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ORIGINAL RESEARCH

Analysis of the Economic and Public Health Impact of New Immunization Strategies in Infants Against Respiratory Syncytial Virus (RSV) in Colombia

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ABSTRACT

***Introduction*:** Respiratory syncytial virus (RSV) infections are a leading cause of lower respiratory tract infections (LRTI), particularly bronchiolitis and pneumonia, leading to significant hospitalizations and economic burden in infants. In Colombia, RSV is endemic with high morbidity and mortality rates, underscoring the need for effective prophylactic technologies to reduce its impact.

***Methods*:** This study aimed to analyze the health and economic impact of new RSV immunization technologies in Colombia, focusing on two interventions: nirsevimab and RSVpreF. A static cohort decision model was used to compare these interventions against the standard of care (palivizumab-SoC), estimating outcomes including hospitalizations, intensive care unit (ICU) admissions, deaths, and event-related healthcare costs. The model included outcomes such as QALYs and direct and indirect event-related costs from the third-party and societal perspectives. Acquisition costs of prophylactic interventions were not included because prices are not publicly available during ongoing negotiations.

***Results*:** Nirsevimab was associated with a greater reduction in healthcare events and costs compared to both SoC and RSVpreF. In the base-case scenario, it prevented an additional 44,039 events and was associated with US$23.4 million lower event-related healthcare costs compared to SoC. When compared with RSVpreF, it averted 14,558 more events and was associated with US$8.4 million lower event-related costs.

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The greatest reduction occurred in primary care visits, with 32,744 and 10,458 fewer cases versus SoC and RSVpreF, respectively, followed by reductions in hospitalizations of 6210 and 2257 cases. Nirsevimab yielded up to 646 additional QALYs compared with RSVpreF and associated with up to US$25.3 million lower event-related costs from avoided health events in societal scenarios. Sensitivity analysis identified nirsevimab efficacy and infection distribution as the key drivers of event-related cost and QALY outcomes.

***Conclusion*:** Nirsevimab was associated with larger reductions in RSV-related events, greater reductions in event-related costs, and higher QALYs than SoC and RSVpreF. Its adoption in national immunization programs could significantly reduce the economic and disease burden of RSV and improve infant health.

Keywords: Respiratory syncytial virus; Infant immunization; Monoclonal antibody; Nirsevimab; RSVpreF vaccine; Colombia; Quality-adjusted life years (QALYs)

Key Summary Points

Why carry out this study?

RSV is a leading cause of lower respiratory tract infections in infants worldwide and follows an endemic, year-round pattern in Colombia, where it was the primary etiological agent of LRTI in 2023 (26.4% of positive samples) and the leading cause of death in children under one year of age. The current standard of care—palivizumab—is restricted to high-risk subgroups and requires monthly dosing, leaving the majority of infants unprotected during the RSV season.

This study aimed to estimate and compare the public health impact and event-related economic burden of two newer RSV prevention strategies—nirsevimab (a single-dose long-acting monoclonal antibody) and RSVpreF (a maternal vaccine)—against the current standard of care (palivizumab) across five immunization scenarios in Colombia, from both payer and societal perspectives.

What was learned from the study?

Nirsevimab was associated with substantially greater reductions in RSV-related health events, event-related costs, and QALYs compared with both RSVpreF and the standard of care across all five scenarios evaluated. In the base-case scenario, nirsevimab prevented an additional 44,039 events and was associated with US$23.4 million lower event-related healthcare costs versus the standard of care; compared with RSVpreF, it averted 14,558 more events and was associated with US$8.4 million lower event-related costs.

The comparative advantage of nirsevimab was consistent across payer and societal perspectives, year-round and seasonal immunization strategies, and both term and preterm infant populations. Nirsevimab also achieved a lower number needed to immunize than RSVpreF in all scenarios, reflecting its broader preventive reach.

These findings provide estimates for the QALYs and event-related costs needed to support future formal economic evaluations, including complete cost-effectiveness analyses, threshold analyses and budget impact analyses, once acquisition prices for nirsevimab and RSVpreF become publicly available in Colombia.

INTRODUCTION

Respiratory syncytial virus (RSV) is one of the leading causes of lower respiratory tract infections (LRTI) [1, 2]. This virus accounts for 22% of LRTI in children worldwide [2], with a positivity rate of 29% in high-income countries compared to 23–26% in low- and middle-income countries among children under 60 months of age [2]. According to the World Health Organization (WHO), the prevalence of RSV is higher in children under 2 years of age and in immunocompromised people, such as the older individuals. Likewise, worldwide, one out of 50 deaths in children aged 0–5 years and one out of 28 deaths in children aged 1–6 months are due to RSV [2].

In Colombia, RSV has shown an endemic pattern, circulating year-round with peaks correlated with the rainy season, ranging from March to June and September to November [3, 4]. In 2023, RSV was the most prevalent etiological agent in Colombia, accounting for 26.4% of positive cases of LRTI samples for all ages identified in sentinel surveillance laboratories. It was also the main cause of death in children under 1 year of age, with 26 deaths attributed to this virus in this age group [5]. This group was particularly affected, accounting for 30.7% of LRTI hospitalizations in Colombia during this period [5]. RSV infection has led to a considerable increase in severe LRTI cases nationwide, exceeding seasonal thresholds since the beginning of the year [5]. Unlike temperate settings with a single winter peak, RSV circulation in many tropical settings occurs across most months with peaks associated with rainfall and local climatic patterns [6]. This epidemiologic profile creates distinct challenges for defining the timing of prevention strategies, making Colombia a useful case study for similar settings.

Although most RSV infections are mild, they can cause serious complications alongside critical consequences such as infant mortality. The potential effects include susceptibility to recurrent episodes of bronchiolitis, pneumonia, and wheezing [7]. For health institutions, RSV prevention represents a significant challenge due to the high hospitalization rate associated with this virus' behavior worldwide, and has been acknowledged as a major global priority [7].

In Colombia, palivizumab, a humanized monoclonal antibody, is the standard of care (SoC) for preventing severe RSV infection in high-risk infants and those younger than 24 months of age, including premature newborns (≤ 35 weeks' gestational age [GA]) or with bronchopulmonary dysplasia, congenital heart disease, or certain immunocompromising conditions. Monthly administration during the RSV season has been shown to be effective in reducing the incidence of severe hospitalizations. Owing to its safety and effectiveness profile, it is the reference for RSV prophylactic intervention [8].

Nevertheless, new technologies and new uses of other prophylactic alternatives have proven high efficacy in impacting the incidence of RSV-related severe outcomes, without the need for monthly dosing (once monthly during season, up to a maximum five doses) [9]. Among these strategies, the use of monoclonal antibodies such as nirsevimab offers a promising option for mitigating the impact of RSV in vulnerable populations.

Nirsevimab is a recombinant, fully humanized monoclonal IgG1κ antibody derived from human B lymphocytes. It targets a unique antigenic site (site Ø) on the prefusion F protein, and its half-life was extended to at least 150 days through YTE technology [10]. It was designed for use in all infants, regardless of gestational age at birth or health status. Notably, clinical trials have demonstrated safety and efficacy results for a single dose of nirsevimab, with favorable results to offer protection for the full RSV season [11].

Similarly, RSVpreF intervention is a vaccine specifically designed for maternal immunization against RSV. It is aimed at pregnant women between 32 0/7 and 36 6/7 weeks' GA to induce the production of protective antibodies that are transferred to the fetus through the placenta. This transfer provides protection to newborns in the first few months of life [12].

Understanding the potential impact of these prevention strategies in Colombia is particularly

important given the significant clinical and economic burden that RSV places on the country's healthcare system. Better characterization of healthcare resource utilization and associated costs can support more accurate burden estimation and budget impact planning. Research on nirsevimab and RSVpreF, a maternal vaccine, may help optimize prevention strategies, reduce hospitalizations, and ultimately improve outcomes for the most vulnerable infants.

