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ORIGINAL RESEARCH



## Cost-effectiveness of strategies using preventive interventions to protect infants in Chile from respiratory syncytial virus

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### ABSTRACT

**Background:** Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract illness (LRTI; RSV-LRTI) among infants in Chile; young infants and infants born prematurely are at greatest risk.

**Research design and methods:** A cohort model was developed to evaluate cost-effectiveness of strategies preventing RSV-LRTI in infants. Using the model, we calculated the economically justifiable price (EJP) of maternal RSVpreF vaccination (MV) versus no intervention and then evaluated the cost-effectiveness of MV (cost/dose assumed at EJP) with complementary use of monoclonal antibody nirsevimab for unprotected infants (MV+N) versus nirsevimab alone (NA) to prevent RSV-LRTI. Nirsevimab published price was \$260.00; costs/prices reported in 2023 US\$.

**Results:** NA yielded 20,247 cases (hospital: 3,773, emergency ward: 16,474) and \$57.2 million (M) in total costs (medical: \$6.3 M, intervention: \$48.7 M, indirect: \$2.2 M). MV+N yielded 23,906 cases (hospital: 3,137, emergency ward: 20,769) and \$28.7 M in costs (medical: \$4.8 M, intervention: \$21.7 M [RSVpreF assumed \$75.77/dose; nirsevimab procured \$260.00/dose], indirect: \$2.2 M). With costs lower by \$28.4 M and increased quality-adjusted life-years, MV+N would be cost-saving versus NA.

**Conclusions:** RSVpreF vaccination among pregnant women along with nirsevimab for unprotected infants in Chile would be the most efficient use of resources, yielding substantial cost savings compared to use of nirsevimab alone.

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Chile

### CLINICAL TRIALS DISCUSSED

**Clinical trial registration:** <https://clinicaltrials.gov/study/NCT04424316>. Data has been published:

Simões EAF, Pahud BA, Madhi SA, et al. Efficacy, Safety, and Immunogenicity of the MATISSE (Maternal Immunization Study for Safety and Efficacy) Maternal Respiratory Syncytial Virus Prefusion F Protein Vaccine Trial. *Obstet Gynecol.* 2025;145(2):157–167.

**Clinical trial registration:** <https://clinicaltrials.gov/study/NCT03979313>. Data has been published:

Simões EAF, Madhi SA, Muller WJ, et al. Efficacy of nirsevimab against respiratory syncytial virus lower respiratory tract infections in preterm and term infants, and pharmacokinetic extrapolation to infants with congenital heart disease and chronic lung disease: a pooled analysis of randomized controlled trials. *Lancet Child Adolesc Health.* 2023;7(3):180–189.

## 1. Introduction

Respiratory syncytial virus (RSV) is a leading cause of lower respiratory tract illness (LRTI; RSV-LRTI) among children in Chile [1–3]. The burden of RSV has continued to increase, with severe outcomes occurring most frequently among young infants and infants born prematurely. In 2023, the clinical burden of RSV across all age groups in Chile was observed to be substantially higher than the burden observed in 2019 and 2022 [3]. While the short-acting monoclonal antibody palivizumab has been recommended since 2019 for the small subset of infants at highest risk of RSV, there was limited

utilization due to its high cost and the need to administer multiple doses to achieve season-long protection [3].

In an effort to rapidly reduce the impact of RSV on the respiratory illness burden in Chile, nirsevimab – a novel, single-dose monoclonal antibody (mAb) indicated for the prevention of RSV-LRTI in infants during their first RSV season – was recommended by the Comité Asesor en Vacunas y Estrategias de Inmunización (CAVEI) in 2023 for use among infants approaching their first RSV season as well as high-risk infants in their second RSV season [3]. In April 2024, the Chilean Ministry of Health (MoH) expedited nirsevimab

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procurement ahead of the 2024 Winter Campaign, which encourages the use of nirsevimab to protect infants in Chile [3,4].

Another novel intervention to prevent RSV-LRTI in infants, the bivalent stabilized prefusion F subunit vaccine (RSVpreF) – which has been shown in the Phase III ‘**MAT**ernal Immunization Study for **S**afety and **E**fficacy’ trial (MATISSE) to protect infants via maternal vaccination – has recently been approved for use in Chile [5,6]. Given that the target populations for RSVpreF and nirsevimab are different, it is possible that both interventions may become available in Chile and used in a complementary manner such that nirsevimab is administered to infants born without protection from maternal RSVpreF. We therefore conducted a modeling study to evaluate the cost-effectiveness of a hypothetical strategy including maternal RSVpreF with complementary nirsevimab to prevent RSV-LRTI among infants in Chile.

## 2. Patients and methods

### 2.1. Model description

We developed a population-based, multi-cohort Markov model to depict clinical outcomes and economic costs of RSV-LRTI from birth to 1 year of age, lifetime consequences of premature RSV-LRTI-related death (i.e. in terms of lost life years and productivity),

as well as the expected impact of maternal vaccination with RSVpreF during pregnancy or immunization with nirsevimab after birth on outcomes and costs among infants (Figure 1) [7]. The model population comprises 12 monthly rolling birth cohorts, each characterized by gestational age in weeks (wGA) at birth. Infants are assumed to be either protected against RSV-LRTI by way of maternal vaccination or via receipt of nirsevimab or to remain unprotected against RSV-LRTI. Uptake of interventions may be specified on a monthly basis; for infants born outside of the RSV season, uptake of nirsevimab may be assumed to be delayed until the beginning of the following RSV season.

