid Decision tree (1 year) + Markov (2-6 years)
- **Perspective:** US healthcare sector
- **Interventions:** Year-round RSVpreF vaccination for pregnant women during weeks 32 through 36, year-round nirsevimab for infants, or no intervention
- **Time Horizon:** 6 years
- **Cycle Length:** 1 year
- **Effectiveness Measure:** Quality adjusted life-years (QALYs)
- **Discount Rate:** 3% for both cost and outcome
- **Results**: Incremental Cost-Effectiveness Ratio (ICER) and Net Monetary Benefit (NMB)
- **Willingness to Pay (WTP) Threshold**: $150,000 per QALY

Model Estimation

- **Vaccine Efficacy:** Nirsevimab and RSVpreF reduced RSV-related medical attention and inpatient rate, with efficacy based on clinical trial and assumed constant over the first year.
- **RSV Related Outcome:** Modeled medically attended RSV cases (outpatient/inpatient) and severe outcomes (ICU, mortality) within Year 1, with sequelae projected over Years 2-6.
- **Cost:** Includes prevention (nirsevimab: $395, RSVpreF: $221.24) and medical costs (outpatient, inpatient, ICU, sequelae), measured in 2024 USD.

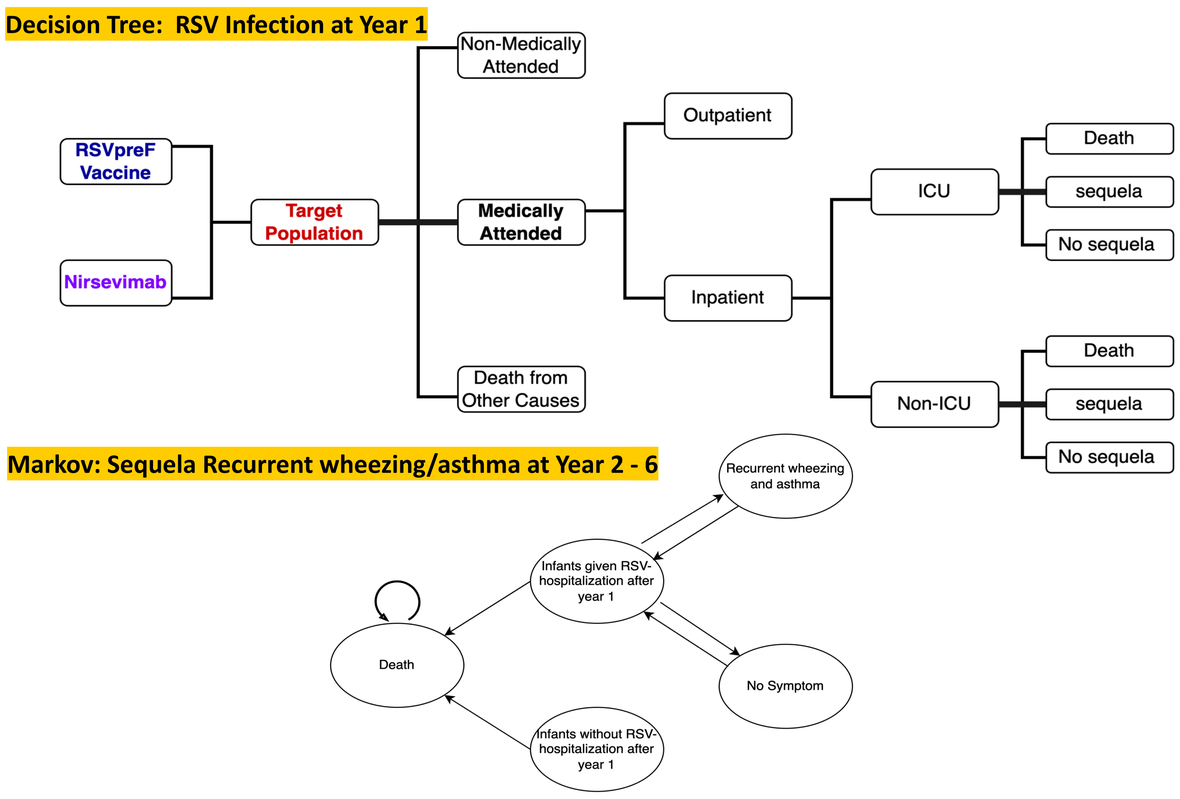
Model Assumption

- Immunization products only reduce RSV-related medical attention and Inpatient rate.
- Only infections that require hospitalization would lead to death and sequelae (wheezing/asthma)
- Each patient can get RSV infection only once during the prevention phase
- Both products maintain a constant mean efficacy only during infants' first year.
- The coverage of both immunization products is set to 100%

Sensitivity Analysis

- We conducted both one-way and probabilistic sensitivity analysis to test model assumptions and robustness.