This study aimed to estimate and compare the clinical outcomes, QALYs, and event-related costs of alternative RSV prevention strategies (nirsevimab and RSVpreF versus standard of care [palivizumab]) to quantify the disease and event-related economic burden of RSV among infants aged < 1 year in Colombia, assuming year-round circulation.

METHODS

Plan of Analysis, Design, and Setting

This study evaluated the public health impact and economic burden of RSV in Colombia using a static cohort decision model. The analysis compared SoC with nirsevimab and RSVpreF and additionally performed an indirect comparison between nirsevimab and RSVpreF to inform national RSV prevention decisions. The model estimated RSV-related healthcare resource utilization, mortality, QALYs, and costs in infants aged < 1 year.

The study was conducted in the Colombian healthcare system. Epidemiologic and healthcare resource utilization inputs were extracted from the National Institute of Health (from the Spanish acronym—INS, Supplementary Material S1) sentinel surveillance (predominantly pediatric hospital and outpatient settings) and the Colombia's Health Services Utilization Database (from the Spanish acronym SISPRO), complemented by a targeted literature review of Colombian studies [3, 4, 13] and expert validation. Model structure and reporting followed ISPOR good research practices and CHEERS 2022 guidance (Fig. 1) [14, 15]. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

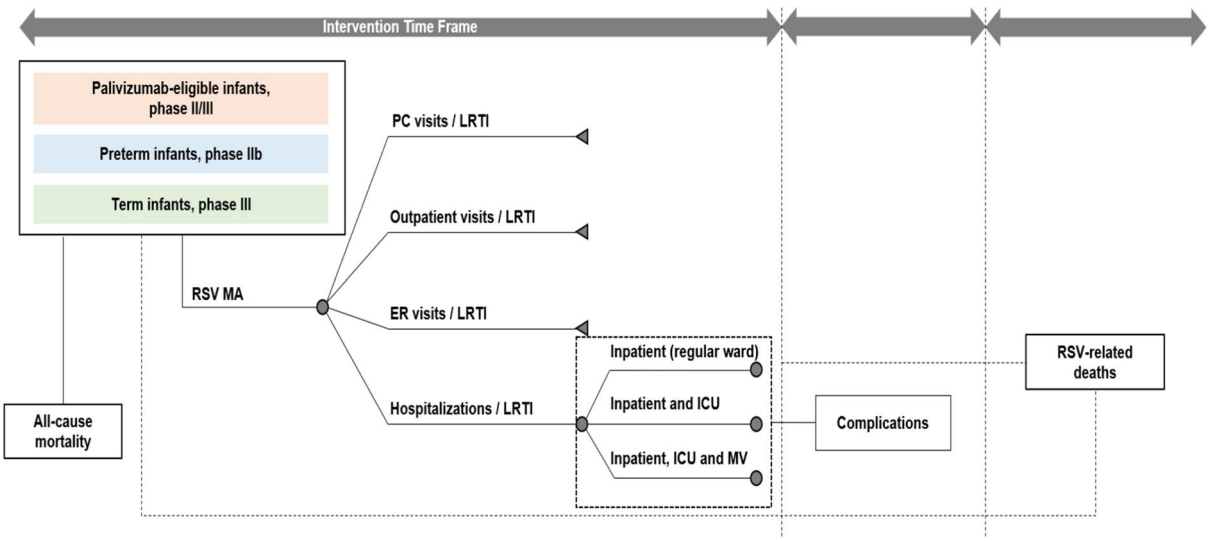

Fig. 1 Model structure. *ER* emergency room, *ICU* intensive care unit, *LRTI* lower respiratory tract infection, *MA* medically attended, *MV* mechanical ventilation, *PC* primary care, *RSV* respiratory syncytial virus

Target Population

We analyzed the newborn cohort in Colombia at risk of their first RSV season using vital statistics for 2023 [16]. The monthly infant at-risk was estimated by considering the monthly distribution of births from the average of the last 5 years. Infants were divided into three groups according to the risk of developing LRTI: (1) palivizumab-eligible (< 32 weeks' GA or with bronchopulmonary dysplasia (BPD), chronic lung disease, congenital heart disease, and/or neuromuscular disease), (6.54%, $n = 33{,}366$); (2) preterm < 35 weeks' GA without bronchopulmonary dysplasia (BPD)/chronic lung disease/congenital heart disease, and/or neuromuscular disease) (1.38%, $n = 7045$); and (3) late preterm/term infants ≥ 35 weeks' GA (92.08%, $n = 469{,}947$).

Intervention and Comparators

Two interventions (nirsevimab and RSVpreF) and one comparator (palivizumab SoC) were evaluated across five RSV prevention strategies (Sect. "Description of Immunization Strategies and Analytical Scenarios"). Nirsevimab was modeled as a single-dose monoclonal antibody administered to infants. RSVpreF was modeled as maternal immunization between 32 0/7 and 36 6/7 weeks' GA, providing passive protection to newborns. The comparator reflected current practice in Colombia using palivizumab as monthly prophylaxis in eligible high-risk infants (up to five doses) during periods of high RSV circulation [8] (product and administration details are presented in Supplementary Material S2).

Intervention Period

Colombia has year-round RSV circulation with seasonal peaks that vary by region and year [4]. Seasonality was parameterized using SISPRO (2015–2022) and cross-checked against INS surveillance data (Fig. 1S) [5, 17]. RSV was assumed to circulate year-round, with a major peak between March and July and a smaller peak around November–January. We defined the primary RSV season as March–July and evaluated two implementation windows: year-round (12 months; administration at birth) and seasonal (5 months; administration at birth for infants born during the season with catch-up in March for infants born outside the season). Additional details on seasonality triangulation and intervention window definitions are provided in Supplementary Material S3.

Rationale and Model Description

A static cohort decision analytic model (Global Sanofi) was used. This model evaluates the costs and clinical outcomes associated with nirsevimab and RSVpreF treatment in three groups of infants (palivizumab-eligible, preterm, and term) against RSV infections, covering a time horizon of 1 year, with long-term follow-up for sequelae and complications, and lifetime for years of life lost due to RSV-related premature death. The model includes different types of medical visits (primary, outpatient, and emergency) and hospitalizations for LRTI, differentiating between hospitalizations in regular wards, intensive care unit (ICU), and ICU with mechanical ventilation. It also considers complications arising from hospitalization, RSV-related mortality, and other causes of mortality. The framework allows for the evaluation of the economic and clinical impact of the intervention over different periods and in different patient groups.

Parameters and Characterization of RSV in Colombia

To parameterize RSV risk in infants aged < 1 year, we triangulated national surveillance (INS), administrative healthcare utilization data (SISPRO), and published evidence [5, 17]. INS data were used as the primary source for RSV positivity and incidence estimates, whereas SISPRO data were used to characterize the infant-specific monthly distribution of medically attended respiratory events. RSV positivity estimates across sources were 31.6% (INS 2023) and 26.87% (WHO 2017–2019 and 2022); the INS estimate

Table 1 Model inputs

Variables	Palivizumab-eligible	Preterm (< 35 weeks' GA)	Late preterm and term (≥ 35 weeks' GA)	Source
Demographics				
Birth cohort size in Colombia (510,357)	6.54%	1.38%	92.08%	DANE 2023 [16]
	32,928	7176	470,253	
Event rates				INS Event Report 995—Average 2017–2019, 2022 [44–46]
RSV positivity	31.6%			Informe de Evento 2023 Infección Respiratoria Aguda INS (2023) [47]
Hospitalizations				
0–11 months	10.99%	5.96%	3.70%	Rodriguez 2014 [3]
ICU admission	14.53%	14.53%	14.53%	INS Event Report 995—Adjusted RR from Rodriguez 2014 [3]
ICU with mechanical ventilation	7.6%	7.6%	7.6%	Rodriguez-Martinez 2022 [13]
Emergency room visits				
0–11 months	13.18%	7.15%	4.44%	Ratio SISPRO 2017–2019, 2022 [17]
Urgency-to-hospitalization ratio	1.20			
Primary care visits				
0–11 months	106.94%	58.02%	36.04%	Ratio Event 995—INS average 2017–2019 and 2022 [44–46]
Consultations-to-hospitalization ratio	9.74			
All-cause mortality (per 100)				
0–5 months	10.18%	10.18%	1.05%	DANE 2017–2019, 2022 [34–36]
6–11 months	0.54%	0.54%	0.20%	
RSV-related mortality (per 100,000)				
0–5 months	23.58	23.58	23.58	
6–11 months	8.29	8.29	8.29	
Recurrent wheezing	31.00%	23.00%	17.00%	Li et al. 2022 [48]