For each strategy, clinical outcomes and economic costs are projected on a monthly basis for the model population based on age, wGA at birth, disease/fatality rates, mother’s vaccination status, and infant’s immunization status. Clinical outcomes include medically attended RSV-LRTI cases – stratified by care setting (hospital or emergency ward [EW]) – and deaths associated with RSV-LRTI requiring hospitalization. Risk of death from both RSV-LRTI and non-RSV-LRTI causes is dependent on age and wGA at birth. Infants whose mothers received RSVpreF during pregnancy or who themselves receive nirsevimab may be assumed to be at lower risk of future RSV-LRTI, with magnitude of intervention-associated risk reduction (i.e. initial effectiveness and waning) dependent on intervention received, clinical presentation (e.g. hospital vs. EW), timing of intervention administration (i.e. relative

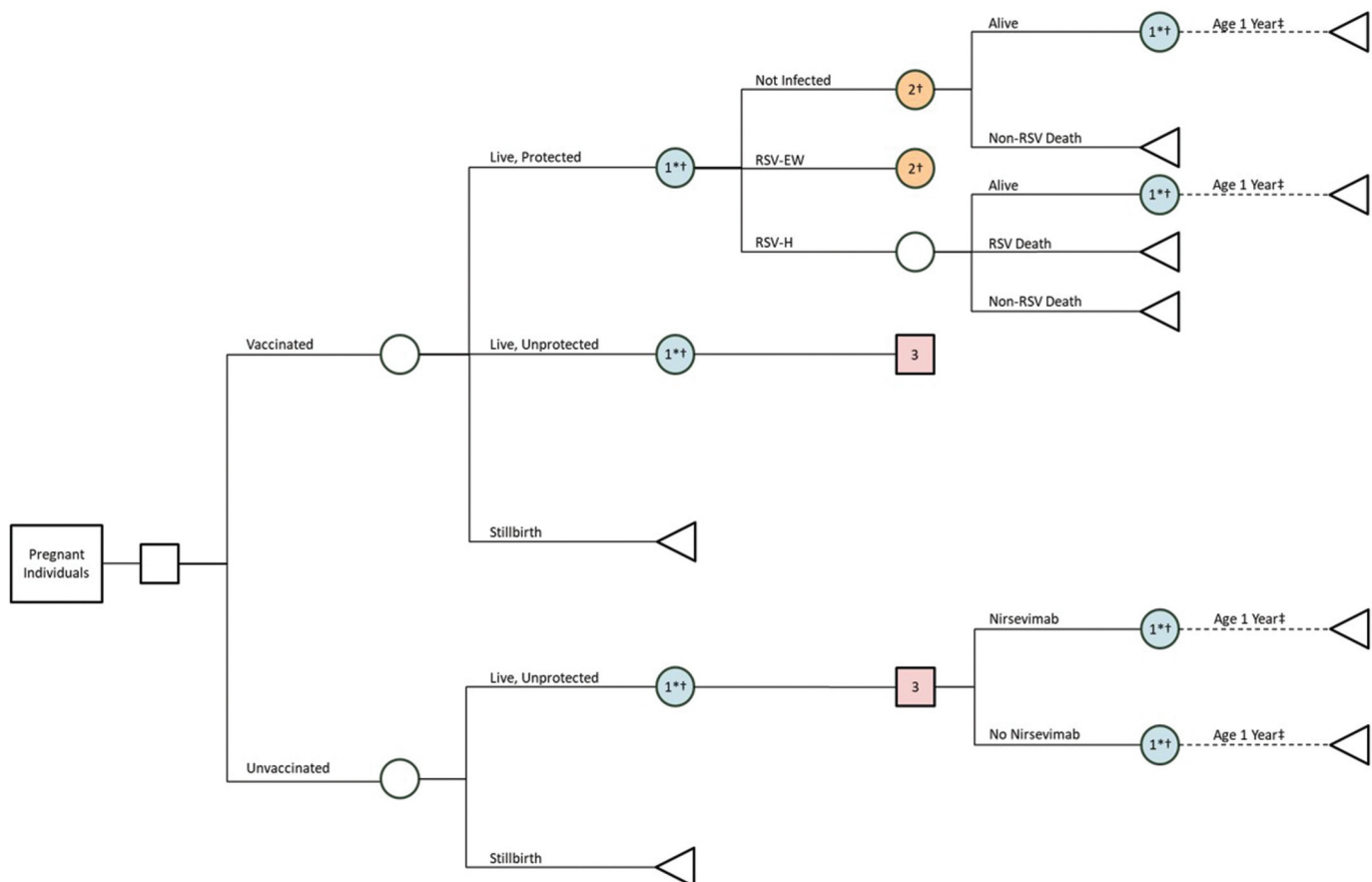


Figure 1. Model schematic (adapted from Langedijk et al. [7]).

\*Protected and unprotected infants may be subject to different probabilities of infection, depending on intervention effectiveness.

†Indicates Markov node.

‡Model tallies RSV-related outcomes until age 1 year or death, whichever occurs first.

squares depict decision nodes, circles depict probability nodes, and triangles depict end nodes.

**Table 1.** Estimates of disease and mortality rates.

|                                        | Age (in months) |         |         |         |         |         |         |         |         |          |           |           |
|----------------------------------------|-----------------|---------|---------|---------|---------|---------|---------|---------|---------|----------|-----------|-----------|
| Model Parameter                        | < 1             | 1 - < 2 | 2 - < 3 | 3 - < 4 | 4 - < 5 | 5 - < 6 | 6 - < 7 | 7 - < 8 | 8 - < 9 | 9 - < 10 | 10 - < 11 | 11 - < 12 |
| Rates of RSV-LRTI episodes (per 1,000) |                 |         |         |         |         |         |         |         |         |          |           |           |
| Hospital                               |                 |         |         |         |         |         |         |         |         |          |           |           |
| Full term                              | 105             | 60      | 46      | 33      | 27      | 23      | 22      | 18      | 16      | 14       | 14        | 11        |
| Late preterm                           | 183             | 105     | 81      | 83      | 68      | 57      | 38      | 31      | 27      | 24       | 23        | 18        |
| Early and extreme preterm              | 50              | 28      | 22      | 79      | 65      | 55      | 151     | 123     | 108     | 96       | 93        | 73        |
| Emergency ward                         |                 |         |         |         |         |         |         |         |         |          |           |           |
| Full term                              | 44              | 146     | 164     | 222     | 245     | 150     | 172     | 118     | 117     | 117      | 85        | 117       |
| Late preterm                           | 77              | 254     | 286     | 548     | 605     | 372     | 294     | 201     | 200     | 200      | 145       | 200       |
| Early and extreme preterm              | 21              | 69      | 78      | 527     | 582     | 357     | 1,174   | 805     | 798     | 798      | 580       | 798       |
| General mortality (per 100)            |                 |         |         |         |         |         |         |         |         |          |           |           |
| Full term                              | 0.11            | 0.04    | 0.04    | 0.04    | 0.04    | 0.04    | 0.01    | 0.01    | 0.01    | 0.01     | 0.01      | 0.01      |
| Late preterm                           | 0.88            | 0.12    | 0.12    | 0.12    | 0.12    | 0.12    | 0.01    | 0.01    | 0.01    | 0.01     | 0.01      | 0.01      |
| Early preterm                          | 4.86            | 0.35    | 0.35    | 0.35    | 0.35    | 0.35    | 0.04    | 0.04    | 0.04    | 0.04     | 0.04      | 0.04      |
| Extreme preterm                        | 54.89           | 1.48    | 1.48    | 1.48    | 1.48    | 1.48    | 0.17    | 0.17    | 0.17    | 0.17     | 0.17      | 0.17      |