Figure 1: Structure of Hybrid Model - Decision tree (Year 1) and Markov model (Years 2-6)



RESULTS

- **Nirsevimab vs No Intervention:** The year-round nirsevimab among infants increased cost by $50.38 with a QALY gain of 0.0012 per patient, yielding an ICER of $42,098 per QALY, indicating cost-effectiveness at $150,000 per QALY threshold.
- **RSVpreF (Maternal Vaccine) vs No Intervention:** The year-round RSVpreF maternal vaccination strategy among pregnant women dominated no intervention, achieving cost savings of $11.78 per patient and a gain of 0.00084 QALYs per patient.
- **Nirsevimab vs RSVpreF:** Nirsevimab provided a slight health benefit (0.00035 QALYs) at an additional cost of $62.16 per patient, with an ICER of $175,350 per QALY, slightly exceeding the $150,000 per QALY threshold.
- **Sensitivity Analysis:** While not cost-effective in the base case at a $150,000 WTP threshold, year-round nirsevimab is more likely to be cost-effective than RSVpreF (92.9% vs. 7.1%) in probabilistic sensitivity analysis due to uncertainty in maternal RSVpreF efficacy for medical attention rates (RR 0.487, 95% CI: 0.332–0.706).

Table 1: Base Case Results

Healthcare	Cost	Difference in Cost	Effectiveness, QALY	Difference in effectiveness	ICER	NMB
No Intervention	$ 457.59		5.54413			
Nirsevimab	$ 507.97	$ 50.38	5.54533	0.00120	$ 42,098 / QALY	$ 129.13
RSVpreF Vaccine	$ 445.81	$ -11.78	5.54497	0.00084	Dominate	$ 138.12

Healthcare	Cost	Difference in Cost	Effectiveness, QALY	Difference in effectiveness	ICER	NMB
RSVpreF vaccine	$ 445.81		5.54497			
Nirsevimab	$ 507.97	$ 62.16	5.54533	0.00035	$ 175,350 / QALY	$ - 8.99

Figure 2: One Way Sensitivity Analysis, Nirsevimab vs RSVpreF

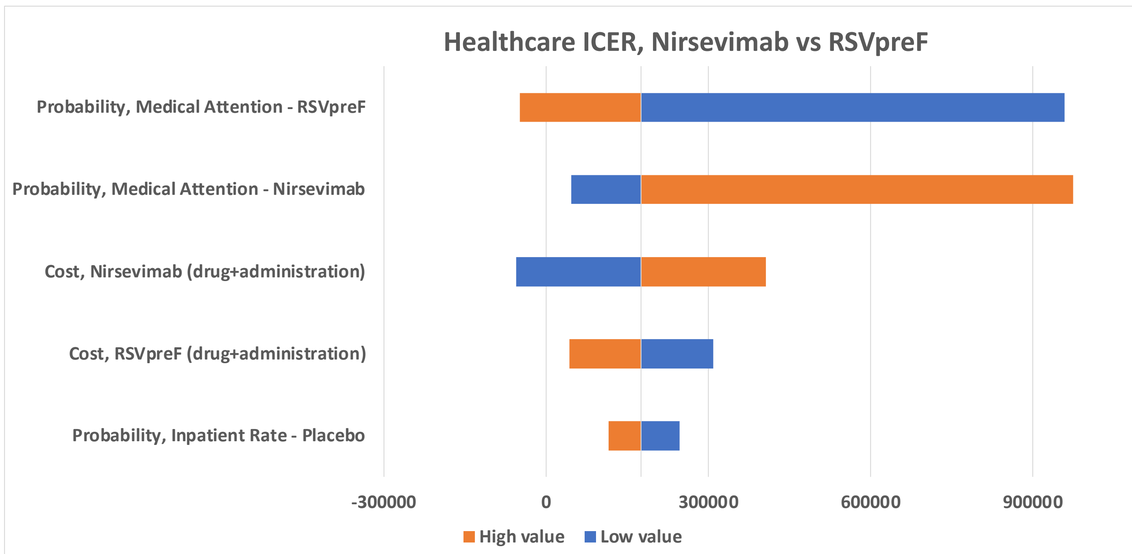
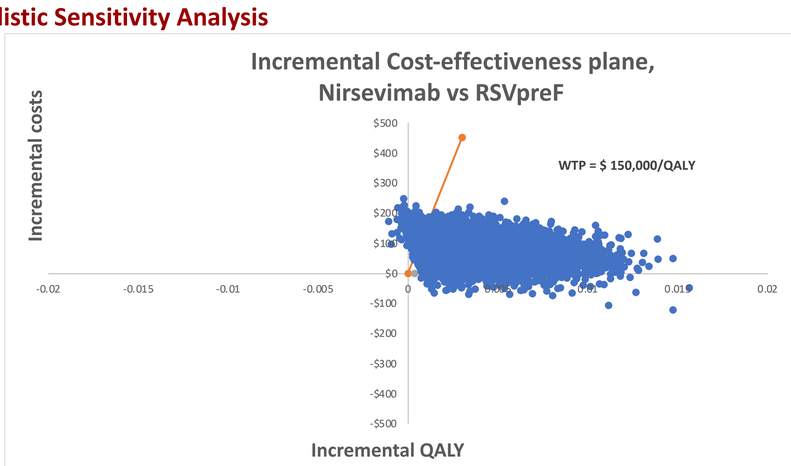


Figure 3: Probabilistic Sensitivity Analysis



CONCLUSION

- Both year-round nirsevimab and RSVpreF prevention strategies are cost-effective compared to no intervention at WTP $150,000/QALY, though RSVpreF is more favorable due to lower costs.
- Limitation: This study assumes constant efficacy and full coverage, which may not reflect real-world conditions. Future research will include scenario analyses to address these factors.

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