Table 1 continued

Variables	Palivizumab-eligible	Preterm (< 35 weeks' GA)	Late preterm and term (≥ 35 weeks' GA)	Source
Utility				
Hospitalizations (incl. ICU & MV)	0.0101	0.0101	0.0101	Mao et al. 2023 [31]
ER and primary care visits	0.0063	0.0063	0.0063	
Recurrent wheezing (first year)	0.0392	0.0373	0.0356	
QALYs lost due to premature death (per infant, lifetime)	18.94	18.94	18.94	
Vaccination coverage				
Palivizumab (% based on SISMED 2023 sales)	62.77%	–	–	SISMED [49]
Nirsevimab (avg. BCG and PENTA newborn vaccines)	93.50%	93.50%	93.50%	MinSalud datosabiertos.gov [50]
RSVpreF [avg. of other maternal vaccines (Tdap, influenza)]		22.20%	74%	MinSalud 2019 [50]

was selected for the base case due to national coverage and surveillance robustness [5]. To account for potential under-ascertainment outside urban sentinel sites, we applied an adjustment informed by the rural population share (DANE 2022) (Supplementary Material S4) [18]. Full derivations for age- and month-specific RSV risk and related assumptions are provided in Supplementary Material (S4–S6), and parameter values are summarized in Table 1. For palivizumab-eligible infants, baseline hospitalization rates prior to palivizumab were derived via back-calculation using observed post-introduction rates, assumed coverage (69%), and palivizumab efficacy (51%) [19] (Supplementary Material S6). Recurrent wheezing probabilities over 3 years following RSV hospitalization were taken from the literature [20].

Efficacy and Coverage Assumptions

Efficacy inputs were obtained from a literature review and published clinical trials for each technology assessed. We assumed that nirsevimab was non-inferior to palivizumab in the palivizumab-eligible population. Palivizumab was modelled as providing 51% protection against RSV outcomes in eligible infants [19], with protection assumed to last 30 days per dose [19, 21] and up to five monthly doses in line with standard practice. For nirsevimab, efficacy was modelled as constant (flat) over the 5-month protection window (150 days). Protection rate against inpatient outcomes was 83.2% for preterm, late-preterm, and term infants [24, 25], whereas in outpatient settings, this percentage was 86.2% for preterm infants and 74.5% for late-preterm and term infants [11, 26, 27].

Maternal RSVpreF vaccination was modelled as reducing infant RSV hospitalizations by 56.8% within the first 6 months of life and outpatient events by 51.3%. RSVpreF efficacy was modelled from birth to 180 days with waning over time [12, 28, 29]. RSVpreF time-varying efficacy was modelled using a polynomial function fitted to published efficacy timepoints (as reported in VRBPAC monthly summaries and MATISSE outputs), allowing interpolation between observed values.

Coverage assumptions were based on national immunization programme data and calibration to observed utilization: nirsevimab coverage at birth was assumed to be 93.5% [30], maternal RSVpreF coverage 74%, and palivizumab coverage 62.77% based on annual sales. More details on efficacy and coverage assumptions are described in Supplementary Material S7.

Perspective

Two key perspectives on the public health and economic impact of RSV were evaluated. From the payer's perspective, we considered direct event-related medical costs and quality-adjusted life years (QALYs) in infants. From a societal perspective, we additionally included direct non-medical costs (out-of-pocket expenditures), indirect costs (e.g., caregiver productivity losses), and QALYs in both infants and caregivers, providing a broader view of the public health and economic impact of RSV prevention strategies.

Description of Immunization Strategies and Analytical Scenarios

The evaluated strategies were (i) Immunization with palivizumab, the SoC currently recommended for high-risk infants; (ii) Nirsevimab: Passive immunization of newborns entering the RSV season with an all-year-round immunization strategy; (iii) Immunizations with RSVpreF targeted pregnant women between 32 0/7 and 36 6/7 weeks' GA. Results were obtained by evaluating the nirsevimab and maternal RSVpreF against SoC across five immunization strategy scenarios (S1–S5) that combined perspective (payer vs societal) and delivery approach (year-round vs seasonal with catch-up). RSVpreF was consistently modeled as a year-round strategy for pregnant women (32 0/7 to 36 6/7 weeks' gestational age). From a payer perspective, the model evaluated year-round infant administration (S1), seasonal infant administration (S2), and a year-round parity scenario assuming equal coverage for RSVpreF and nirsevimab interventions (S5). From a societal perspective, the model evaluated year-round (S3) and seasonal (S4) infant administration. Full scenario definitions are provided in the Supplementary Material S8.

Time Horizon

The time horizon of the burden analysis of nirsevimab in infants with RSV in Colombia was 1 year. The horizon can be adapted to short- or long-term goals and can even extend to the patient's lifetime, considering all-cause mortality and the long-term impacts of RSV infection.

Discount Rate

In the base case of the analysis, the results are presented both without discounting and applying a discount rate of 5% to health costs and benefits. This rate was considered the most appropriate for the Colombian context, in line with the recommendations of the Institute for Health Technology Assessment (IETS) established in its methodological manual. The choice of 5% reflects the need to capture the present value of health costs and outcomes over time.

Outcome Selection

The effects of RSV on disease burden were measured by considering various events, as previously mentioned. Regarding complications of RSV-related events in the long term, recurrent wheezing was the only one captured in the model, and complications were simulated as a one-time risk over a 3-year time horizon. In addition, a comprehensive analysis of disease-related costs was conducted, including a detailed assessment of expenditures and QALYs associated with various RSV-related health outcomes. The QALY loss per event was obtained from the RESCEU prospective study on healthy term infants [31], utilities associated with recurrent wheezing were obtained from Li et al. 2022 [20], and the QALY loss due to RSV-related premature death was estimated, based on the remaining life expectancy at the average age of death from RSV, adjusted by an age-specific utility weight and discounted at the annual rate.

To evaluate the effectiveness of the proposed intervention strategies, we used the number needed to immunize (NNI), a public health

metric indicating how many individuals must be immunized to prevent a single RSV-associated adverse event.

Outcome Measurement and Validation of Model Parameters Outcome measurements in this economic analysis were performed following the principles of the Institute for Health Technology Assessment (IETS). Health outcomes were expressed in QALYs, and the direct and indirect costs of care were considered. The validation of the model parameters and assumptions was based on a targeted literature review in Colombia, complemented by the experience of local clinical and methodological experts, ensuring the relevance of the results for the national context.