RSV-LRTI: lower respiratory tract infection due to respiratory syncytial virus; wGA: weeks gestational age.

Full term:  $\geq 37$  wGA; late preterm: 32–36 wGA; early preterm: 28–31 wGA; extreme preterm  $\leq 27$  wGA.

to birth), and wGA at birth. Economic costs include both direct (i.e. medical) and indirect costs, as well as costs of interventions and their administration. Direct medical costs for RSV in both hospital and EW settings are generated based on event rates and unit costs in relation to the setting of care. Indirect costs capture caregiver productivity loss based on event rates, loss of work, and the value of lost work, as well as the impact of premature infant death in terms of expected future earnings. Discounting is applied monthly, beginning 1 month after the first maternal vaccine is administered.

## 2.2. Model estimation

Model inputs were estimated by age, care setting, and/or gestational age at birth, as appropriate, based on data from published sources. Data from comparable country settings were employed as needed (i.e. in instances that data specific to Chile were unavailable). Parameter values employed in base case analyses are summarized in [Tables 1–3](#); [Figure 2](#); parameter values employed in scenario analyses and probabilistic sensitivity analyses (PSA) are summarized in Supplement Table S1 and Supplement Table S2, respectively.

### 2.2.1. Population

The model population comprised 209,516 liveborn infants born to 206,623 pregnant women during a one-year period (March to February), estimated based on data from the Instituto Nacional de Estadísticas (INE) [8,9]. Infants were characterized by term status at birth (i.e. full term [ $\geq 37$  wGA], late preterm [32–36 wGA], early preterm [28–31 wGA], and extreme preterm [ $\leq 27$  wGA]) [10].

### 2.2.2. Disease rates

Incidence rates of RSV requiring hospitalization were derived based on Chilean MoH data which reported the absolute number of hospitalized RSV cases by age in 2023; all cases were assumed to manifest as LRTI ([Table 1](#)) [11]. RSV-EW incidence rates were based on publicly available Chilean MoH data reporting the overall incidence of RSV-EW among children aged  $< 1$  year in 2019; because more recent data were not available, RSV-EW rates were downwardly adjusted based on the decrease in hospitalization

**Table 2.** Estimates of direct and indirect costs.

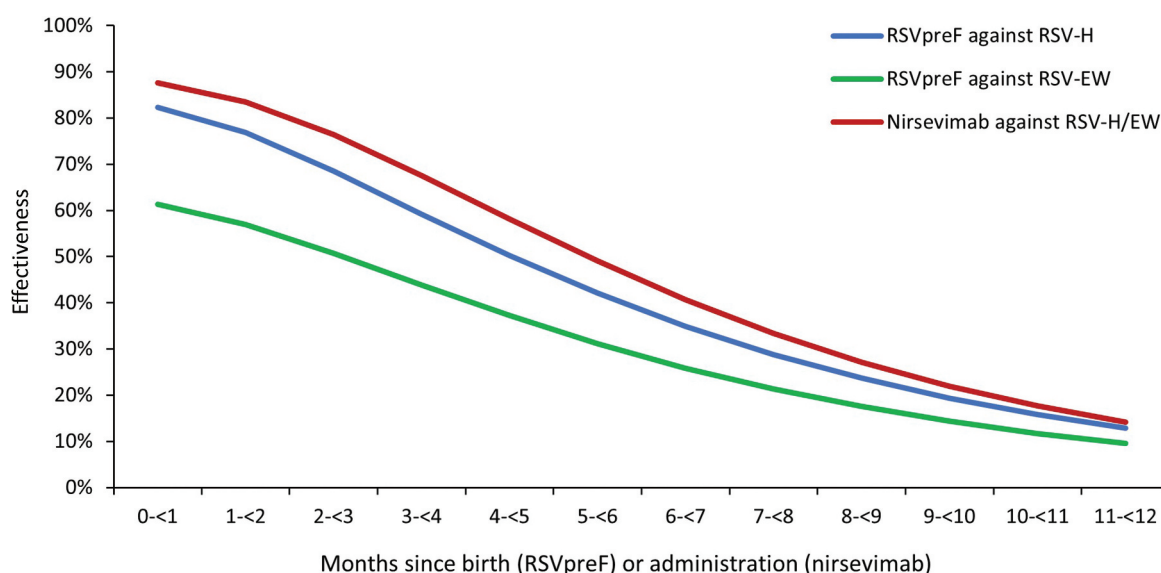
| Model Parameter        | Month of Age |          |          |
|------------------------|--------------|----------|----------|
|                        | < 3          | 3 - < 6  | 6 - < 12 |
| Costs (\$ per episode) |              |          |          |
| Direct                 |              |          |          |
| Hospital               | \$2,246      | \$2,246  | \$2,246  |
| Emergency ward         | \$67         | \$67     | \$67     |
| Indirect               |              |          |          |
| Morbidity-related      |              |          |          |
| Hospital               |              |          |          |
| Full term              | \$148        | \$99     | \$89     |
| Late preterm           | \$152        | \$112    | \$90     |
| Early preterm          | \$185        | \$122    | \$107    |
| Extreme preterm        | \$226        | \$144    | \$126    |
| Emergency ward         |              |          |          |
| All term status groups | \$57         | \$57     | \$57     |
| Mortality-related      | \$85,154     | \$85,154 | \$85,154 |

Full term:  $\geq 37$  wGA; late preterm: 32–36 wGA; early preterm: 28–31 wGA; extreme preterm  $\leq 27$  wGA.