Measurement and Assessment of Resources and Costs

Model inputs for healthcare resource utilization and costs are described in Table 2. Resource assessment was performed based on the following key cost categories: hospitalization, ICU, emergency department (ER) visits, mechanical ventilation, and primary care visits. In addition, direct non-medical costs were included from a societal perspective. ICU use, including hospitalization, was derived from previous local studies [13, 32], which were used to estimate the average cost per day of ICU stay. ER visits were calculated from specific cohort registries, in which the use of emergency services for patients with similar conditions was detailed, allowing a more granular approach to cost estimation. From a societal perspective, out-of-pocket expenditure was estimated with standard resources use and cost unit from Salcedo-Mejía et al. [32], indirect cost was obtained with minimum wage by law [33] in Colombia, and the productivity time loss from medical attention and premature deaths using human capital approach [34–36]. Total costs were calculated based solely on health event-related expenses. Acquisition costs or prices related to the prophylactic interventions were not included, as official negotiations or reference prices are not currently available for all evaluated technologies. All costs were reported in 2023 US dollars (TRM 3800 Colombian pesos)

Table 2 Model inputs for healthcare resource utilization and costs

Type of cost per event	Event duration	Total event costs USD 2023	Source
Hospitalizations	7 days	$1462	Rodriguez-Martinez 2019 [51]
ICU (includes hospitalization)	7–12 days	$8170	Castillo-Rodríguez et al. 2022 [52]
Mechanical ventilation (includes hospitalization and ICU)	10.8–15.8 days	$12,605	Castillo-Rodríguez et al. 2022 (with assumption based on increased ICU days for MV as reported in Pineros et al. 2014 of 3.8 days) [13, 52]
Emergency room visits	1 day	$84	RSV cohort estimate—EAPB 2017–2021, EAPB for RSV ($n = 357$)
Primary care visits	1 day	$45	RSV cohort estimate—EAPB 2017–2021 ($n = 357$ RSV)
Direct non-medical costs (out-of-pocket) per hospitalization	8.9 days	$45	Salcedo-Mejía 2019 [32]
Productivity loss costs (lifetime)	–	$208,901	Life expectancy DANE 2023 and SMLVA 2023 Min. Labor; adjusted by %GTP 64.1% 2023

and adjusted for inflation when required. The average costs reflect the study period estimates for hospitalization and RSV care services.

Characterization of Uncertainty

Uncertainty related to the parameters affecting estimates of RSV infection risk, hospitalization costs, and effectiveness of interventions was addressed through deterministic (DSA) and probabilistic (PSA) sensitivity analyses. To obtain more precise estimates, outliers derived from the pandemic were excluded by using the most representative scenario. This robust approach allowed us to characterize the sources of uncertainty in the analysis and improve our understanding of the variability in the results.

Modeled Population and Risks

The study population consisted of a simulated cohort of 510,357 live births in Colombia (2023), followed from birth to 12 months of age and stratified into the three risk groups described in Sect. "Target Population" and summarized in Table 1. Baseline RSV hospitalization rates in the first year of life were 10.99% for palivizumab-eligible infants, 5.96% for preterm infants, and 3.70% for late preterm/term infants; ICU admission parameters are summarized in Table 1 (including 47.5% among late preterm infants and 14.53% among term births). ER and primary care visits were estimated by applying nationally derived service-use ratios to age-specific RSV hospitalization incidence (ER-to-hospitalization ratio = 1.20; consultations-to-hospitalization ratio = 9.74). Additional details are provided in the Supplementary Material S9.

RESULTS

The results of the different scenarios compared with SoC are presented in Table 3 and Figs. 2, 3, 4, 5, showing health events, healthcare cost, QALYS, and NNI, respectively. Absolute outcomes for each strategy and scenario are summarized in Table 3, including total clinical events, deaths, QALYs, and total event-related costs (excluding prophylaxis acquisition costs). Differences versus SoC are shown in Figs. 2, 3, 4, 5 (events avoided, event-related cost differences, QALY differences, and NNI, respectively), and correspond to simple subtraction of Table 3 totals (SoC minus intervention).

The burden of SoC in a 1 year-round immunization strategy was estimated in 249,508 total health events and 26 deaths, of which 81.7% were primary care visits, 8.3% were hospitalizations, 10% were ER visits and 0.01% were deaths. The total cost of health events was $83,023,302. For the 5-month and catch-up scenario, SoC reported 246,670 total health events, 25 deaths and $82,521,467 total costs (Table 3).

Scenario 1-Base Case: Payer Perspective at 12 Months of Immunization with Nirsevimab

Nirsevimab prevented 2257 more hospitalizations and 14,558 more total events than RSVpreF, and the most common event avoided was primary care visits (Fig. 2, Table 3). These findings suggest a broader impact of nirsevimab on reducing RSV-related healthcare burden.

The nirsevimab intervention resulted in $8,438,626 lower event-related costs compared with RSVpreF, reflecting fewer costs attributable to hospitalizations, primary care visits, and ER visits. Moreover, nirsevimab showed a greater reduction in health resources than did RSVpreF and SoC (Fig. 3).

The use of nirsevimab resulted in 218.92 additional QALYs in the baseline scenario compared with RSVpreF (Fig. 4). In addition, the NNI to prevent health events was lower with nirsevimab than with RSVpreF, with an NNI of 11 vs. 13 to prevent one case of RSV and 77 vs. 121 to prevent one hospitalization (Fig. 5).

In scenario 5, the behavior was similar to that in scenario 1. Although the coverage of the interventions was matched, results showed a similar pattern.

Table 3 Absolute clinical outcomes, QALYs, and RSV event-related costs (excluding prophylaxis acquisition costs) by strategy and scenario

Outcomes	Scenarios S1, S5: SoC (a)	Scenarios S1, S5: nirsevimab (b)	Scenarios S1, S2: RSVpreF (c)	Scenarios S2: SoC (d)	Scenarios S2: nirsevimab (e)	Scenarios S5: RSVpreF (f)
Clinical outcomes						
Total cases	249,508	205,469	220,027	246,670	160,081	212,259
Hospitalization cases	20,724	14,515	16,771	20,618	12,046	15,730
ICU admissions	4586	3212	3711	4562	2666	3481
ICU admissions—mechanical ventilation	1575	1103	1275	1567	916	1195
Emergency (ER) visits	24,996	19,919	21,760	24,743	15,493	20,907
Primary care visits	203,762	171,018	181,476	201,285	132,527	175,604
Deaths*	25.5	17.9	20.8	25.4	15.6	19.5
Outcomes—third payer ($USD)						
Total QALYs—caregivers	0	0	0	0	0	0
Total QALYs	2721	2100	2319	2698	1691	2212
Total costs (excluding prophylaxis)	$83,023,302	$59,622,933	$68,061,558	$82,521,467	$48,972,461	$64,118,937
Outcomes—societal ($USD)—strategy S3, S4**						
Total QALYs—caregivers	184.6	152.0	162.8	182.5	118.4	160.7
Total QALYs	2906	2252	2481	2880.51	1809.59	2455.97
Total costs (excluding prophylaxis)	$83,955,902	$60,276,090	$73,157,944	$88,764,126	$52,777,082	$71,881,349

S1 (Base case): Payer perspective with 12-month nirsevimab immunization. S2: Payer perspective with 5-month immunization. S3: Societal perspective (including indirect costs and caregiver QALYs) with 12-month immunization. S4: Societal perspective with 5-month immunization. S5: Matched intervention coverage (parameters and outcomes consistent with S1)

QALY quality-adjusted life year, *RSVpreF* respiratory syncytial virus prefusion F vaccine, *SoC* standard of care, *S* scenario, *ICU* intensive care unit, *ER* emergency room

*Deaths are not included in total cases

**Clinical outcomes in the societal scenarios (S3 and S4) are identical to those in their respective payer scenarios (S1 and S2); differences are driven solely by the inclusion of indirect costs and caregiver QALYs