**Table 3.** Estimates of utility and disutility.

| Model Parameter                           | Value  |
|-------------------------------------------|--------|
| Caregiver baseline utility values, by age |        |
| 1–4 years                                 | 0.9510 |
| 5–17 years                                | 0.9510 |
| 18–49 years                               | 0.9353 |
| 50–64 years                               | 0.8860 |
| 65–74 years                               | 0.8350 |
| 75–84 years                               | 0.7560 |
| 85–99 years                               | 0.7560 |
| QALY loss due to RSV                      |        |
| Infant                                    |        |
| Hospital                                  | 0.0157 |
| Emergency ward                            | 0.0061 |
| Caregiver                                 |        |
| Hospital                                  | 0.0066 |
| Emergency ward                            | 0.0068 |

rates from 2019 to 2023 [11,12]. RSV-EW rates were allocated by single month of age based on Lively et al. [13]. Lacking data on the proportion of EW cases that manifest as LRTI, all cases treated in EW were assumed to manifest as LRTI. Overall incidence rates were allocated by term status based on age-specific relative rates of RSV-LRTI by term status derived from Rha et al. [14] and the distribution of infants by term status [10]; note, due to small sample sizes,



**Figure 2.** Estimates of intervention effectiveness (adapted from Langedijk et al. [7]).

\*RSVpreF effectiveness assumed to be 0% for infants born <2 weeks after vaccine was administered and early/extreme preterm infants.

combined relative rates were derived for early and extreme preterm infants. Rates of RSV were allocated across calendar months using MoH data [11].

### 2.2.3. Case-fatality and mortality rates

RSV-related death was assumed to occur only among hospitalized cases of RSV-LRTI. The case-fatality rate (CFR) for RSV-H was estimated to be 0.28 per 100 cases based on MoH data [11]. CFR was assumed to be invariant by age and term status group.

Mortality unrelated to RSV-LRTI was based on age-specific infant mortality rates reported by the INE and was distributed across term status groups based on United States (US) Centers for Disease Control and Prevention (CDC) data [15,16].

### 2.2.4. Effectiveness of interventions

Effectiveness for RSVpreF and nirsevimab, respectively, was from a published cost-effectiveness analysis of the two interventions in which Hodgson et al. estimated effectiveness based on published clinical trial data from MATISSE (RSVpreF) and MELODY (nirsevimab) (Figure 2) [5,7,17,18]. Hodgson et al. applied a Bayesian framework to estimate the effectiveness and waning of each intervention through 12 months (i.e. since birth for RSVpreF; since administration for nirsevimab) [17]. For RSVpreF, trial-based efficacy for severe RSV-positive MA-LRTI was used as a proxy for vaccine effectiveness (VE) against RSV-LRTI requiring hospitalization and trial-based efficacy against RSV-positive MA-LRTI was used as a proxy for VE against RSV-LRTI treated in the ambulatory setting. For nirsevimab, trial-based efficacy against RSV-related LRTI was applied for RSV-LRTI treated in both care settings [17]. For maternal vaccine, early preterm infants, extreme preterm infants, and all infants born <2 weeks after maternal administration of RSVpreF were assumed to receive 0% effectiveness. There was assumed to be a one-week delay in nirsevimab effectiveness after administration, based on Moline et al. [19].

### 2.2.5. Direct costs

Direct medical costs associated with RSV-LRTI hospitalizations were based on data from a prospective longitudinal study of infants hospitalized due to RSV in Chile (Table 2) [20]. The cost of RSV-LRTI treated in the EW setting (\$67) was based on expert opinion and assumed to be invariant by age and term status [21]. All costs were adjusted to reflect 2023 United States dollars (USD) [22,23].

### 2.2.6. Indirect costs

Caregiver productivity loss (i.e. for family/household caregivers) was estimated based on labor force participation, average daily wage, and work-loss days assuming infants would receive care throughout the duration of illness from one parent. Caregiver labor force participation was based on the percent of infants with their primary caregiver in the workforce extracted from Servicio Nacional de Capacitación y Empleo (SENCE) data for persons aged 15–49 years as well as the percent of caregivers with full-time employment based on INE data on the proportion of employed persons working  $\geq 45$  h per week (i.e. given that  $\geq 45$  h per week is considered full-time employment in Chile) [24,25]. The average value of a workday (i.e. daily wage) for a full-time employed caregiver was estimated based on INE data specific to persons working  $\geq 45$  h per week. Average number of work-loss days among caregivers with hospitalized infants was based on an active surveillance study of infants hospitalized with acute lower respiratory infection in Argentina [26]. Caregiver work-loss days corresponding to infants with RSV-EW were based on the length of RSV-LRTI episodes in a recently published study and assuming the average work week is 5 days [27]; work loss for RSV-EW was assumed to be invariant by age and term status. The impact of premature infant death due to RSV-LRTI was captured by tallying expected future earnings based on age-specific estimates of work force participation rates for adults, annual earnings (discounted at 3%), and life expectancy [24,28,29].

### 2.2.7. Intervention costs

The price of nirsevimab was assumed to be \$260 based on the contracted net price per dose published in January 2024 by the Chilean authorities [30] and converted from Chilean Peso to USD [23]. The price of RSVpreF in Chile is yet unknown, therefore the economically justifiable price (EJP) of RSVpreF was estimated in analyses. Both interventions were assumed to have additional administration costs of \$4.00 per dose.

### 2.2.8. Utilities and disutilities

Lacking robust data, utility for infants without RSV was assumed to be 1. For infants with RSV, utility value during the period of illness (14 days, irrespective of care setting) was 0.59 for RSV-H and 0.84 for RSV-EW based on Roy (Table 3) [31]. Quality-adjusted life-year (QALY) loss was thus estimated to be 0.0157 for RSV-H and 0.0061 for RSV-EW. QALY losses were assumed to be invariant by term status [32].

Utility values for persons aged 18–99 years were based on EQ-5D scores in Argentina reported by Szende and Janssen [33]. For children aged 1–17 years, utility values were estimated by linearly interpolating between values for children aged <1 year and adults aged ≥18 years, respectively. Health-related quality of life loss for caregivers of infants with RSV was also considered. QALY loss was estimated to be 0.0066 for RSV-H and 0.0068 for RSV-EW, estimated based on life days lost (2.4 and 2.5, respectively) [34].

## 2.3. Analyses

Four strategies were considered in base case analyses: RSVpreF with complementary nirsevimab (herein ‘Complementary’; i.e. RSVpreF for pregnant women and nirsevimab for infants who were not already protected by RSVpreF), Nirsevimab Alone, RSVpreF Alone, and No Intervention. We compared RSVpreF Alone versus No Intervention in order to estimate the EJP of RSVpreF assuming a willingness-to-pay (WTP) of \$17,093 per QALY gained (i.e. based on 2023 gross domestic product per capita in Chile) [35]. The estimated EJP of RSVpreF was then employed in all analyses comparing the Complementary strategy versus Nirsevimab Alone.

In both the Complementary strategy and the RSVpreF Alone strategy, 90% of women were assumed to receive RSVpreF year-round (i.e. regardless of expected delivery month) based on uptake of the influenza vaccine among pregnant women in Chile in 2019 [36]. RSVpreF was assumed to be administered to pregnant women between the 32nd and 36th week of gestation based on recommendations from the Argentina MoH, Canada’s National Advisory Committee on Immunization, and the US Advisory Committee on Immunization Practices [37–39]; distribution of uptake within the recommended wGA window was based on maternal Tdap uptake observed in the US [34].

In both the Complementary and Nirsevimab Alone strategies, nirsevimab was assumed to be administered to 90% of eligible infants based on uptake of nirsevimab observed in Chile during the 2024 Winter Campaign, and taking into consideration that uptake may vary in the future, based on factors including public health campaigns to promote adherence to the national immunization program and overall disease awareness [40]. In the Nirsevimab

Alone strategy, all infants aged <1 year were considered candidates for receipt of one dose of nirsevimab; in the Complementary strategy, infants who were protected by RSVpreF were not eligible to receive nirsevimab. To be considered protected by RSVpreF, an infant’s mother must have received RSVpreF ≥2 weeks before the infant was born, and the infant had to be born at ≥32 weeks of gestation. All other infants aged <1 year – including those whose mothers were vaccinated but did not meet the aforementioned criteria as well as those whose mothers were not vaccinated – were assumed to be unprotected by RSVpreF (i.e. effectiveness = 0%) and were therefore candidates for receipt of a single dose of nirsevimab in the Complementary strategy.

In both the Complementary strategy and the Nirsevimab Alone strategy, infants receiving nirsevimab who were born during the RSV season (i.e. April through September) were assumed to receive nirsevimab during the season. Infants born outside of RSV season (i.e. October through March) were assumed to receive nirsevimab during the first 2 months of the next RSV season (i.e. administration in the following April [50%] or May [50%]). The months during which nirsevimab is administered in the model are aligned with the 2024 winter campaign in Chile [41]. Among in-season full term or late preterm births, it was assumed that 95% of infants receiving nirsevimab would receive it during their birth hospitalization based on early nirsevimab uptake data in Chile (i.e. estimated from 90.4% to 97.5%) [42]. This estimate is aligned with in-hospital vaccination rates for Bacille Calmette-Guérin (BCG) vaccine in Chile (i.e. estimated from 94% to 91% in 2015 and 2016, respectively) [43]. The remaining 5% of infants who were born in-season and were full term or late preterm were assumed to receive nirsevimab at 2 weeks of age. For early preterm and extreme preterm infants, nirsevimab was assumed to be administered upon discharge from their birth hospitalization (i.e. approximately 1–3 months after birth/when infants reach ~35wGA). In the No Intervention strategy, all infants were assumed to remain unprotected against RSV.

Deterministic sensitivity analyses (DSAs) were conducted to evaluate the impact of changes to key model parameters (i.e. RSV hospitalization rates, medical care costs, price of RSVpreF). Hospitalization rates and medical care costs were varied to ± 20% of base case inputs. To test the durability of results to changes in price of RSVpreF (i.e. because price was based on EJP of RSVpreF alone versus No Intervention), the price was varied to increase by 50% and, alternatively, 100% of the price employed in base case analyses. Scenario analyses were also conducted in which alternative input values were employed for select model inputs to determine the relevance and significance of inputs and assumptions. Model inputs that were varied include: intervention uptake rates (uptake of RSVpreF and nirsevimab assumed to be 70% [36]), administration windows (RSVpreF administered between 24 and 36 weeks of gestation; RSVpreF seasonally to women whose expected delivery data range from April to September; effectiveness of interventions (assuming VE for RSVpreF from Hodgson et al. applies for both RSVpreF and nirsevimab and, assuming VE for nirsevimab from Hodgson et al. assumed to apply for both RSVpreF and nirsevimab [17]), and duration of protection (effectiveness truncated to duration of clinical trial follow-up [i.e. 5 months for nirsevimab, 6 months for RSVpreF]). PSA

were conducted to evaluate the cost-effectiveness of the Complementary strategy versus Nirsevimab Alone accounting for uncertainty in key model parameters.

Results of base case, sensitivity, and scenario analyses included total clinical outcomes (i.e. cases, costs, life-years [LYs], QALYs) and economic costs (i.e. direct and indirect). Cost-effectiveness was reported in terms of the incremental cost-effectiveness ratio (ICER), which was estimated based on the ratio of the difference in costs and difference in QALYs; results were also estimated as cost per LY for purposes of comparison. Analyses were conducted from the societal perspective. All costs are reported in 2023 USD; costs, LYs, and QALYs were discounted by 3% annually.