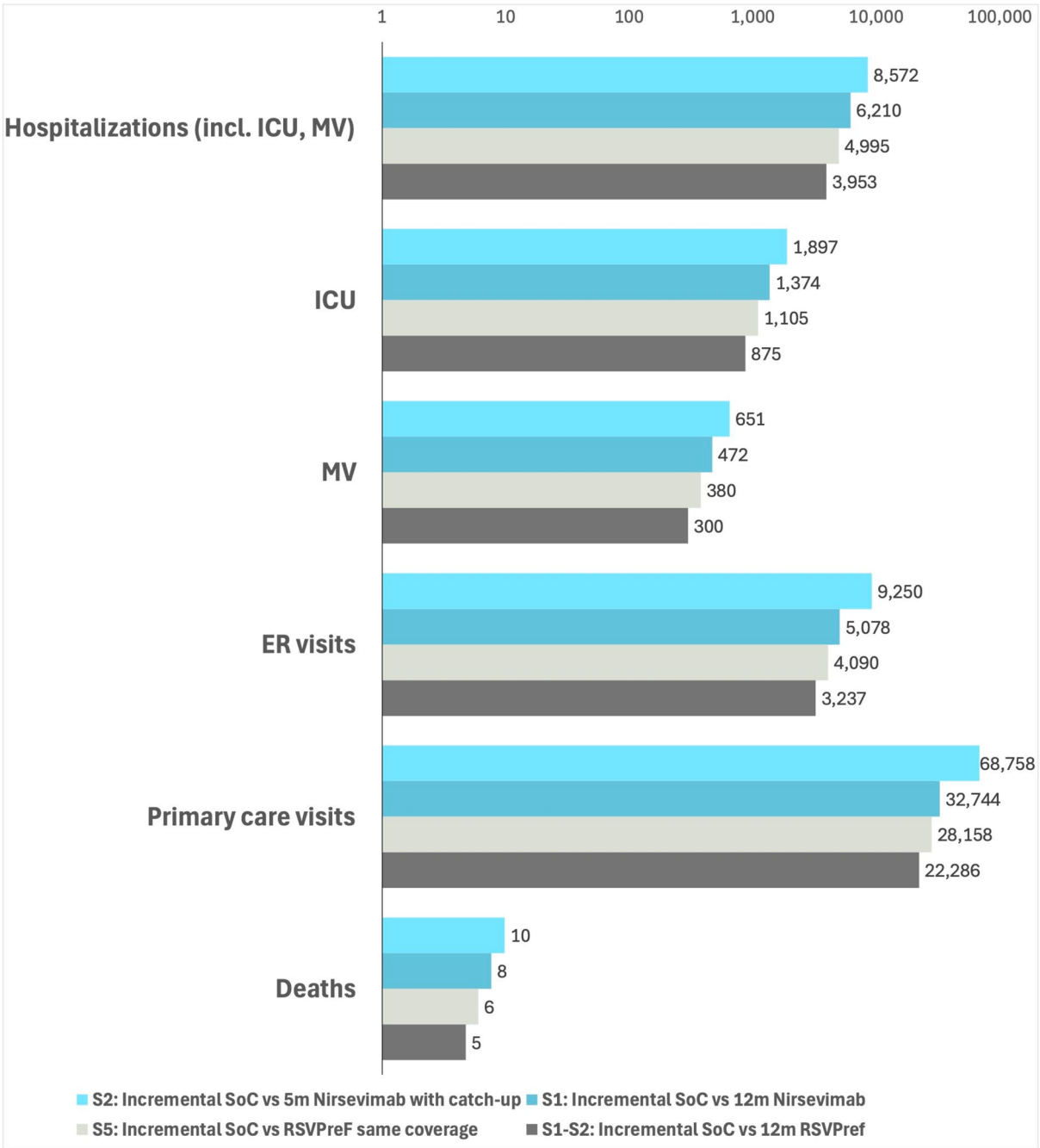

Fig. 2 Health events related to hospitalizations, emergency room visits, primary care visits and deaths avoided with the use of nirsevimab or RSVpreF in comparison with SoC by scenarios*. From the payer perspective, scenario 1 (S1) assumes 12 months of immunization of all newborns entering the RSV season with nirsevimab, and maternal vaccination with RSVpreF between 32 0/7 and 36 6/7 weeks' GA for the same period. Scenario 2 (S2) represents 5 months of immunization with nirsevimab for all newborns entering the season, including a catch-up for infants ≤ 6 months old at season onset. For RSVpreF vs SoC S1 remains equivalent to S2. From the societal perspective, scenario 3 (S3) mirrors S1, scenario 4 (S4) mirrors S2, and scenario 5 (S5) assumes equal coverage of nirsevimab and RSVpreF for 12 months, with indications and GA windows as defined above. *Societal scenarios were not shown in the graph since the number of events remained unchanged. Bars show differences versus SoC (SoC minus intervention). Absolute totals are reported in Table 3. *ER* emergency room, *GA* gestational age, *ICU* intensive care unit, *MV* mechanical ventilation, *RSVpreF* respiratory syncytial virus prefusion F protein vaccine, *SoC* standard of care (palivizumab)

Scenario 2: Payer Perspective at 5 Months of Immunization with Nirsevimab

Nirsevimab demonstrated a greater reduction in events across all categories, particularly primary care visits (68,758 events avoided vs. 22,286 with RSVpreF) and hospitalizations (8572 vs. 3953). Reductions were also observed for emergency visits (9250 vs. 3237) and deaths (10 vs. 5) (Fig. 2, Table 3).

In the 5-month scenario, nirsevimab reduced RSV-related health outcomes more than the SoC and RSVpreF (Fig. 2), and was associated with 2.24-fold lower event-related healthcare costs compared with RSVpreF.

Scenario 3: Societal Perspective with 12 Months of Immunization with Nirsevimab

In scenario 3, nirsevimab was associated with US$7,544,882 lower total event-related costs than RSVpreF (Fig. 3). Nirsevimab was also associated with higher QALYs for both infants and their caregivers (229.64 additional QALYs versus RSVpreF) (Fig. 4). In this scenario, significant reductions in indirect costs, such as the loss of caregiver productivity and out-of-pocket expenses, were also observed (Fig. 3S). In this scenario, health outcomes were the same as those reported in scenario 1.

Scenario 4: Societal Perspective with 5 Months of Immunization with Nirsevimab

In scenario 4, nirsevimab was associated with larger reductions in event-related costs, with total event-related cost differences of US$35,987,044 for nirsevimab versus US$10,640,118 for RSVpreF compared to SoC (Table 3). Event-related cost differences by outcome ranged from US$1.2 million to US$15.8 million for nirsevimab (Fig. 3). In terms of QALYs, nirsevimab generates up to 2.52 times more QALYs than RSVpreF, with 1070.92 QALYs gained in this scenario (Fig. 4). From a societal perspective, which includes both infant and caregiver QALYs, the impact is considerably greater, including larger reductions in indirect costs and improvements in quality-of-life outcomes.

Scenario 5: Payer Perspective with 12 Months of Immunization with Nirsevimab and RSVpreF Same Coverage

In scenario 5, reductions in RSV-related outcomes and event-related costs of nirsevimab were consistent with scenario 1 and larger than those observed for SoC and RSVpreF. Nirsevimab yielded 1.22 times more QALYs, avoided 1.18 times more health events, and generated 1.24 greater savings in healthcare cost of events in comparison with RSVpreF.

Comparing the different immunization scenarios in terms of avoided costs, it is evident that the scenarios with nirsevimab for 12 months (S1 and S3) present intermediate costs, while the highest avoided cost corresponds to societal scenario S4 (Fig. 3).

Sensitivity Analysis

The DSA showed that, in terms of event-related costs, the most influential factors were the age-specific risk of RSV in term infants, variability in the distribution of infections per month, and the efficacy of nirsevimab in hospital settings (Fig. 6). In contrast, factors such as the unit cost of palivizumab and the cost of RSV treatment in premature infants had less impact on the total costs.

On the other hand, in terms of QALYs, the factors with the greatest influence were the variability in the distribution of RSV infections, the end of protection provided by nirsevimab, and the age-specific risk of RSV in term infants. The impact of disability associated with RSV events and mortality associated with preterm birth have also been highlighted. Factors with less impact on QALYs included the efficacy of palivizumab in hospital settings and risk of RSV mortality in term infants (Fig. 6).

In the PSA, results were consistent with the deterministic findings across iterations, with

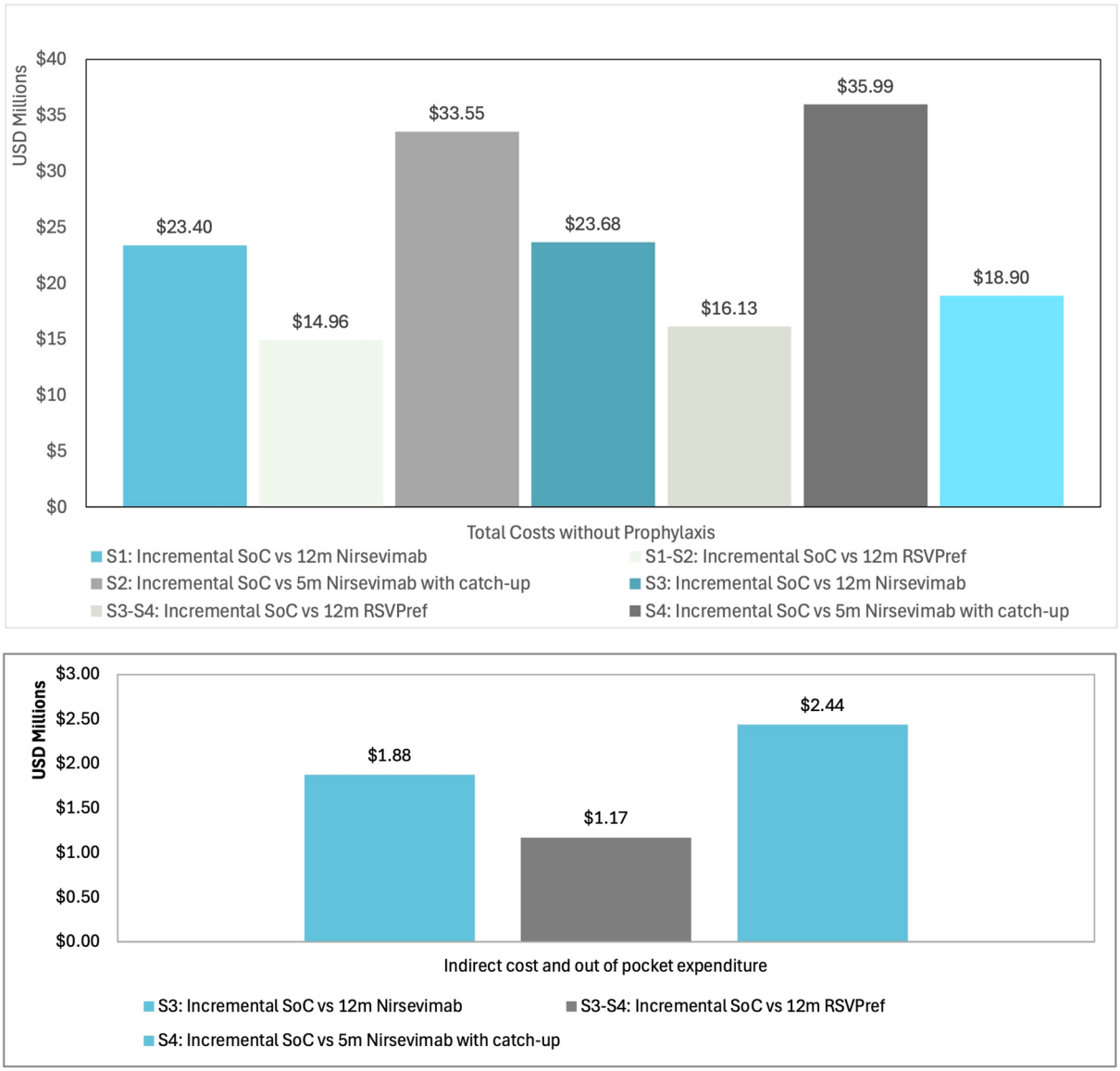

Fig. 3 Healthcare costs of events avoided with the use of nirsevimab or RSVpreF in comparison with SoC, comparison of scenarios. Description of modeled scenarios as in Fig. 2. *RSVpreF* respiratory syncytial virus prefusion F protein vaccine, *SoC* standard of care (palivizumab), *USD* United States dollars

separation between strategies generally preserved under parameter uncertainty (Fig. 7).

DISCUSSION

The results of the present study suggest that immunization with nirsevimab in infants under 1 year of age in Colombia is a highly effective strategy for reducing the RSV burden. With respect to health outcomes avoided, it was found that in the baseline scenario, the intervention with nirsevimab resulted in a greater reduction in health outcomes than RSVpreF, estimated at 1.49 times more health events prevented, and representing a 17.7% reduction in overall RSV cases compared to SoC. Relative to SoC and RSVpreF, in scenario 2, nirsevimab prevented

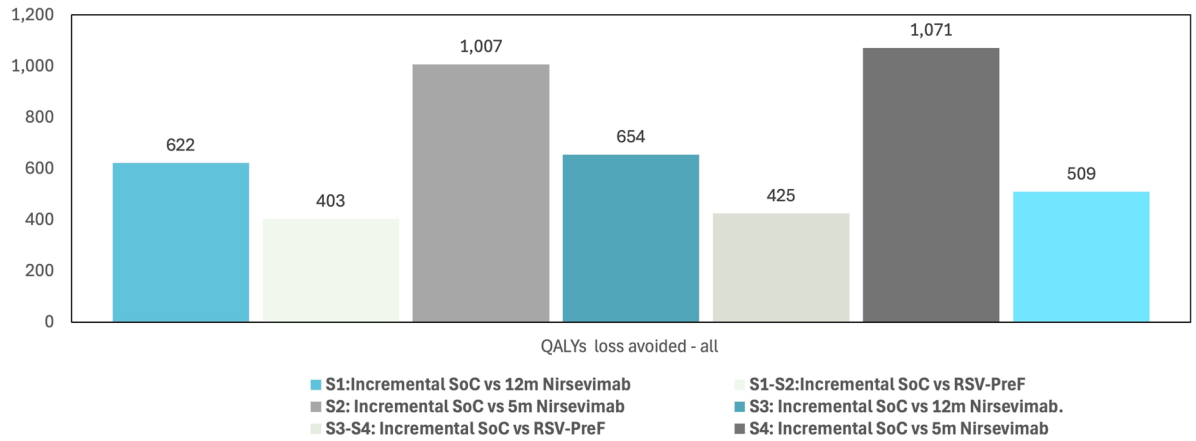

Fig. 4 Comparative scenarios: QALYs gained/saved. Description of modeled scenarios as in Fig. 2. *QALYs* quality-adjusted life years, *RSV-PreF* respiratory syncytial virus prefusion F protein vaccine, *SoC* standard of care (palivizumab)

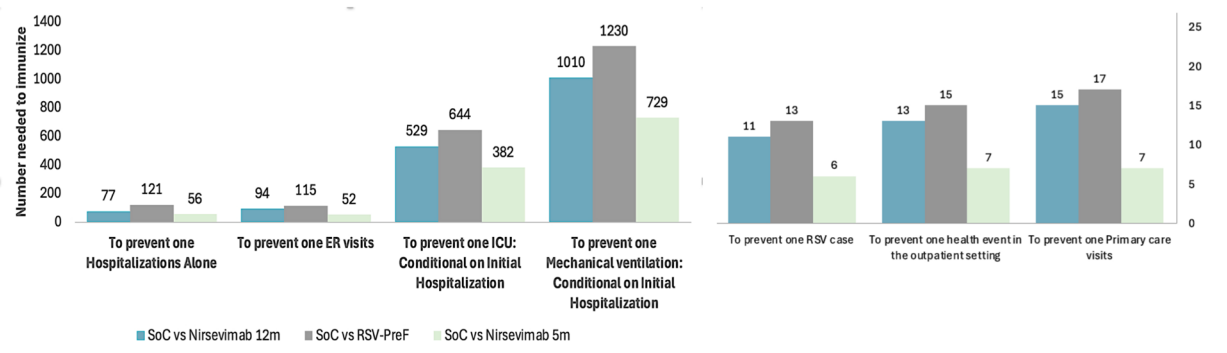

Fig. 5 Number needed to immunize (NNI). From the payer and societal perspective, SoC vs Nirsevimab 12 m (S1) assumes 12 months of immunization of all newborns entering the RSV season with nirsevimab. SoC vs RSVpreF assumes 12 months of and maternal vaccination with RSVpreF between 32 0/7 and 36 6/7 weeks' GA for the same period. SoC vs Nirsevimab 5 m (S2) represents 5 months of immunization with nirsevimab for all newborns entering the season, including a catch-up for infants ≤ 6 months old at season onset. For RSVpreF vs SoC S1 remains equivalent to S2. From the societal perspective, the number of NNI remained unchanged. *ER* emergency room, *ICU* intensive care unit, *NNI* number needed to immunize, *RSV* respiratory syncytial virus, *SoC* standard of care (palivizumab)

2.17, 2.86, and 2.94 times more hospitalizations, ER visits, and overall health events, respectively, than RSVpreF, resulting in a significant increase in QALYs and 2.24-fold lower event-related costs. Across all scenarios, nirsevimab was also associated with a lower NNI than RSVpreF, consistent with its broader preventive impact.