### 3. Results

#### 3.1. Economically justifiable price

With No Intervention, expected numbers of cases would total 39,894 (RSV-H: 7,334; RSV-EW: 32,560), and there would be 21 RSV-H-associated deaths among infants in Chile ( $N = 209,516$ ) (Supplemental Table S3). Direct costs would total \$12.1 million (82% attributable to hospitalizations), and indirect costs would be \$4.3 million. RSVpreF would prevent 12,190 cases of RSV-LRTI (RSV-H: 3,549; RSV-EW: 8,640), 10 RSV-LRTI-related deaths, and would reduce costs by \$7.2 million (direct: \$6.1 M; indirect: \$1.7 M). The EJP of RSVpreF therefore was \$75.77.

#### 3.2. Base case

With the Nirsevimab Alone strategy, expected cases of RSV-LRTI would total 20,247 (RSV-H: 3,773; RSV-EW: 16,474) with 11 RSV-H-associated deaths (Table 4). Direct costs would total \$55.0 million (medical care: \$6.3 M; nirsevimab: \$48.7 M), and indirect costs would total \$2.2 million. With the Complementary strategy, cases of RSV-LRTI would total 23,906 (RSV-H: 3,137; RSV-EW: 20,769) with nine RSV-H-associated deaths. Expected direct costs would total \$26.5 million (medical

care: \$4.8 M; RSVpreF: \$14.5 M; nirsevimab: \$7.2 M) and indirect costs would total \$2.2 million; note, total cost of RSVpreF is tallied assuming intervention price per dose equal to EJP (\$75.77). Thus, with costs lower by \$28.4 million and 35 QALYs gained, the Complementary strategy would be dominant (i.e. more effective and less costly) compared to Nirsevimab Alone.

#### 3.3. Deterministic sensitivity analyses

Across all DSAs, the Complementary strategy remained dominant over Nirsevimab Alone (Table 5, Supplementary Tables S4–S9). In DSAs employing alternative hospitalization rates and medical care costs, the Complementary strategy yielded increases in QALYs and reductions in costs that ranged from 23.1 to 47.4 and \$28.0 million to \$28.7 million, respectively, versus Nirsevimab Alone. For DSAs employing RSVpreF prices 50% and 100% higher than the base case price, the Complementary strategy remained substantially less costly than Nirsevimab Alone, with cost differentials of \$21.5 million and \$14.7 million, respectively.

#### 3.4. Scenario analyses

The Complementary strategy remained dominant across all scenario analyses conducted (Table 5; Supplementary Tables 10–15). In the scenario with RSVpreF administration beginning earlier during pregnancy (i.e. between 24 and 36 wGA), total QALYs gained with the Complementary strategy (vs. Nirsevimab Alone) was the same as in the base case, but cost savings were slightly greater (\$25.34 M) because earlier administration of RSVpreF leaves fewer babies unprotected, thus fewer doses of nirsevimab are needed. In the scenario with 70% uptake of RSVpreF and nirsevimab, fewer doses of RSVpreF administered resulted in more infants eligible for nirsevimab and more doses of nirsevimab administered. Thus, total QALYs gained with the Complementary strategy, compared to Nirsevimab Alone, increased (92 QALYs) while cost savings (\$13.1 M) were reduced to approximately 50% of those in the base case, due to high nirsevimab acquisition costs. In the scenarios with seasonally administered vaccine and

**Table 4.** Clinical outcomes and economic costs among Chilean infants aged <1 year with use of Complementary strategy vs. Nirsevimab Alone strategy for prevention of RSV – base case.

|                                        | Complementary | Nirsevimab | Difference |
|----------------------------------------|---------------|------------|------------|
| Intervention use                       |               |            |            |
| RSVpreF doses administered             | 181,555       | —          | 181,555    |
| Number of infants protected by RSVpreF | 177,761       | —          | 177,761    |
| Nirsevimab doses administered          | 27,922        | 187,728    | –159,806   |
| Clinical outcomes                      |               |            |            |
| No. of cases                           |               |            |            |
| RSV-H                                  | 3,137         | 3,773      | –635       |
| RSV-EW                                 | 20,769        | 16,474     | 4,295      |
| No. of RSV-related deaths              | 9             | 11         | –2         |
| QALYs (discounted)                     | 5,916,027     | 5,915,991  | 35         |
| Economic outcomes (in millions)        |               |            |            |
| Direct costs                           |               |            |            |
| Medical care                           | \$4.8         | \$6.3      | –\$1.5     |
| Intervention                           |               |            |            |
| Maternal vaccination                   | \$14.5        | \$0.0      | \$14.5     |
| Nirsevimab                             | \$7.2         | \$48.7     | –\$41.4    |
| Medical + intervention                 | \$26.5        | \$55.0     | –\$28.4    |
| Indirect costs (non-medical)           | \$2.2         | \$2.2      | \$0.0      |
| Total costs (direct + indirect)        | \$28.7        | \$57.2     | –\$28.4    |
| Cost-effectiveness                     |               |            |            |
| Cost per LY (societal perspective)     |               |            | Dominant   |
| Cost per QALY (societal perspective)   |               |            | Dominant   |

Table 5. Results of scenario analyses.

| Analysis                                                        | $\Delta$ Costs<br>(in millions) | $\Delta$ QALYs | ICER     |
|-----------------------------------------------------------------|---------------------------------|----------------|----------|
| Base case analysis                                              | -\$28.4                         | 35.3           | Dominant |
| Deterministic sensitivity analyses                              |                                 |                |          |
| Hospitalization rate lower bound (–20% of base case inputs)     | -\$28.0                         | 23.1           | Dominant |
| Hospitalization rate upper bound (+20% of base case inputs)     | -\$28.8                         | 47.4           | Dominant |
| Medical care costs lower bound (–20% of base case inputs)       | -\$28.1                         | 35.3           | Dominant |
| Medical care costs upper bound (+20% of base case inputs)       | -\$28.7                         | 35.3           | Dominant |
| RSVpreF price \$113.66 (+50% of base case input)                | -\$21.5                         | 35.3           | Dominant |
| RSVpreF price \$151.55 (+100% of base case input)               | -\$14.7                         | 35.3           | Dominant |
| Scenario analyses                                               |                                 |                |          |
| Uptake of interventions = 70%                                   | -\$16.1                         | 88.1           | Dominant |
| RSVpreF administration between 24–36 weeks gestation            | -\$29.8                         | 37.1           | Dominant |
| Seasonal RSVpreF administration                                 | -\$14.2                         | 13.1           | Dominant |
| Effectiveness truncated to duration of clinical trial follow-up | -\$28.4                         | 28.3           | Dominant |
| RSVpreF effectiveness from Hodgson applied to nirsevimab        | -\$29.3                         | 85.3           | Dominant |
| Nirsevimab effectiveness from Hodgson applied to RSVpreF        | -\$29.6                         | 96.3           | Dominant |