The comparative reductions observed across scenarios are consistent with the well-documented burden that RSV imposes on infants, particularly in preterm populations, who are more vulnerable to developing severe respiratory infections owing to their immature immune system [37]. From a public health perspective, preventive interventions early in life, such as immunization with nirsevimab, are highly effective because they act before children are exposed to viral agents, which can trigger severe complications. Interventions that reduce severe outcomes and RSV-related healthcare utilization early in life may help mitigate the clinical and

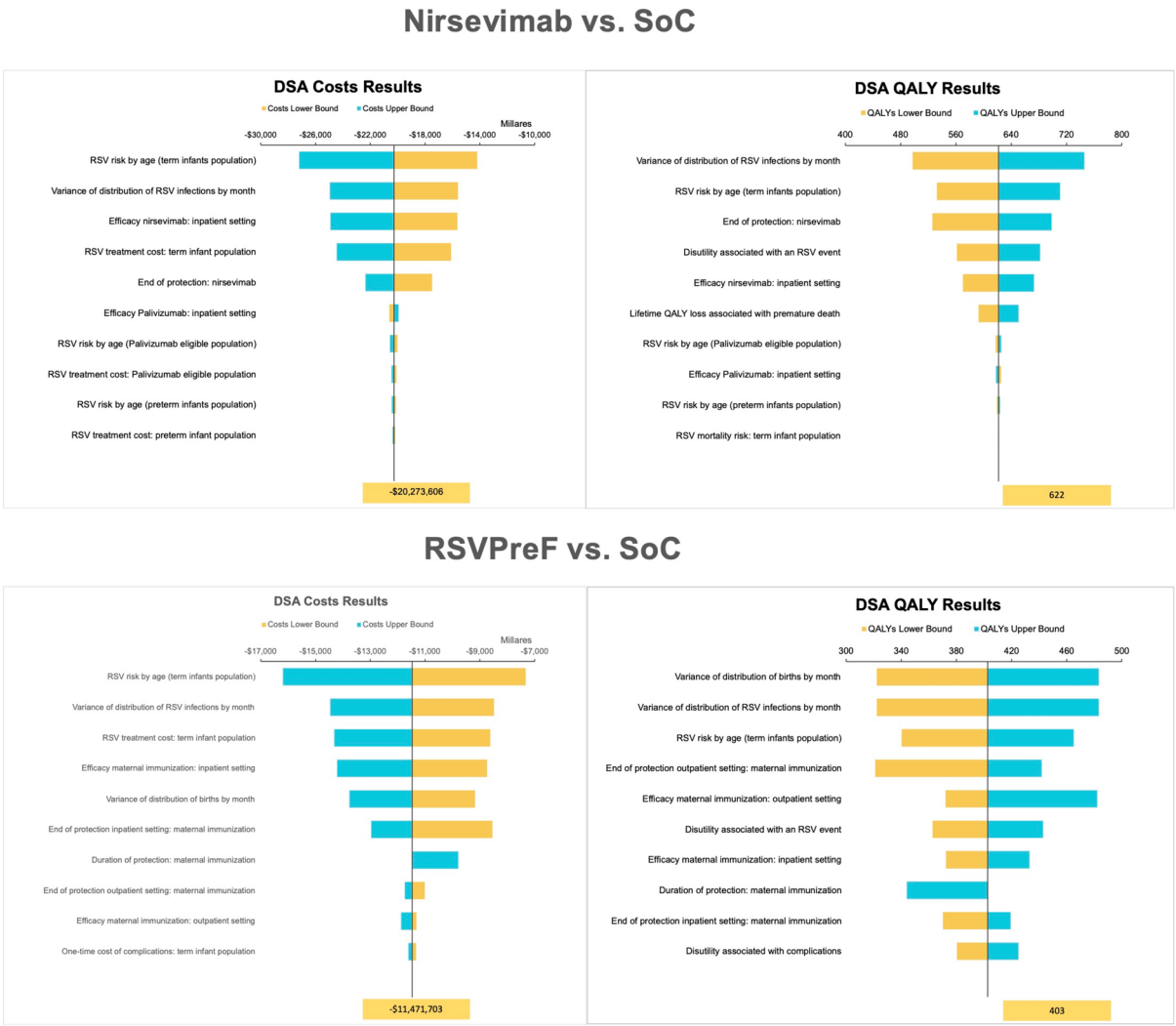

Fig. 6 Deterministic sensitivity analysis. Base-case scenario. *DSA* deterministic sensitivity analysis, *QALYs* quality-adjusted life years, *RSV* respiratory syncytial virus, *RSVpreF* respiratory syncytial virus prefusion F protein vaccine, *SoC* standard of care (palivizumab)

economic burden in settings with constrained healthcare resources.

The clinical risk patterns observed in our model are broadly consistent with prior Colombian and international evidence. Higher RSV hospitalization rates among preterm newborns align with findings described by Rodriguez-Martinez et al. [13], who reported similar rates of hospitalization in vulnerable infants in Colombia. The higher rate of ICU admission among late preterm infants observed in our study is also consistent with international studies, such as that by Hammitt et al. which highlight the greater vulnerability of these infants to severe RSV infections [11].

The greater effectiveness of nirsevimab compared with RSVpreF and SoC may be explained by its ability to provide extended protection with a single dose across all infants (both preterm and term), rather than being limited to a specific subgroup or requiring multiple doses. This broader coverage may facilitate implementation and adherence by reducing the operational complexity associated with repeated dosing. In contrast, palivizumab is typically restricted to a small high-risk subgroup, leaving