effectiveness truncated to duration of clinical trial follow-up, the Complementary strategy yielded a smaller reduction in QALYs (versus Nirsevimab Alone) compared to the base case, but remained dominant. Lastly, when effectiveness of interventions was assumed to be the same for both interventions, the Complementary strategy yielded greater increases in QALYs and reduction in costs (versus Nirsevimab Alone) compared to in the base case, regardless of whether the effectiveness assumption for RSVpreF or nirsevimab was employed.

### 3.5. Probabilistic sensitivity analyses

In PSA, the Complementary strategy was found to be dominant versus Nirsevimab Alone in 679 out of 1,000 simulations (67.9%) (Figure 3). In the remaining 321 simulations, the Complementary strategy was less costly than Nirsevimab Alone (\$27.7 M less costly on average) but yielded fewer QALYs (31.8 fewer QALYs on average). Due to the relatively small difference in QALYs but large difference in total costs, the average ICER associated with Nirsevimab Alone (versus

Complementary strategy) among these 321 simulations would be \$4,189,005/QALY gained.

## 4. Discussion

The present study found that maternal RSVpreF with complementary use of nirsevimab for infants would be more impactful in preventing the most severe RSV episodes among infants (i.e. those that result in hospitalization) than use of nirsevimab alone among infants. The Complementary strategy would, however, prevent slightly fewer cases of ambulatory RSV treated in emergency wards. Because RSV resulting in hospitalization has a greater impact on quality-of-life for both infants and their caregivers, the Complementary strategy yielded nine more QALYs than Nirsevimab Alone in the base case analysis. Assuming that RSVpreF price per dose equals the EJP (\$75.77, based on RSVpreF Alone vs. No Intervention) and nirsevimab price per dose equals the procured price (\$260.00), the total cost of interventions in the Complementary strategy (base case: \$21.7 M) was substantially lower than in the Nirsevimab Alone strategy (base case: \$48.7 M);

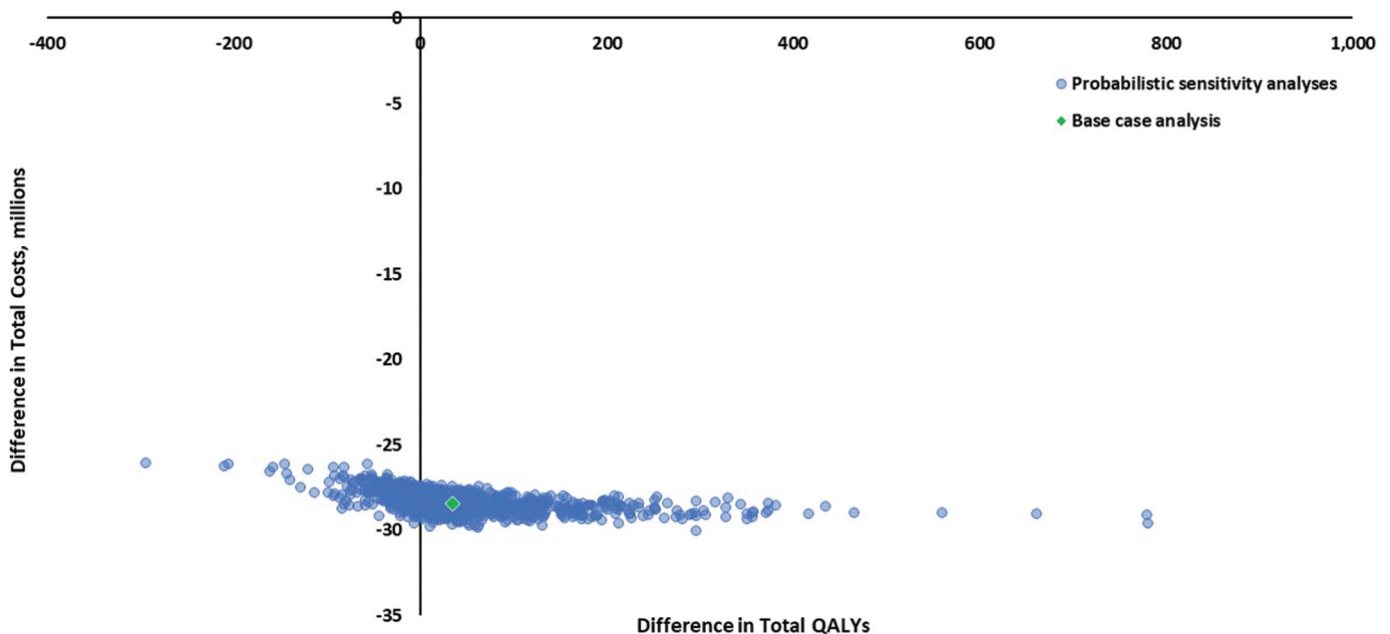


Figure 3. Results of probabilistic sensitivity analyses.

the Complementary strategy was therefore found to be dominant compared to Nirsevimab Alone in the base case.

Results of sensitivity and scenario analyses generally supported base case findings; however, in 32.1% of PSA iterations, the total number of QALYs with use of the Complementary strategy was lower than in the Nirsevimab Alone strategy. These findings highlight the comparability of the interventions, rather than the definitive superiority of one over the other. Citing the lack of a head-to-head clinical trial, the United Kingdom's (UK) Joint Committee on Vaccination and Immunisation (JCVI) noted that randomized clinical trial data suggest efficacy against severe disease to be similar for both products, lending to considerable uncertainty as to whether one product was better than the other [44]. We therefore conducted two scenario analyses assuming equal effectiveness for both interventions in order to address concerns regarding the lack of head-to-head efficacy data. In both scenario analyses, the Complementary strategy protected a greater number of infants, prevented more cases and deaths due to RSV-LRTI, and was found to be cost saving (vs. Nirsevimab). Across all analyses conducted herein (i.e. including all PSA replications), the Complementary strategy was found to be less costly (vs. Nirsevimab Alone), which further highlights the benefit of a multi-intervention strategy.

To the best of our knowledge, there are no published studies evaluating the use of immunization strategies involving RSVpreF with complementary nirsevimab to protect infants in Chile against RSV; however, there are three recent studies that provide context for the present analysis. First, a recent simulation-based retrospective analysis by Sauré et al. evaluated the clinical and economic impact of nirsevimab in preventing RSV in Chilean infants [45]. Comparing findings from Sauré et al. versus those reported herein is challenging as the methodology Sauré et al. used to calculate outcomes varied considerably from the methodology employed in the present analysis, which is aligned with conventional health economics approaches for health technology assessment [45,46]. In addition, many of the key inputs reported by Sauré et al. were either ambiguously reported or excluded from the publication entirely. For example, although the text implies that rates of ambulatory encounters for RSV include treatment in both the emergency ward and physician office settings, the cost of medical care is reported only for the emergency ward setting (i.e. cost of physician office visits was not included). Similarly, authors report total number of hospital bed days for RSV and cost per bed day, without providing information on number of bed days per hospitalization [45]. Due to these limitations, it was not possible to employ inputs from Sauré et al. in our model for purposes of comparison. Based on the outcomes reported in the publication, RSV rates and medical care costs (in all settings) seem considerably higher than those applied in our analyses. Adopting those higher rates and medical care costs within the present analyses would impact the magnitude of the estimated clinical and economic benefits for both strategies modeled; however, the relative results for Complementary vs. Nirsevimab Alone would be directionally aligned with the findings we have reported.

In 2023, Shoukat et al. published a study estimating the value-based prices of both nirsevimab and RSVpreF required to yield a cost-effective ICER in the Canadian context [47]. Despite differences in input values, Shoukat et al. also found that when

employing sigmoidal estimates for intervention effectiveness, the RSVpreF with complementary nirsevimab strategy prevented more hospitalizations and fewer outpatient cases than nirsevimab alone. Lastly, in 2024, Hodgson and colleagues published a study estimating cost-effective prices of alternative strategies for use of nirsevimab and RSVpreF among infants in the UK; however, their analyses did not consider a strategy involving RSVpreF with complementary nirsevimab, thus comparison of their results to the present analysis is not possible [17].

The principal limitation of our study is uncertainty around some parameter estimates. While the effectiveness of RSVpreF was based on data from MATISSE, we conservatively assumed that VE among early and extreme preterm infants would be 0%. Additionally, reduction in RSV hospitalization was a secondary endpoint in MATISSE that tracked reductions in all hospitalized RSV respiratory tract infections (i.e. not limited to LRTI) [5]. Because the RSV-H incidence rates employed in our analysis are specific to RSV-LRTI and because we employed VE exactly as estimated by Hodgson et al. [17], VE was based on the primary endpoint of efficacy against severe RSV MA-LRTI. Other outcomes in our cost-effectiveness model (i.e. RSV treated in EW) also are not necessarily aligned with pre-defined endpoints in MATISSE. Additionally, caution should be used in comparing results across interventions as clinical trials for RSVpreF and nirsevimab applied different epidemiological circumstances and trial endpoints.

For the Complementary strategy, because the contracted price per dose of RSVpreF is not yet available, the EJP of RSVpreF (versus No Intervention) was employed; we note that the EJP is sensitive to burden of disease data employed. For example, when applying 2019 RSV incidence data, the EJP was \$94.34 [48]. To address uncertainty regarding the price of RSVpreF, we conducted DSAs which confirm the economic benefit of the Complementary strategy (vs. Nirsevimab Alone) for a wide range of prices.

Published data specific to Chile was employed to the extent possible; however, some model input values were based on data from comparable country settings. For example, caregiver work loss and QALY loss were derived from US and Argentinian data [26,27,31,33,34]. We also note that the recommendation for nirsevimab in Chile has recently been extended to include immunization of infants going into their second RSV season who are considered to be at especially high risk of infection [49]. Because the model does not follow children beyond their first year of life nor is it capable of modeling receipt of >1 dose of nirsevimab, the impact of this expanded protection is not reflected in the present analyses. The multi-cohort Markov model employed also does not allow for the consideration of indirect impacts of interventions due to reduced disease transmission. However, a recent publication that employed a dynamic transmission model to evaluate RSV outcomes among infants in Germany reported that indirect effects of infant immunization on other age-based subgroups of the overall population were minimal [50]. Our model also does not capture the potential direct impacts of vaccination on pregnant women. Inclusion of the impact of intervention on pregnant women would make the Complementary strategy more favorable compared to Nirsevimab Alone with no additional cost. The model also does not evaluate the burden of non-medically attended disease (i.e. due to caregiver work loss) or potential short- and long-term sequelae of RSV (e.g. secondary bacterial infections,

reactive airway disease/wheezing) [51,52]. We did not model the burden of RSV manifesting as upper respiratory tract infection (URTI). Had RSV-URTI been modeled, the Complementary strategy would have reduced the burden of RSV-URTI as RSVpreF is proven to provide some protection against RSV-URTI. Published nirsevimab trial data, however, does not report on the impact of nirsevimab against URTI, thus it is not possible to estimate the impact that nirsevimab would have on rates of RSV-URTI (if any).

## 5. Conclusions

The results of this evaluation suggest that use of RSVpreF vaccine among pregnant women in Chile along with nirsevimab for infants not protected by vaccine would be the most efficient use of resources and yield substantial cost savings compared to use of nirsevimab alone.

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## Data availability statement

The authors confirm that the data supporting the findings of this study are available within the article or its supplementary materials.

## AI-based tools and technologies

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## Author contributions

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