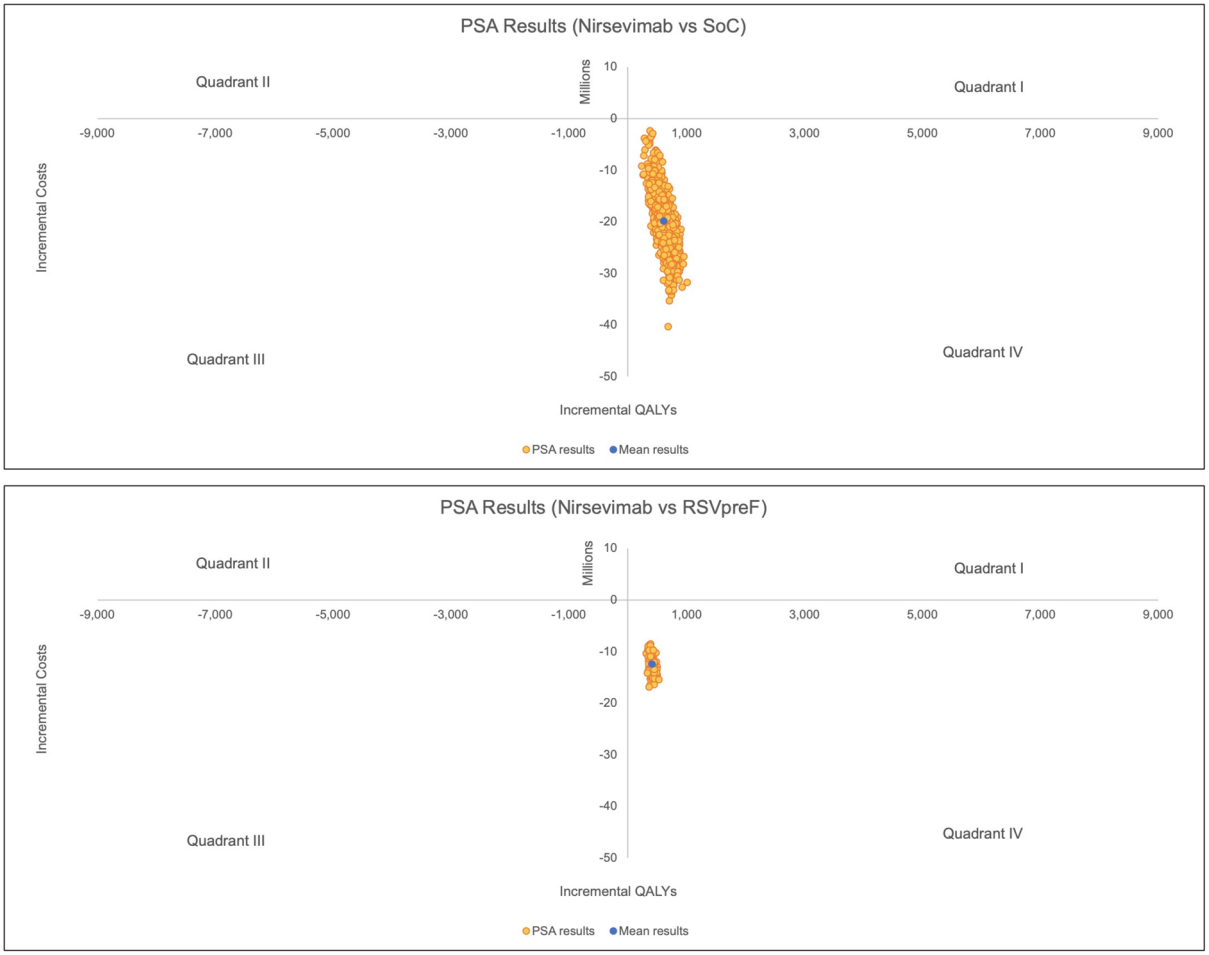

Fig. 7 Probabilistic sensitivity analyses (PSA). *QALYs* quality-adjusted life years, *RSVpreF* respiratory syncytial virus prefusion F protein vaccine, *SoC* standard of care (palivizumab)

a substantial proportion of infants unprotected, and monthly administration during the RSV season can pose practical challenges for scheduling and timely dosing [38]. These programmatic considerations help contextualize the "prevention gap" that newer strategies aim to address. This is supported by the study of Griffin et al. [26], who also highlighted the advantage of a single immunization in reducing severe cases of RSV. In addition, previous modelling studies have evaluated RSV prevention strategies reporting substantial reductions in medically attended RSV outcomes under certain assumptions regarding effectiveness, coverage, and seasonality [39]. These findings are consistent with our results regarding the comparative reduction in RSV-related events [39].

Modelling analyses from other settings have reported that long-acting monoclonal antibodies may reduce RSV-related hospitalizations compared with alternative prevention strategies under certain epidemiologic and implementation assumptions [40, 41]. Although results vary across settings, the direction of comparative health impact reported in these analyses is consistent with our findings.

Our analysis used a static cohort framework and therefore does not capture indirect protection through reduced transmission. This choice was aligned with our primary objective

of estimating comparative clinical outcomes, QALYs, and event-related costs in infants during the first year of life under alternative prevention strategies. Evidence from a multi-model comparison of RSV preventive interventions, including both static and dynamic transmission models, suggests that, while dynamic models can differ from static models for outcomes that are highly sensitive to transmission assumptions, overall hospitalization and death estimates may be similar across model types [39]. In addition, very young infants are typically infected via close household contacts and have limited opportunities to transmit infection outside the household, which may constrain the magnitude of indirect effects from preventing RSV in this age group [39]. Nevertheless, dynamic transmission models could be informative in settings where indirect effects or age shifts are expected to materially influence comparative outcomes, and this remains an important area for future work.

Although this analysis relies on Colombian data, several elements of our framework are transferable to other tropical settings with year-round RSV circulation and rainfall-associated peaks [6]. Specifically, the underlying model structure—such as risk stratification by infant subgroup, defined clinical outcomes, and seasonality-adjusted implementation windows—can be adapted using locally available data. Conversely, inputs such as RSV positivity, healthcare utilization patterns, coverage, and unit costs are highly context-specific and require local substitution. Ultimately, we present Colombia as a case study to illustrate how triangulating surveillance (INS) and administrative healthcare data (SISPRO) can inform comparative estimates of public health impact and event-related burden, even when underlying data are fragmented [5, 17].

One of the strengths of this study is the use of high-quality data from efficacy studies of high reliability [42, 43], which increases the internal validity of the results. Similarly, nationally representative sources support the external validity of the results for the regional context in Colombia.

Although the present study used the most recent and robust data available, the long-term effects of the interventions have not been evaluated with a prolonged follow-up of patients. One of the limitations of this research is the lack of long-term follow-up data, which introduces uncertainty about the sustained impact of the evaluated interventions on health status in infants. In addition, the model used for the estimations is a static cohort model, which implies that effects on the transmission of infection and indirect effects such as herd immunity were not considered, which could underestimate the epidemiological and economic effects of the interventions. Another limitation of this study is that acquisition costs and prices associated with the evaluated prophylactic technologies were not included in the analysis, given the absence of official negotiations or publicly available reference prices currently in use in the Colombian market for all evaluated technologies. Therefore, we did not conduct threshold analyses or estimate incremental cost-effectiveness ratios, and the reported cost differences should be interpreted as RSV event-related medical and societal costs (i.e., costs related to healthcare utilization and productivity losses associated with RSV events), rather than net costs or overall economic value of implementation. Future work incorporating local relevant acquisition prices will be needed to inform affordability, budget impact, and any formal economic evaluation, including threshold analyses under country-specific decision criteria.

CONCLUSIONS

The technologies evaluated in this study revealed that nirsevimab is an intervention with considerable potential public health impact in Colombia in infants born at term, preterm, and those at high risk of developing severe RSV complications. In this evaluation, this strategy was associated with larger reductions in RSV-related outpatient and inpatient events compared with SoC and RSVpreF. Its ability to prevent serious outcomes is an important advancement in protecting vulnerable populations.

In addition, nirsevimab is not only clinically effective but also associated with lower RSV event-related medical and societal costs. This strategy achieves a greater reduction in the direct medical and societal costs associated with RSV in

infants than other prevention approaches. This, coupled with the improvement in the quality of life of both the infants and their caregivers, reinforces the feasibility of its national implementation. Nirsevimab also has a lower expected NNI than other alternatives evaluated, consistent with the larger reductions in RSV-related outcomes observed across scenarios.

Author Contributions. Maria Carrasquilla-Sotomayor led the study design, conducted the analysis, and was the primary author of the manuscript. Nelson J. Alvis-Zakzuk contributed to manuscript review and provided scientific inputs. Wilfrido Coronell-Rodríguez and Andres Arias served as clinical and epidemiological experts, validating input parameters and model results, and participated in manuscript revisions. Lina Moyano-Tamara was responsible for data management and coordination of research meetings. Juan Carlos Alvarado-González assisted in the acquisition and verification of input data. Fernando De la Hoz-Restrepo and Nelson Alvis-Guzmán served as methodological advisors, validating model structure, assumptions, input parameters, and outcomes, and contributed to critical revisions of the manuscript. All authors critically reviewed and approved the final version of this manuscript.

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Data Availability. Data and materials used to conduct this analysis are available upon request.

Declarations

Conflict of Interest. The authors (Maria Carrasquilla-Sotomayor, Nelson J. Alvis-Zakzuk, Wilfrido Coronell- Rodríguez, Andres Arias, Lina Moyano-Tamara, Juan Carlos Alvarado-Gonzalez, Fernando De la Hoz-Restrepo, Nelson Alvis-Guzman) declare no conflicts of interest related to the conduct, interpretation, or publication of this study.

Ethical Approval. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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